DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 801, 803, 812, 860, 862, 864, 866, 868, 872, 874, 876, 878, 880, 882, 886, 888, 890, and 892

[Docket No. FDA–2025–N–4635]

Medical Devices; Quality Management System Regulation Technical Amendments

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; technical amendments.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is amending certain medical device regulations to revise references and language in existing Code of Federal Regulations (CFR) provisions to conform with the final rule ''Medical Devices; Quality System Regulation Amendments'' (QMSR Final Rule). This rule does not impose any new requirements on affected parties. This action is editorial in nature to correct errors, conform regulatory references, and ensure accuracy and clarity in the Agency's regulations.

DATES: This rule is effective February 2, 2026.

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SUPPLEMENTARY INFORMATION:

I. Background

As a part of this technical amendment, FDA is making changes to 21 CFR parts 801, 803, 812, 860, 862, 864, 866, 868, 872, 874, 876, 878, 880, 882, 886, 888, 890, and 892 to revise existing regulatory provisions for consistency with the QMSR Final Rule [1] to correct errors, conform regulatory references, and ensure accuracy and clarity in the Agency's medical device regulations. The changes published in this notice are non-substantive and editorial in nature.

On February 2, 2024, FDA issued the QMSR Final Rule. This rule amended the device current good manufacturing practice (CGMP) requirements of the Quality System Regulation (QSR) to harmonize and modernize the regulation. The QMSR incorporates by reference an international standard for device quality management systems (ISO 13485:2016, Medical devices—Quality management systems—Requirements for regulatory purposes) and establishes additional requirements and provisions that clarify certain expectations and concepts used in ISO 13485. The purpose of this technical amendment is to update references from the QSR in existing FDA regulations to references to the QMSR that becomes effective on February 2, 2026, and to correct errors and ensure consistency and clarity in FDA's regulations.

II. Description of the Technical Amendments

We are amending 179 sections of Title 21 of the CFR, spread throughout 18 parts, in this technical amendment. Each section that is being modified includes a change to conform existing regulations for consistency with the QMSR. FDA is also clarifying the authority citations for three parts. The changes made in this technical amendment can be summarized as follows:

- One hundred and sixty-two of these amendments change the wording in the classification regulations for certain class I device types.[2] Specifically, these classification regulations currently exempt their respective devices, with various qualifications depending on the device, from the majority of the QSR. The QSR provisions that are not exempted in all of these sections (except one [3]) are §§ 820.180 and 820.198 (21 CFR 820.180 and 820.198). This amendment updates the references to the non-exempted activities for these devices from §§ 820.180 (Records—General requirements) and 820.198 (Records—Complaint files) in the QSR to the equivalent requirement in the QMSR (§ 820.35 (Control of Records) (21 CFR 820.35)).
- Section 801.30(a)(2) (21 CFR 801.30(a)(2)), which is a specific exemption to the unique device identification requirement, is being modified in the same way as the classification regulations in the preceding bullet by changing references from §§ 820.180 and 820.198 in the QSR to the equivalent requirement in the QMSR (§ 820.35).
- In the classification regulation for the Keratoscope (§ 886.1350(b) (21 CFR 886.1350(b))), in addition to the updated language described in the first bullet, we are also adding the words ''Classification. Class I (general controls).'' This is because the statement that the device was classified as class I [4] was inadvertently deleted from the CFR when the section was last edited in 2000.[5]
- Nine class II classification regulations [6] are being modified to change references to § 820.30 (Design Controls) (21 CFR 820.30) in the QSR to the equivalent provision in the QMSR (§ 820.10(c) (21 CFR 820.10(c))).
- In part 812 (Investigational Device Exemptions) an additional two sections (§§ 812.1(a) and 812.35(a)(3)(iii)(A) (21 CFR 812.1(a) and 812.35(a)(3)(iii)(A))) are being modified to also change references from § 820.30 in the QSR to the equivalent provision in the QMSR (§ 820.10(c)). A second revision to § 812.35 revises § 812.35(a)(3)(iv)(A) to insert a clarifying reference to § 820.10(c) of the QMSR.
- One change in § 801.45(e) (21 CFR 801.45(e)) changes a reference from the design history file in the QSR to the design and development files of the QMSR.
- Four sections are modified in this technical amendment by updating the phrase ''quality system regulation'' to

[1] In this technical amendment, FDA uses the terms below in the following manner: when referring to 21 CFR part 820 as amended and effective on February 2, 2026, FDA uses the terms ''Quality Management System Regulation'' or ''QMSR.'' When referring to the regulation at 21 CFR part 820 in effect before February 2, 2026, FDA uses the terms ''Quality System Regulation'' or ''QSR.''

[2] Class I devices are those devices for which the general controls within the Federal Food, Drug, and Cosmetic Act (FD&C Act) (controls authorized by or under section 501, 502, 510, 516, 518, 519, or 520 (21 U.S.C. 351, 352, 360, 360f, 360h, 360i, or 360j) or any combination of such sections) are sufficient to provide reasonable assurance of safety and effectiveness; or those devices for which insufficient information exists to determine that general controls are sufficient to provide reasonable assurance of safety and effectiveness or to establish special controls to provide such assurance, but because the devices are not purported or represented to be for a use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health, and do not present a potential unreasonable risk of illness or injury, are to be regulated by general controls (section 513(a)(1)(A) of the FD&C Act (21 U.S.C. 360c(a)(1)(A))).

[3] Section 864.3260(b) (21 CFR 864.3260(b)) currently exempts over-the-counter (OTC) test sample collection systems for drugs of abuse testing, if the device is not labeled or otherwise represented as sterile, from all of the QSR except for § 820.198.

[4] 55 FR 48436 at 48438.

[5] See 65 FR 2296 at 2320.

[6] Class II devices are those devices for which general controls by themselves are insufficient to provide reasonable assurance of safety and effectiveness, and for which there is sufficient information to establish special controls to provide such assurance, including the issuance of performance standards, postmarket surveillance, patient registries, development and dissemination of guidelines, recommendations, and other appropriate actions the Agency deems necessary to provide such assurance (section 513(a)(1)(B) of the FD&C Act).

the phrase ''quality management system regulation.''

• FDA is clarifying the authority citations in parts 862, 876, and 878 to italicize the 'l' in 21 U.S.C. 360*l* to more clearly distinguish it from a numeral 1.

In some of the edited sections we have also made minor wording changes to standardize language across sections and/or correct non-substantive typographic errors. The changes to all 179 sections are non-substantive and are intended to conform existing regulations to the requirements in the QMSR that mirror the requirements in the QSR. This rule does not impose any new regulatory requirements on affected parties. The amendments are editorial in nature and should not be construed as modifying any substantive standards or requirements.

III. Notice and Public Comment

Publication of this document constitutes final action under the Administrative Procedure Act (APA) (5 U.S.C. 551–559). Section 553 of the APA generally exempts ''rules of agency organization, procedure, or practice'' from proposed rulemaking (*i.e.,* notice and comment rulemaking) (5 U.S.C. 553(b)(4)(A)). Rules are also exempt when an agency finds ''good cause'' that notice and comment rulemaking procedures would be ''impracticable, unnecessary, or contrary to the public interest'' (5 U.S.C. 553(b)(4)(B)).

FDA has determined that this rulemaking meets the APA's notice and comment exemption requirements under 5 U.S.C. 553(b)(4)(B). All the revisions in this rule are technical or non-substantive changes. These revisions update the language in certain regulations to be consistent with other regulations and the FD&C Act without changing the actions required under the regulations. Such technical, non-substantive changes are ''a routine determination, insignificant in nature and impact, and inconsequential to the industry and to the public.'' *Mack Trucks, Inc.* v. *EPA,* 682 F.3d 87, 94 (D.C. Cir. 2012) (quotation marks and citation omitted). FDA accordingly for good cause finds that notice and public procedure thereon are unnecessary for these amendments.

IV. Effective Date

This amendment is effective on February 2, 2026. This is the same date that the QMSR final rule becomes effective.

List of Subjects

21 CFR Part 801

Labeling, Medical devices, Reporting and recordkeeping requirements.

21 CFR Part 803

Imports, Medical devices, Reporting and recordkeeping requirements.

21 CFR Part 812

Health records, Medical devices, Medical research, Reporting and recordkeeping requirements.

21 CFR Part 860

Administrative practice and procedure, Medical devices.

21 CFR Part 862

Medical devices.

21 CFR Part 864

Blood, Medical devices, Packaging and containers.

21 CFR Part 866

Biologics, Laboratories, Medical devices.

21 CFR Parts 868, 872, 874, 876, 878, 880, and 882

Medical devices.

21 CFR Part 886

Medical devices, Ophthalmic goods and services.

21 CFR Parts 888 and 890

Medical devices.

21 CFR Part 892

Medical devices, Radiation protection, X-rays.

Therefore, under the Federal Food, Drug, and Cosmetic Act, and under the authority delegated to the Commissioner of Food and Drugs, 21 CFR parts 801, 803, 812, 860, 862, 864, 866, 868, 872, 874, 876, 878, 880, 882, 886, 888, 890, and 892 are amended as follows:

PART 801—LABELING

■ 1. The authority citation for part 801 continues to read as follows:

Authority: 21 U.S.C. 321, 331–334, 351, 352, 360d, 360i, 360j, 371, 374.

■ 2. In § 801.30, revise paragraph (a)(2) to read as follows:

§ 801.30 General exceptions from the requirement for the label of a device to bear a unique device identifier.

(a) * * *

(2) A class I device that FDA has by regulation exempted from the good manufacturing practice requirements of part 820 of this chapter, exclusive of any continuing requirement for recordkeeping under § 820.35 of this chapter.

* * * * *

■ 3. In § 801.45, revise paragraph (e) to read as follows:

§ 801.45 Devices that must be directly marked with a unique device identifier.

* * * * *

(e) *Exception to be noted in design and development files.* A labeler that decides to make use of an exception under paragraph (d) of this section must document the basis of that decision in the design and development files required by § 820.10(c) of this chapter.

PART 803—MEDICAL DEVICE REPORTING

■ 4. The authority citation for part 803 continues to read as follows:

Authority: 21 U.S.C. 352, 360, 360i, 360j, 371, 374.

■ 5. In § 803.18, revise paragraph (e) to read as follows:

§ 803.18 What are the requirements for establishing and maintaining MDR files or records that apply to me?

* * * * *

(e) If you are a manufacturer, you may maintain MDR event files as part of your complaint file, under part 820 of this chapter, if you prominently identify these records as MDR reportable events. We will not consider your submitted MDR report to comply with this part unless you evaluate an event in accordance with the quality management system requirements described in part 820 of this chapter. You must document and maintain in your MDR event files an explanation of why you did not submit or could not obtain any information required by this part, as well as the results of your evaluation of each event.

PART 812—INVESTIGATIONAL DEVICE EXEMPTIONS

■ 6. The authority citation for part 812 continues to read as follows:

Authority: 21 U.S.C. 331, 351, 352, 353, 355, 360, 360c–360f, 360h–360j, 360hh–360pp, 360rr–360ss, 360bbb–8b, 371, 372, 374, 379e, 381, 382; 42 U.S.C. 216, 241, 262.

■ 7. In § 812.1, revise paragraph (a) to read as follows:

§ 812.1 Scope.

(a) The purpose of this part is to encourage, to the extent consistent with the protection of public health and safety and with ethical standards, the discovery and development of useful devices intended for human use, and to that end to maintain optimum freedom for scientific investigators in their pursuit of this purpose. This part provides procedures for the conduct of clinical investigations of devices. An approved investigational device exemption (IDE) permits a device that

otherwise would be required to comply with a performance standard or to have premarket approval to be shipped lawfully for the purpose of conducting investigations of that device. An IDE approved under § 812.30 or considered approved under § 812.2(b) exempts a device from the requirements of the following sections of the Federal Food, Drug, and Cosmetic Act (the act) and the regulations in this chapter issued thereunder: Misbranding under section 502 of the act, registration, listing, and premarket notification under section 510, performance standards under section 514, premarket approval under section 515, a banned device regulation under section 516, records and reports under section 519, restricted device requirements under section 520(e), good manufacturing practice requirements under section 520(f) except for the requirements found in § 820.10(c), if applicable (unless the sponsor states an intention to comply with these requirements under § 812.20(b)(3) or § 812.140(b)(4)(v)) and color additive requirements under section 721.

* * * * *

■ 8. In § 812.35, revise paragraphs (a)(3)(iii)(A) and (a)(3)(iv)(A) to read as follows:

§ 812.35 Supplemental applications.

(a) * * *

(3) * * *

(iii) * * *

(A) Credible information to support developmental changes in the device (including manufacturing changes) includes data generated under the design and development activities of § 820.10(c) of this chapter, preclinical/animal testing, peer reviewed published literature, or other reliable information such as clinical information gathered during a trial or marketing.

* * * * *

(iv) * * *

(A) For a developmental or manufacturing change to the device, the notice shall include a summary of the relevant information gathered during the course of the investigation upon which the change was based; a description of the change to the device or manufacturing process (cross-referenced to the appropriate sections of the original device description or manufacturing process); and, if the design and development activities of § 820.10(c) of this chapter were used to assess the change, a statement that no new risks were identified by appropriate risk analysis and that the verification and validation testing, as appropriate, demonstrated that the design outputs met the design input requirements. If another method of assessment was used, the notice shall include a summary of the information which served as the credible information supporting the change.

* * * * *

PART 860—MEDICAL DEVICE CLASSIFICATION PROCEDURES

■ 9. The authority citation for part 860 continues to read as follows:

Authority: 21 U.S.C. 321(h), 353(g), 360c, 360d, 360e, 360i, 360j, 371, 374.

■ 10. In § 860.15, revise paragraph (a) to read as follows:

§ 860.15 Exemptions from sections 510, 519, and 520(f) of the Federal Food, Drug, and Cosmetic Act.

(a) A panel recommendation to the Commissioner that a device be classified or reclassified into class I will include a recommendation as to whether the device should be exempted from some or all of the requirements of one or more of the following sections of the Federal Food, Drug, and Cosmetic Act: Section 510 (registration, product listing, and premarket notification), section 519 (records and reports) and section 520(f) (good manufacturing practice requirements of the quality management system regulation), and, in the case of a recommendation for classification into class II, whether the device should be exempted from the premarket notification requirement under section 510.

* * * * *

■ 11. In § 860.84, revise paragraph (d)(4) to read as follows:

§ 860.84 Classification procedures for "preamendments devices."

* * * * *

(d) * * *

(4) In the case of a recommendation for classification into class I, a recommendation as to whether the device should be exempted from the requirements of one or more of the following sections of the Federal Food, Drug, and Cosmetic Act: Section 510 (registration, product listing, and premarket notification), section 519 (records and reports), and section 520(f) (good manufacturing practice requirements of the quality management system regulation) and, in the case of a recommendation for classification into class II, whether the device should be exempted from the premarket notification requirement under section 510, in accordance with § 860.15;

* * * * *

■ 12. In § 860.240, revise paragraph (c)(2) to read as follows:

§ 860.240 Procedures for review of a De Novo request.

* * * * *

(c) * * *

(2) That implementation of Quality Management System Regulation (part 820 of this chapter) requirements, in addition to other general controls and any specified special controls, provide adequate assurance that critical and/or novel manufacturing processes produce devices that meet specifications necessary to ensure reasonable assurance of safety and effectiveness.

PART 862—CLINICAL CHEMISTRY AND CLINICAL TOXICOLOGY DEVICES

■ 13. The authority citation for part 862 is revised to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 360*l,* 371.

■ 14. In § 862.1220, revise paragraph (b)(2) to read as follows:

§ 862.1220 Acute kidney injury test system.

* * * * *

(b) * * *

(2) As part of the risk management activities performed as part of your 21 CFR 820.10(c) design and development activities, you must document the appropriate end user device training program provided in your premarket notification submission to satisfy the special control in paragraph (b)(1) of this section that will be offered while marketing the device as part of your efforts to mitigate the risk of incorrect interpretation of test results.

* * * * *

■ 15. In § 862.2050, revise paragraph (b) to read as follows:

§ 862.2050 General purpose laboratory equipment labeled or promoted for a specific medical use.

* * * * *

(b) *Classification.* Class I (general controls). The device is identified in paragraph (a) of this section and is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 862.9. The device is also exempt from the current good manufacturing practice requirements of the quality management system regulation in part 820 of this chapter, except for requirements concerning records and complaint files under § 820.35 of this chapter.

■ 16. In § 862.2270, revise paragraph (b) to read as follows:

§ 862.2270 Thin-layer chromatography system for clinical use.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 862.9. Particular components of TLC systems, *i.e.,* the thin-layer chromatography apparatus, TLC atomizer, TLC developing tanks, and TLC ultraviolet light, are exempt from the current good manufacturing practice requirements of the quality management system regulation in part 820 of this chapter, except for requirements concerning records and complaint files under § 820.35 of this chapter.

PART 864—HEMATOLOGY AND PATHOLOGY DEVICES

■ 17. The authority citation for part 864 continues to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 360*l,* 371.

■ 18. In § 864.1850, revise paragraph (b) to read as follows:

§ 864.1850 Dye and chemical solution stains.

* * * * *

(b) *Classification.* Class I (general controls). These devices are exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 864.9. These devices are also exempt from the current good manufacturing practice requirements of the quality management system regulation in part 820 of this chapter, except for requirements concerning records and complaint files under § 820.35 of this chapter.

■ 19. In § 864.2240, revise paragraph (b) to read as follows:

§ 864.2240 Cell and tissue culture supplies and equipment.

* * * * *

(b) *Classification.* Class I (general controls). These devices are exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 864.9. If the devices are not labeled or otherwise represented as sterile, they are exempt from the current good manufacturing practice requirements of the quality management system regulation in part 820 of this chapter, except for requirements concerning records and complaint files under § 820.35 of this chapter.

■ 20. In § 864.3010, revise paragraph (b) to read as follows:

§ 864.3010 Tissue processing equipment.

* * * * *

(b) *Classification.* Class I (general controls). These devices are exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 864.9. The devices are also exempt from the current good manufacturing practice requirements of the quality management system regulation in part 820 of this chapter, except for requirements concerning records and complaint files under § 820.35 of this chapter.

■ 21. In § 864.3250, revise paragraph (b) to read as follows:

§ 864.3250 Specimen transport and storage container.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 864.9. If the device is not labeled or otherwise represented as sterile, it is exempt from the current good manufacturing practice requirements of the quality management system regulation in part 820 of this chapter, except for requirements concerning records and complaint files under § 820.35 of this chapter.

■ 22. In § 864.3260, revise paragraph (b) to read as follows:

§ 864.3260 OTC test sample collection systems for drugs of abuse testing.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification requirements in part 807, subpart E of this chapter subject to the limitations in § 864.9 if it is sold, distributed, and used in accordance with the restrictions set forth in § 809.40 of this chapter. If the device is not labeled or otherwise represented as sterile, it is exempt from the current good manufacturing practice requirements of the quality management system regulation in part 820 of this chapter, except for requirements concerning complaint files under § 820.35(a) of this chapter.

■ 23. In § 864.3600, revise paragraph (b) to read as follows:

§ 864.3600 Microscopes and accessories.

* * * * *

(b) *Classification.* Class I (general controls). These devices are exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 864.9. If the device is not labeled or otherwise represented as sterile, it is exempt from the current good manufacturing practice requirements of the quality management system regulation in part 820 of this chapter, except for requirements concerning records and complaint files under § 820.35 of this chapter.

■ 24. In § 864.4010, revise paragraph (b) to read as follows:

§ 864.4010 General purpose reagent.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 864.9. If the device is not labeled or otherwise represented as sterile, it is exempt from the current good manufacturing practice requirements of the quality management system regulation in part 820 of this chapter, except for requirements concerning records and complaint files under § 820.35 of this chapter.

■ 25. In § 864.7010, revise paragraph (b)(3) to read as follows:

§ 864.7010 Flow cytometric test system for hematopoietic neoplasms.

* * * * *

(b) * * *

(3) As part of the risk management activities performed under 21 CFR 820.10(c) design and development, product labeling and instruction manuals must include clear examples of all expected phenotypic patterns and gating strategies using well-defined clinical samples representative of both abnormal and normal cellular populations. These samples must be selected based upon the indications described in paragraph (b)(1)(i) of this section.

PART 866—IMMUNOLOGY AND MICROBIOLOGY DEVICES

■ 26. The authority citation for part 866 continues to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 360*l,* 371.

■ 27. In § 866.2120, revise paragraph (b) to read as follows:

§ 866.2120 Anaerobic chamber.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 866.9. The device is also exempt from the good manufacturing practice requirements of the quality management system regulation in part 820 of this chapter, except for requirements concerning records and complaint files under § 820.35 of this chapter.

■ 28. In § 866.2180, revise paragraph (b) to read as follows:

§ 866.2180 Manual colony counter.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 866.9. The device is also exempt from the good manufacturing practice requirements of the quality management system regulation in part 820 of this chapter, except for requirements concerning records and complaint files under § 820.35 of this chapter.

■ 29. In § 866.2190, revise paragraph (b)(7) to read as follows:

§ 866.2190 Automated image assessment system for microbial colonies on solid culture media.

* * * * *

(b) * * *

(7) Under 21 CFR 820.10(c) design and development, device manufacturers must, as appropriate:

(i) Conduct human factors/usability validation testing with the final version of the labeling and related materials to adequately mitigate the risk of failure to operate the instrument correctly.

(ii) Document a device training program that will be offered to the end user to adequately mitigate the risk of failure to operate the instrument correctly.

■ 30. In § 866.2440, revise paragraph (b) to read as follows:

§ 866.2440 Automated medium dispensing and stacking device.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 866.9. The device is also exempt from the good manufacturing practice requirements of the quality management system regulation in part 820 of this chapter, except for requirements concerning records and complaint files under § 820.35 of this chapter.

■ 31. In § 866.2540, revise paragraph (b) to read as follows:

§ 866.2540 Microbiological incubator.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 866.9. The device is also exempt from the good manufacturing practice requirements of the quality management system regulation in part 820 of this chapter, except for requirements concerning records and complaint files under § 820.35 of this chapter.

■ 32. In § 866.2600, revise paragraph (b) to read as follows:

§ 866.2600 Wood's fluorescent lamp.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 866.9. The device is also exempt from the good manufacturing practice requirements of the quality management system regulation in part 820 of this chapter, except for requirements concerning records and complaint files under § 820.35 of this chapter.

■ 33. In § 866.3215, revise paragraph (b)(6) to read as follows:

§ 866.3215 Device to detect and measure non-microbial analyte(s) in human clinical specimens to aid in assessment of patients with suspected sepsis.

* * * * *

(b) * * *

(6) As part of the risk management activities performed under 21 CFR 820.10(c) design and development, you must document an appropriate end user device training program that will be offered as part of your efforts to mitigate the risk of failure to correctly operate the instrument.

* * * * *

■ 34. In § 866.3309, revise paragraph (b)(7) to read as follows:

§ 866.3309 Herpes virus nucleic acid-based cutaneous and mucocutaneous lesion panel.

* * * * *

(b) * * *

(7) The risk management activities performed as part of the manufacturer's 21 CFR 820.10(c) design and development activities must document an appropriate end user device training program that will be offered as part of efforts to mitigate the risk of failure to correctly operate the instrument.

■ 35. In § 866.3361, revise paragraph (b)(4) to read as follows:

§ 866.3361 Mass spectrometer system for clinical use for the identification of microorganisms.

* * * * *

(b) * * *

(4) As part of the risk management activities performed under 21 CFR 820.10(c) design and development, you must document an appropriate end user device training program that will be offered as part of your efforts to mitigate the risk of failure to correctly operate the instrument.

* * * * *

■ 36. In § 866.3960, revise paragraph (b)(8) to read as follows:

§ 866.3960 Nucleic acid-based device for the amplification, detection, and identification of microbial pathogens directly from whole blood specimens.

* * * * *

(b) * * *

(8) As part of the risk management activities performed under 21 CFR 820.10(c) design and development, you must document an appropriate end user device training program that will be offered as part of your efforts to mitigate the risk of failure to correctly operate the instrument.

■ 37. In § 866.3970, revise paragraph (b)(10) to read as follows:

§ 866.3970 Device to detect and identify microbial pathogen nucleic acids in cerebrospinal fluid.

* * * * *

(b) * * *

(10) As part of the risk management activities performed under 21 CFR 820.10(c) design and development, you must document an appropriate end user device training program that will be offered as part of your efforts to mitigate the risk of failure to correctly operate the instrument.

PART 868—ANESTHESIOLOGY DEVICES

■ 38. The authority citation for part 868 continues to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 360*l,* 371.

■ 39. In § 868.1030, revise paragraph (b) to read as follows:

§ 868.1030 Manual algesimeter.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 868.9. The device is also exempt from the current good manufacturing practice requirements of the quality management system regulation in part 820 of this chapter, except for requirements concerning records and complaint files under § 820.35 of this chapter.

■ 40. In § 868.1965, revise paragraph (b) to read as follows:

§ 868.1965 Switching valve (ploss).

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 868.9. The device is also exempt from the current

good manufacturing practice requirements of the quality management system regulation in part 820 of this chapter, except for requirements concerning records and complaint files under § 820.35 of this chapter.

■ 41. In § 868.5220, revise paragraph (b) to read as follows:

§ 868.5220 Blow bottle.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 868.9. If the device is not labeled or otherwise represented as sterile, it is exempt from the current good manufacturing practice requirements of the quality management system regulation in part 820 of this chapter, except for requirements concerning records and complaint files under § 820.35 of this chapter.

■ 42. In § 868.5420, revise paragraph (b) to read as follows:

§ 868.5420 Ether hook.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 868.9. If the device is not labeled or otherwise represented as sterile, it is exempt from the current good manufacturing practice requirements of the quality management system regulation in part 820 of this chapter, except for requirements concerning records and complaint files under § 820.35 of this chapter.

■ 43. In § 868.5760, revise paragraph (b) to read as follows:

§ 868.5760 Cuff spreader.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 868.9. If the device is not labeled or otherwise represented as sterile, it is exempt from the current good manufacturing practice requirements of the quality management system regulation in part 820 of this chapter, except for requirements concerning records and complaint files under § 820.35 of this chapter.

■ 44. In § 868.5795, revise paragraph (b) to read as follows:

§ 868.5795 Tracheal tube cleaning brush.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 868.9. If the device is not labeled or otherwise represented as sterile, it is exempt from the current good manufacturing practice requirements of the quality management system regulation in part 820 of this chapter, except for requirements concerning records and complaint files under § 820.35 of this chapter.

■ 45. In § 868.6175, revise paragraph (b) to read as follows:

§ 868.6175 Cardiopulmonary emergency cart.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 868.9. The device is also exempt from the current good manufacturing practice requirements of the quality management system regulation in part 820 of this chapter, except for requirements concerning records and complaint files under § 820.35 of this chapter.

■ 46. In § 868.6225, revise paragraph (b) to read as follows:

§ 868.6225 Nose clip.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 868.9. The device is also exempt from the current good manufacturing practice requirements of the quality management system regulation in part 820 of this chapter, except for requirements concerning records and complaint files under § 820.35 of this chapter.

PART 872—DENTAL DEVICES

■ 47. The authority citation for part 872 continues to read as follows:

Authority: 21 U.S.C. 351, 360 360c, 360e, 360j, 360*l,* 371.

■ 48. In § 872.1905, revise paragraph (b) to read as follows:

§ 872.1905 Dental x-ray film holder.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 872.9. If the device is not labeled or otherwise represented as sterile, it is also exempt from the current good manufacturing practice requirements of the quality management system regulation in part 820 of this chapter, except for requirements concerning records and complaint files under § 820.35 of this chapter.

■ 49. In § 872.3140, revise paragraph (b) to read as follows:

§ 872.3140 Resin applicator.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 872.9. If the device is not labeled or otherwise represented as sterile, the device is exempt from the current good manufacturing practice requirements of the quality management system regulation in part 820 of this chapter, except for requirements concerning records and complaint files under § 820.35 of this chapter.

■ 50. In § 872.3150, revise paragraph (b) to read as follows:

§ 872.3150 Articulator.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 872.9. If the device is not labeled or otherwise represented as sterile, the device is exempt from the current good manufacturing practice requirements of the quality management system regulation in part 820 of this chapter, except for requirements concerning records and complaint files under § 820.35 of this chapter.

■ 51. In § 872.3220, revise paragraph (b) to read as follows:

§ 872.3220 Facebow.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 872.9. If the device is not labeled or otherwise represented as sterile, the device is exempt from the current good manufacturing practice requirements of the quality management system regulation in part 820 of this chapter, except for requirements concerning records and complaint files under § 820.35 of this chapter.

■ 52. In § 872.3670, revise paragraph (b) to read as follows:

§ 872.3670 Resin impression tray material.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 872.9. If

the device is not labeled or otherwise represented as sterile, it is exempt from the current good manufacturing practice requirements of the quality management system regulation in part 820 of this chapter, except for requirements concerning records and complaint files under § 820.35 of this chapter.

■ 53. In § 872.3730, revise paragraph (b) to read as follows:

§ 872.3730 Pantograph.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 872.9. If the device is not labeled or otherwise represented as sterile, it is exempt from the current good manufacturing practice requirements of the quality management system regulation in part 820 of this chapter, except for requirements concerning records and complaint files under § 820.35 of this chapter.

■ 54. In § 872.6010, revise paragraph (b) to read as follows:

§ 872.6010 Abrasive device and accessories.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 872.9. If the device is not labeled or otherwise represented as sterile, it is exempt from the current good manufacturing practice requirements of the quality management system regulation in part 820 of this chapter, except for requirements concerning records and complaint files under § 820.35 of this chapter.

■ 55. In § 872.6050, revise paragraph (b) to read as follows:

§ 872.6050 Saliva absorber.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 872.9. If the device is not labeled or otherwise represented as sterile, it is exempt from the current good manufacturing practice requirements of the quality management system regulation in part 820 of this chapter, except for requirements concerning records and complaint files under § 820.35 of this chapter.

■ 56. In § 872.6140, revise paragraph (b) to read as follows:

§ 872.6140 Articulation paper.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 872.9. If the device is not labeled or otherwise represented as sterile, it is exempt from the current good manufacturing practice requirements of the quality management system regulation in part 820 of this chapter, except for requirements concerning records and complaint files under § 820.35 of this chapter.

■ 57. In § 872.6200, revise paragraph (b) to read as follows:

§ 872.6200 Base plate shellac.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 872.9. If the device is not labeled or otherwise represented as sterile, it is exempt from the current good manufacturing practice requirements of the quality management system regulation in part 820 of this chapter, except for requirements concerning records and complaint files under § 820.35 of this chapter.

■ 58. In § 872.6290, revise paragraph (b) to read as follows:

§ 872.6290 Prophylaxis cup.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 872.9. If the device is not labeled or otherwise represented as sterile, it is exempt from the current good manufacturing practice requirements of the quality management system regulation in part 820 of this chapter, except for requirements concerning records and complaint files under § 820.35 of this chapter.

■ 59. In § 872.6300, revise paragraph (b) to read as follows:

§ 872.6300 Rubber dam and accessories.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 872.9. If the device is not labeled or otherwise represented as sterile, it is exempt from the current good manufacturing practice requirements of the quality management system regulation in part 820 of this chapter, except for requirements concerning records and complaint files under § 820.35 of this chapter.

■ 60. In § 872.6570, revise paragraph (b) to read as follows:

§ 872.6570 Impression tube.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 872.9. If the device is not labeled or otherwise represented as sterile, it is exempt from the current good manufacturing practice requirements of the quality management system regulation in part 820 of this chapter, except for requirements concerning records and complaint files under § 820.35 of this chapter.

■ 61. In § 872.6650, revise paragraph (b) to read as follows:

§ 872.6650 Massaging pick or tip for oral hygiene.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 872.9. If the device is not labeled or otherwise represented as sterile, it is exempt from the current good manufacturing practice requirements of the quality management system regulation in part 820 of this chapter, except for requirements concerning records and complaint files under § 820.35 of this chapter.

■ 62. In § 872.6670, revise paragraph (b) to read as follows:

§ 872.6670 Silicate protector.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 872.9. If the device is not labeled or otherwise represented as sterile, it is exempt from the current good manufacturing practice requirements of the quality management system regulation in part 820 of this chapter, except for requirements concerning records and complaint files under § 820.35 of this chapter.

■ 63. In § 872.6855, revise paragraph (b) to read as follows:

§ 872.6855 Manual toothbrush.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 872.9. If the device is not labeled or otherwise represented as sterile, it is exempt from the current good manufacturing practice requirements of the quality management system regulation in part 820 of this chapter, except for requirements

concerning records and complaint files under § 820.35 of this chapter.

■ 64. In § 872.6870, revise paragraph (b) to read as follows:

§ 872.6870 Disposable fluoride tray.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 872.9. If the device is not labeled or otherwise represented as sterile, it is exempt from the current good manufacturing practice requirements of the quality management system regulation in part 820 of this chapter, except for requirements concerning records and complaint files under § 820.35 of this chapter.

■ 65. In § 872.6880, revise paragraph (b) to read as follows:

§ 872.6880 Preformed impression tray.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 872.9. If the device is not labeled or otherwise represented as sterile, it is exempt from the current good manufacturing practice requirements of the quality management system regulation in part 820 of this chapter, except for requirements concerning records and complaint files under § 820.35 of this chapter.

■ 66. In § 872.6890, revise paragraph (b) to read as follows:

§ 872.6890 Intraoral dental wax.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 872.9. If the device is not labeled or otherwise represented as sterile, it is exempt from the current good manufacturing practice requirements of the quality management system regulation in part 820 of this chapter, except for requirements concerning records and complaint files under § 820.35 of this chapter.

PART 874—EAR, NOSE, AND THROAT DEVICES

■ 67. The authority citation for part 874 continues to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 360*l,* 371.

■ 68. In § 874.1500, revise paragraph (b) to read as follows:

§ 874.1500 Gustometer.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 874.9. If the device is not labeled or otherwise represented as sterile, it is exempt from the current good manufacturing practice requirements of the quality management system regulation in part 820 of this chapter, except for requirements concerning records and complaint files under § 820.35 of this chapter.

■ 69. In § 874.3540, revise paragraph (b) to read as follows:

§ 874.3540 Prosthesis modification instrument for ossicular replacement surgery.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 874.9. If the device is not labeled or otherwise represented as sterile, it is exempt from the current good manufacturing practice requirements of the quality management system regulation in part 820 of this chapter, except for requirements concerning records and complaint files under § 820.35 of this chapter.

■ 70. In § 874.5220, revise paragraph (b) to read as follows:

§ 874.5220 Ear, nose, and throat drug administration device.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 874.9. If the device is not labeled or otherwise represented as sterile, it is exempt from the current good manufacturing practice requirements of the quality management system regulation in part 820 of this chapter, except for requirements concerning records and complaint files under § 820.35 of this chapter.

PART 876—GASTROENTEROLOGY-UROLOGY DEVICES

■ 71. The authority citation for part 876 is revised to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 360*l,* 371.

■ 72. In § 876.5210, revise paragraph (b) to read as follows:

§ 876.5210 Enema kit.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 876.9. The device is exempt from the current good manufacturing practice requirements of the quality management system regulation in part 820 of this chapter, except for requirements concerning records and complaint files under § 820.35 of this chapter.

■ 73. In § 876.5250, revise paragraph (b)(2) to read as follows:

§ 876.5250 Urine collector and accessories.

* * * * *

(b) * * *

(2) *Class I (general controls).* For a urine collector and accessories not intended to be connected to an indwelling catheter, the device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 876.9. If the device is not labeled or otherwise represented as sterile, it is exempt from the current good manufacturing practice requirements of the quality management system regulation in part 820 of this chapter, except for requirements concerning records and complaint files under § 820.35 of this chapter.

■ 74. In § 876.5920, revise paragraph (b) to read as follows:

§ 876.5920 Protective garment for incontinence.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 876.9. The device is also exempt from the current good manufacturing practice requirements of the quality management system regulation in part 820 of this chapter, except for requirements concerning records and complaint files under § 820.35 of this chapter.

■ 75. In § 876.5970, revise paragraph (b) to read as follows:

§ 876.5970 Hernia support.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 876.9. The device is also exempt from the current good manufacturing practice requirements of the quality management system regulation in part 820 of this chapter, except for requirements concerning records and complaint files under § 820.35 of this chapter.

PART 878—GENERAL AND PLASTIC SURGERY DEVICES

■ 76. The authority citation for part 878 is revised to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 360*l,* 371.

■ 77. In § 878.3800, revise paragraph (b) to read as follows:

§ 878.3800 External aesthetic restoration prosthesis.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 878.9. If the device is intended for use without an external prosthesis adhesive to fasten it to the body, the device is exempt from the current good manufacturing practice requirements of the quality management system regulation in part 820 of this chapter, except for requirements concerning records and complaint files under § 820.35 of this chapter.

■ 78. In § 878.3910, revise paragraph (b) to read as follows:

§ 878.3910 Noninflatable extremity splint.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 878.9. If the device is not labeled or otherwise represented as sterile, it is exempt from the current good manufacturing practice requirements of the quality management system regulation in part 820 of this chapter, except for requirements concerning records and complaint files under § 820.35 of this chapter.

PART 880—GENERAL HOSPITAL AND PERSONAL USE DEVICES

■ 79. The authority citation for part 880 continues to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 360*l,* 371.

■ 80. In § 880.2700, revise paragraph (b) to read as follows:

§ 880.2700 Stand-on patient scale.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 880.9. The device also is exempt from the current good manufacturing practice requirements of the quality management system regulation in part 820 of this chapter, except for requirements concerning records and complaint files under § 820.35 of this chapter.

■ 81. In § 880.2740, revise paragraph (b) to read as follows:

§ 880.2740 Surgical sponge scale.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 880.9. The device also is exempt from the current good manufacturing practice requirements of the quality management system regulation in part 820 of this chapter, except for requirements concerning records and complaint files under § 820.35 of this chapter.

■ 82. In § 880.2930, revise paragraph (b) to read as follows:

§ 880.2930 Apgar timer.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 880.9. The device is also exempt from the current good manufacturing practice requirements of the quality management system regulation in part 820 of this chapter, except for requirements concerning records and complaint files under § 820.35 of this chapter.

■ 83. In § 880.5075, revise paragraph (b) to read as follows:

§ 880.5075 Elastic bandage.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 880.9. The device also is exempt from the current good manufacturing practice requirements of the quality management system regulation in part 820 of this chapter, except for requirements concerning records and complaint files under § 820.35 of this chapter.

■ 84. In § 880.5120, revise paragraph (b) to read as follows:

§ 880.5120 Manual adjustable hospital bed.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 880.9. The device is also exempt from the current good manufacturing practice requirements of the quality management system regulation in part 820 of this chapter, except for requirements concerning records and complaint files under § 820.35 of this chapter.

■ 85. In § 880.5150, revise paragraph (b) to read as follows:

§ 880.5150 Nonpowered flotation therapy mattress.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 880.9. The device also is exempt from the current good manufacturing practice requirements of the quality management system regulation in part 820 of this chapter, except for requirements concerning records and complaint files under § 820.35 of this chapter.

■ 86. In § 880.5160, revise paragraph (b) to read as follows:

§ 880.5160 Therapeutic medical binder.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 880.9. If the device is not labeled or otherwise represented as sterile, it is also exempt from the current good manufacturing practice requirements of the quality management system regulation in part 820 of this chapter, except for requirements concerning records and complaint files under § 820.35 of this chapter.

■ 87. In § 880.5270, revise paragraph (b) to read as follows:

§ 880.5270 Neonatal eye pad.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 880.9. If the device is not labeled or otherwise represented as sterile, it is exempt from the current good manufacturing practice requirements of the quality management system regulation in part 820 of this chapter, except for requirements concerning records and complaint files under § 820.35 of this chapter.

■ 88. In § 880.5300, revise paragraph (b) to read as follows:

§ 880.5300 Medical absorbent fiber.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 880.9. If the device is not labeled or otherwise represented as sterile, it is also exempt

from the current good manufacturing practice requirements of the quality management system regulation in part 820 of this chapter, except for requirements concerning records and complaint files under § 820.35 of this chapter.

■ 89. In § 880.5640, revise paragraph (b) to read as follows:

§ 880.5640 Lamb feeding nipple.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 880.9. If the device is not labeled or otherwise represented as sterile, it is also exempt from the current good manufacturing practice requirements of the quality management system regulation in part 820 of this chapter, except for requirements concerning records and complaint files under § 820.35 of this chapter.

■ 90. In § 880.5680, revise paragraph (b) to read as follows:

§ 880.5680 Pediatric position holder.

* * * * *

(b) *Classification.* Class I (general controls). Except when the device is an infant positioner for prescription use in highly monitored settings or an infant sleep position holder, it is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 880.9. The device is exempt from the current good manufacturing practice requirements of the quality management system regulation in part 820 of this chapter, except for requirements concerning records and complaint files under § 820.35 of this chapter.

■ 91. In § 880.5780, revise paragraph (b)(2) to read as follows:

§ 880.5780 Medical support stocking.

* * * * *

(b) * * *

(2) *Classification.* Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 880.9. The device is also exempt from the current good manufacturing practice requirements of the quality management system regulation in part 820 of this chapter, except for requirements concerning records and complaint files under § 820.35 of this chapter.

■ 92. In § 880.5820, revise paragraph (b) to read as follows:

§ 880.5820 Therapeutic scrotal support.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 880.9. The device also is exempt from the current good manufacturing practice requirements of the quality management system regulation in part 820 of this chapter, except for requirements concerning records and complaint files under § 820.35 of this chapter.

■ 93. In § 880.6025, revise paragraph (b) to read as follows:

§ 880.6025 Absorbent tipped applicator.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 880.9. If the device is not labeled or otherwise represented as sterile, it is also exempt from the current good manufacturing practice requirements of the quality management system regulation in part 820 of this chapter, except for requirements concerning records and complaint files under § 820.35 of this chapter.

■ 94. In § 880.6050, revise paragraph (b) to read as follows:

§ 880.6050 Ice bag.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 880.9. If the device is not labeled or otherwise represented as sterile, it is also exempt from the current good manufacturing practice requirements of the quality management system regulation in part 820 of this chapter, except for requirements concerning records and complaint files under § 820.35 of this chapter.

■ 95. In § 880.6060, revise paragraph (b) to read as follows:

§ 880.6060 Medical disposable bedding.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 880.9. If the device is not labeled or otherwise represented as sterile, it is also exempt from the current good manufacturing practice requirements of the quality management system regulation in part 820 of this chapter, except for requirements concerning records and complaint files under § 820.35 of this chapter.

■ 96. In § 880.6070, revise paragraph (b) to read as follows:

§ 880.6070 Bed board.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 880.9. The device is also exempt from the current good manufacturing practice requirements of the quality management system regulation in part 820 of this chapter, except for requirements concerning records and complaint files under § 820.35 of this chapter.

■ 97. In § 880.6080, revise paragraph (b) to read as follows:

§ 880.6080 Cardiopulmonary resuscitation board.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 880.9. The device is also exempt from the current good manufacturing practice requirements of the quality management system regulation in part 820 of this chapter, except for requirements concerning records and complaint files under § 820.35 of this chapter.

■ 98. In § 880.6085, revise paragraph (b) to read as follows:

§ 880.6085 Hot/cold water bottle.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 880.9. The device is also exempt from the current good manufacturing practice requirements of the quality management system regulation in part 820 of this chapter, except for requirements concerning records and complaint files under § 820.35 of this chapter.

■ 99. In § 880.6140, revise paragraph (b) to read as follows:

§ 880.6140 Medical chair and table.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 880.9. The device is also exempt from the current good manufacturing practice requirements of the quality management system regulation in part 820 of this chapter, except for requirements concerning records and complaint files under § 820.35 of this chapter.

■ 100. In § 880.6185, revise paragraph (b) to read as follows:

§ 880.6185 Cast cover.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 880.9. If the device is not labeled or otherwise represented as sterile, it is also exempt from the current good manufacturing practice requirements of the quality management system regulation in part 820 of this chapter, except for requirements concerning records and complaint files under § 820.35 of this chapter.

■ 101. In § 880.6190, revise paragraph (b) to read as follows:

§ 880.6190 Mattress cover for medical purposes.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 880.9. If the device is not labeled or otherwise represented as sterile, it is also exempt from the current good manufacturing practice requirements of the quality management system regulation in part 820 of this chapter, except for requirements concerning records and complaint files under § 820.35 of this chapter.

■ 102. In § 880.6200, revise paragraph (b) to read as follows:

§ 880.6200 Ring cutter.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 880.9. The device also is exempt from the current good manufacturing practice requirements of the quality management system regulation in part 820 of this chapter, except for requirements concerning records and complaint files under § 820.35 of this chapter.

■ 103. In § 880.6230, revise paragraph (b) to read as follows:

§ 880.6230 Tongue depressor.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 880.9. If the device is not labeled or otherwise represented as sterile, it is also exempt from the current good manufacturing practice requirements of the quality management system regulation in part 820 of this chapter, except for requirements concerning records and complaint files under § 820.35 of this chapter.

■ 104. In § 880.6265, revise paragraph (b) to read as follows:

§ 880.6265 Examination gown.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 880.9. If the device is not labeled or otherwise represented as sterile, it is also exempt from the current good manufacturing practice requirements of the quality management system regulation in part 820 of this chapter, except for requirements concerning records and complaint files under § 820.35 of this chapter.

■ 105. In § 880.6350, revise paragraph (b) to read as follows:

§ 880.6350 Battery-powered medical examination light.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 880.9. The device also is exempt from the current good manufacturing practice requirements of the quality management system regulation in part 820 of this chapter, except for requirements concerning records and complaint files under § 820.35 of this chapter.

■ 106. In § 880.6430, revise paragraph (b) to read as follows:

§ 880.6430 Liquid medication dispenser.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 880.9. The device is also exempt from the current good manufacturing practice requirements of the quality management system regulation in part 820 of this chapter, except for requirements concerning records and complaint files under § 820.35 of this chapter.

■ 107. In § 880.6450, revise paragraph (b) to read as follows:

§ 880.6450 Skin pressure protectors.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 880.9. The device is also exempt from the current good manufacturing practice requirements of the quality management system regulation in part 820 of this chapter, except for requirements concerning records and complaint files under § 820.35 of this chapter.

■ 108. In § 880.6730, revise paragraph (b) to read as follows:

§ 880.6730 Body waste receptacle.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 880.9. The device also is exempt from the current good manufacturing practice requirements of the quality management system regulation in part 820 of this chapter, except for requirements concerning records and complaint files under § 820.35 of this chapter.

■ 109. In § 880.6785, revise paragraph (b) to read as follows:

§ 880.6785 Manual patient transfer device.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 880.9. The device is also exempt from the current good manufacturing practice requirements of the quality management system regulation in part 820 of this chapter, except for requirements concerning records and complaint files under § 820.35 of this chapter.

■ 110. In § 880.6800, revise paragraph (b) to read as follows:

§ 880.6800 Washers for body waste receptacles.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 880.9. The device also is exempt from the current good manufacturing practice requirements of the quality management system regulation in part 820 of this chapter, except for requirements concerning records and complaint files under § 820.35 of this chapter.

■ 111. In § 880.6900, revise paragraph (b) to read as follows:

§ 880.6900 Hand-carried stretcher.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter,

subject to the limitations in § 880.9. The device is also exempt from the current good manufacturing practice requirements of the quality management system regulation in part 820 of this chapter, except for requirements concerning records and complaint files under § 820.35 of this chapter.

■ 112. In § 880.6960, revise paragraph (b) to read as follows:

§ 880.6960 Irrigating syringe.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 880.9. If the device is not labeled or otherwise represented as sterile, it is also exempt from the current good manufacturing practice requirements of the quality management system regulation in part 820 of this chapter, except for requirements concerning records and complaint files under § 820.35 of this chapter.

■ 113. In § 880.6980, revise paragraph (b) to read as follows:

§ 880.6980 Vein stabilizer.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 880.9. If the device is not labeled or otherwise represented as sterile, it is also exempt from the current good manufacturing practice requirements of the quality management system regulation in part 820 of this chapter, except for requirements concerning records and complaint files under § 820.35 of this chapter.

PART 882—NEUROLOGICAL DEVICES

■ 114. The authority citation for part 882 continues to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 360*l,* 371.

■ 115. In § 882.1200, revise paragraph (b) to read as follows:

§ 882.1200 Two-point discriminator.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 882.9. The device is also exempt from the current good manufacturing practice requirements of the quality management system regulation in part 820 of this chapter, except for requirements concerning records and complaint files under § 820.35 of this chapter.

■ 116. In § 882.1500, revise paragraph (b) to read as follows:

§ 882.1500 Esthesiometer.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 882.9. The device is also exempt from the current good manufacturing practice requirements of the quality management system regulation in part 820 of this chapter, except for requirements concerning records and complaint files under § 820.35 of this chapter.

■ 117. In § 882.1525, revise paragraph (b) to read as follows:

§ 882.1525 Tuning fork.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 882.9. The device is also exempt from the current good manufacturing practice requirements of the quality management system regulation in part 820 of this chapter, except for requirements concerning records and complaint files under § 820.35 of this chapter.

■ 118. In § 882.1700, revise paragraph (b) to read as follows:

§ 882.1700 Percussor.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 882.9. The device is also exempt from the current good manufacturing practice requirements of the quality management system regulation in part 820 of this chapter, except for requirements concerning records and complaint files under § 820.35 of this chapter.

PART 886—OPHTHALMIC DEVICES

■ 119. The authority citation for part 886 continues to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 360*l,* 371.

■ 120. In § 886.1140, revise paragraph (b) to read as follows:

§ 886.1140 Ophthalmic chair.

* * * * *

(b) *Classification.* Class I. The AC-powered device and the manual device are exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 886.9. The manual device is also exempt from the current good manufacturing practice requirements of the quality management system regulation in part 820 of this chapter, except for requirements concerning records and complaint files under § 820.35 of this chapter.

■ 121. In § 886.1150, revise paragraph (b) to read as follows:

§ 886.1150 Visual acuity chart.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 886.9. The device is also exempt from the current good manufacturing practice requirements of the quality management system regulation in part 820 of this chapter, except for requirements concerning records and complaint files under § 820.35 of this chapter.

■ 122. In § 886.1170, revise paragraph (b) to read as follows:

§ 886.1170 Color vision tester.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 886.9. The device is also exempt from the current good manufacturing practice requirements of the quality management system regulation in part 820 of this chapter, except for requirements concerning records and complaint files under § 820.35 of this chapter.

■ 123. In § 886.1190, revise paragraph (b) to read as follows:

§ 886.1190 Distometer.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 886.9. The device is also exempt from the current good manufacturing practice requirements of the quality management system regulation in part 820 of this chapter, except for requirements concerning records and complaint files under § 820.35 of this chapter.

■ 124. In § 886.1200, revise paragraph (b) to read as follows:

§ 886.1200 Optokinetic drum.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter,

subject to the limitations in § 886.9. The device is also exempt from the current good manufacturing practice requirements of the quality management system regulation in part 820 of this chapter, except for requirements concerning records and complaint files under § 820.35 of this chapter.

■ 125. In § 886.1320, revise paragraph (b) to read as follows:

§ 886.1320 Fornixscope.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 886.9. The device is also exempt from the current good manufacturing practice requirements of the quality management system regulation in part 820 of this chapter, except for requirements concerning records and complaint files under § 820.35 of this chapter.

■ 126. In § 886.1330, revise paragraph (b) to read as follows:

§ 886.1330 Amsler grid.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 886.9. The device is also exempt from the current good manufacturing practice requirements of the quality management system regulation in part 820 of this chapter, except for requirements concerning records and complaint files under § 820.35 of this chapter.

■ 127. In § 886.1350, revise paragraph (b) to read as follows:

§ 886.1350 Keratoscope.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 886.9. The battery-powered device is exempt from the current good manufacturing practice requirements of the quality management system regulation in part 820 of this chapter, except for requirements concerning records and complaint files under § 820.35 of this chapter.

■ 128. In § 886.1375, revise paragraph (b) to read as follows:

§ 886.1375 Bagolini lens.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 886.9. The device is also exempt from the current good manufacturing practice requirements of the quality management system regulation in part 820 of this chapter, except for requirements concerning records and complaint files under § 820.35 of this chapter.

■ 129. In § 886.1380, revise paragraph (b) to read as follows:

§ 886.1380 Diagnostic condensing lens.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 886.9. The device is also exempt from the current good manufacturing practice requirements of the quality management system regulation in part 820 of this chapter, except for requirements concerning records and complaint files under § 820.35 of this chapter.

■ 130. In § 886.1390, revise paragraph (b) to read as follows:

§ 886.1390 Flexible diagnostic Fresnel lens.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 886.9. The device is also exempt from the current good manufacturing practice requirements of the quality management system regulation in part 820 of this chapter, except for requirements concerning records and complaint files under § 820.35 of this chapter.

■ 131. In § 886.1395, revise paragraph (b) to read as follows:

§ 886.1395 Diagnostic Hruby fundus lens.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 886.9. The device is also exempt from the current good manufacturing practice requirements of the quality management system regulation in part 820 of this chapter, except for requirements concerning records and complaint files under § 820.35 of this chapter.

■ 132. In § 886.1400, revise paragraph (b) to read as follows:

§ 886.1400 Maddox lens.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 886.9. The device is also exempt from the current good manufacturing practice requirements of the quality management system regulation in part 820 of this chapter, except for requirements concerning records and complaint files under § 820.35 of this chapter.

■ 133. In § 886.1415, revise paragraph (b) to read as follows:

§ 886.1415 Ophthalmic trial lens frame.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 886.9. The device is also exempt from the current good manufacturing practice requirements of the quality management system regulation in part 820 of this chapter, except for requirements concerning records and complaint files under § 820.35 of this chapter.

■ 134. In § 886.1460, revise paragraph (b) to read as follows:

§ 886.1460 Stereopsis measuring instrument.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 886.9. The device is also exempt from the current good manufacturing practice requirements of the quality management system regulation in part 820 of this chapter, except for requirements concerning records and complaint files under § 820.35 of this chapter.

■ 135. In § 886.1500, revise paragraph (b) to read as follows:

§ 886.1500 Headband mirror.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 886.9. The device is also exempt from the current good manufacturing practice requirements of the quality management system regulation in part 820 of this chapter, except for requirements concerning records and complaint files under § 820.35 of this chapter.

■ 136. In § 886.1605, revise paragraph (b) to read as follows:

§ 886.1605 Perimeter.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 886.9. The

device is also exempt from the current good manufacturing practice requirements of the quality management system regulation in part 820 of this chapter, except for requirements concerning records and complaint files under § 820.35 of this chapter.

■ 137. In § 886.1650, revise paragraph (b) to read as follows:

§ 886.1650 Ophthalmic bar prism.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 886.9. The device is also exempt from the current good manufacturing practice requirements of the quality management system regulation in part 820 of this chapter, except for requirements concerning records and complaint files under § 820.35 of this chapter.

■ 138. In § 886.1655, revise paragraph (b) to read as follows:

§ 886.1655 Ophthalmic Fresnel prism.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 886.9. The device is also exempt from the current good manufacturing practice requirements of the quality management system regulation in part 820 of this chapter, except for requirements concerning records and complaint files under § 820.35 of this chapter.

■ 139. In § 886.1665, revise paragraph (b) to read as follows:

§ 886.1665 Ophthalmic rotary prism.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 886.9. The device is also exempt from the current good manufacturing practice requirements of the quality management system regulation in part 820 of this chapter, except for requirements concerning records and complaint files under § 820.35 of this chapter.

■ 140. In § 886.1700, revise paragraph (b) to read as follows:

§ 886.1700 Pupillometer.

* * * * *

(b) *Classification.* Class I (general controls). The AC-powered device and the manual device are exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 886.9. The manual device is also exempt from the current good manufacturing practice requirements of the quality management system regulation in part 820 of this chapter, except for requirements concerning records and complaint files under § 820.35 of this chapter.

■ 141. In § 886.1770, revise paragraph (b) to read as follows:

§ 886.1770 Manual refractor.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 886.9. The device is also exempt from the current good manufacturing practice requirements of the quality management system regulation in part 820 of this chapter, except for requirements concerning records and complaint files under § 820.35 of this chapter.

■ 142. In § 886.1780, revise paragraph (b)(2) to read as follows:

§ 886.1780 Retinoscope.

* * * * *

(b) * * *

(2) Class I (general controls) for the battery-powered device. The class I battery-powered device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 886.9. The battery-powered device is exempt from the current good manufacturing practice requirements of the quality management system regulation in part 820 of this chapter, except for requirements concerning records and complaint files under § 820.35 of this chapter.

■ 143. In § 886.1790, revise paragraph (b) to read as follows:

§ 886.1790 Nearpoint ruler.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 886.9. The device is also exempt from the current good manufacturing practice requirements of the quality management system regulation in part 820 of this chapter, except for requirements concerning records and complaint files under § 820.35 of this chapter.

■ 144. In § 886.1810, revise paragraph (b) to read as follows:

§ 886.1810 Tangent screen (campimeter).

* * * * *

(b) *Classification.* Class I (general controls). The AC-powered device and the battery-powered device are exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 886.9. The battery-powered device is also exempt from the current good manufacturing practice requirements of the quality management system regulation in part 820 of this chapter, except for requirements concerning records and complaint files under § 820.35 of this chapter.

■ 145. In § 886.1840, revise paragraph (b) to read as follows:

§ 886.1840 Simulatan (including crossed cylinder).

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 886.9. The device is also exempt from the current good manufacturing practice requirements of the quality management system regulation in part 820 of this chapter, except for requirements concerning records and complaint files under § 820.35 of this chapter.

■ 146. In § 886.1860, revise paragraph (b) to read as follows:

§ 886.1860 Ophthalmic instrument stand.

* * * * *

(b) *Classification.* Class I (general controls). The AC-powered device and the battery-powered device are exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 886.9. The battery-powered device is also exempt from the current good manufacturing practice requirements of the quality management system regulation in part 820 of this chapter, except for requirements concerning records and complaint files under § 820.35 of this chapter.

■ 147. In § 886.1870, revise paragraph (b) to read as follows:

§ 886.1870 Stereoscope.

* * * * *

(b) *Classification.* Class I (general controls). The AC-powered device and the battery-powered device are exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 886.9. The battery-powered device is also exempt from the current good manufacturing practice requirements of the quality management system regulation in part 820 of this chapter, except for requirements concerning records and complaint files under § 820.35 of this chapter.

■ 148. In § 886.1880, revise paragraph (b) to read as follows:

§ 886.1880 Fusion and stereoscopic target.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 886.9. The device is also exempt from the current good manufacturing practice requirements of the quality management system regulation in part 820 of this chapter, except for requirements concerning records and complaint files under § 820.35 of this chapter.

■ 149. In § 886.1905, revise paragraph (b) to read as follows:

§ 886.1905 Nystagmus tape.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 886.9. The device is also exempt from the current good manufacturing practice requirements of the quality management system regulation in part 820 of this chapter, except for requirements concerning records and complaint files under § 820.35 of this chapter.

■ 150. In § 886.1910, revise paragraph (b) to read as follows:

§ 886.1910 Spectacle dissociation test system.

* * * * *

(b) *Classification.* Class I (general controls). The AC-powered device and the battery-powered device are exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 886.9. The battery-powered device is also exempt from the current good manufacturing practice requirements of the quality management system regulation in part 820 of this chapter, except for requirements concerning records and complaint files under § 820.35 of this chapter.

■ 151. In § 886.4230, revise paragraph (b) to read as follows:

§ 886.4230 Ophthalmic knife test drum.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 886.9. The device is also exempt from the current good manufacturing practice requirements of the quality management system regulation in part 820 of this chapter, except for requirements concerning records and complaint files under § 820.35 of this chapter.

■ 152. In § 886.4445, revise paragraph (b) to read as follows:

§ 886.4445 Permanent magnet.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 886.9. The device is also exempt from the current good manufacturing practice requirements of the quality management system regulation in part 820 of this chapter, except for requirements concerning records and complaint files under § 820.35 of this chapter.

■ 153. In § 886.4750, revise paragraph (b) to read as follows:

§ 886.4750 Ophthalmic eye shield.

* * * * *

(b) *Classification.* Class I (general controls). When made only of plastic or aluminum, the device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to § 886.9. When made only of plastic or aluminum, the devices are exempt from the current good manufacturing practice requirements of the quality management system regulation in part 820 of this chapter, except for requirements concerning records and complaint files under § 820.35 of this chapter.

■ 154. In § 886.4770, revise paragraph (b) to read as follows:

§ 886.4770 Ophthalmic operating spectacles (loupes).

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 886.9. The device is also exempt from the current good manufacturing practice requirements of the quality management system regulation in part 820 of this chapter, except for requirements concerning records and complaint files under § 820.35 of this chapter.

■ 155. In § 886.4855, revise paragraph (b) to read as follows:

§ 886.4855 Ophthalmic instrument table.

* * * * *

(b) *Classification.* Class I (general controls). The AC-powered device and the manual device are exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 886.9. The manual device is also exempt from the current good manufacturing practice requirements of the quality management system regulation in part 820 of this chapter, except for requirements concerning records and complaint files under § 820.35 of this chapter.

■ 156. In § 886.5120, revise paragraph (b) to read as follows:

§ 886.5120 Low-power binocular loupe.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 886.9. The device is also exempt from the current good manufacturing practice requirements of the quality management system regulation in part 820 of this chapter, except for requirements concerning records and complaint files under § 820.35 of this chapter.

■ 157. In § 886.5540, revise paragraph (b) to read as follows:

§ 886.5540 Low-vision magnifier.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 886.9. The device is also exempt from the current good manufacturing practice requirements of the quality management system regulation in part 820 of this chapter, except for requirements concerning records and complaint files under § 820.35 of this chapter.

■ 158. In § 886.5600, revise paragraph (b) to read as follows:

§ 886.5600 Ptosis crutch.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 886.9. The device is also exempt from the current good manufacturing practice requirements of the quality management system regulation in part 820 of this chapter, except for requirements concerning records and complaint files under § 820.35 of this chapter.

■ 159. In § 886.5800, revise paragraph (b) to read as follows:

§ 886.5800 Ophthalmic bar reader.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 886.9. The device is also exempt from the current good manufacturing practice requirements of the quality management system regulation in part 820 of this chapter, except for requirements

concerning records and complaint files under § 820.35 of this chapter.

■ 160. In § 886.5810, revise paragraph (b) to read as follows:

§ 886.5810 Ophthalmic prism reader.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 886.9. The device is also exempt from the current good manufacturing practice requirements of the quality management system regulation in part 820 of this chapter, except for requirements concerning records and complaint files under § 820.35 of this chapter.

■ 161. In § 886.5870, revise paragraph (b) to read as follows:

§ 886.5870 Low-vision telescope.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 886.9. The device is also exempt from the current good manufacturing practice requirements of the quality management system regulation in part 820 of this chapter, except for requirements concerning records and complaint files under § 820.35 of this chapter.

■ 162. In § 886.5910, revise paragraph (b) to read as follows:

§ 886.5910 Image intensification vision aid.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 886.9. The device is also exempt from the current good manufacturing practice requirements of the quality management system regulation in part 820 of this chapter, except for requirements concerning records and complaint files under § 820.35 of this chapter.

■ 163. In § 886.5915, revise paragraph (b) to read as follows:

§ 886.5915 Optical vision aid.

* * * * *

(b) *Classification.* Class I (general controls). The AC-powered device and the battery-powered device are exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 886.9. The battery-powered device is also exempt from the current good manufacturing practice requirements of the quality management system regulation in part 820 of this chapter, except for requirements concerning records and complaint files under § 820.35 of this chapter.

PART 888—ORTHOPEDIC DEVICES

■ 164. The authority citation for part 888 continues to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 360l, 371.

■ 165. In § 888.5850, revise paragraph (b) to read as follows:

§ 888.5850 Non-powered orthopedic traction apparatus and accessories.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 888.9. The device is also exempt from the current good manufacturing practice requirements of the quality management system regulation in part 820 of this chapter, except for requirements concerning records and complaint files under § 820.35 of this chapter.

■ 166. In § 888.5890, revise paragraph (b) to read as follows:

§ 888.5890 Non-invasive traction component.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 888.9. The device is also exempt from the current good manufacturing practice requirements of the quality management system regulation in part 820 of this chapter, except for requirements concerning records and complaint files under § 820.35 of this chapter.

■ 167. In § 888.5940, revise paragraph (b) to read as follows:

§ 888.5940 Cast component.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 888.9. The device is also exempt from the current good manufacturing practice requirements of the quality management system regulation in part 820 of this chapter, except for requirements concerning records and complaint files under § 820.35 of this chapter.

■ 168. In § 888.5980, revise paragraph (b) to read as follows:

§ 888.5980 Manual cast application and removal instrument.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 888.9. The device is also exempt from the current good manufacturing practice requirements of the quality management system regulation in part 820 of this chapter, except for requirements concerning records and complaint files under § 820.35 of this chapter.

PART 890—PHYSICAL MEDICINE DEVICES

■ 169. The authority citation for part 890 continues to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 360*l,* 371.

■ 170. In § 890.3025, revise paragraph (b) to read as follows:

§ 890.3025 Prosthetic and orthotic accessory.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 890.9. The device is also exempt from the current good manufacturing practice requirements of the quality management system regulation in part 820 of this chapter, except for requirements concerning records and complaint files under § 820.35 of this chapter.

■ 171. In § 890.3075, revise paragraph (b) to read as follows:

§ 890.3075 Cane.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 890.9. The device is also exempt from the current good manufacturing practice requirements of the quality management system regulation in part 820 of this chapter, except for requirements concerning records and complaint files under § 820.35 of this chapter.

■ 172. In § 890.3150, revise paragraph (b) to read as follows:

§ 890.3150 Crutch.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 890.9. The device is also exempt from the current good manufacturing practice requirements of the quality management system regulation in part 820 of this

chapter, except for requirements concerning records and complaint files under § 820.35 of this chapter.

■ 173. In § 890.3410, revise paragraph (b) to read as follows:

§ 890.3410 External limb orthotic component.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 890.9. The device is also exempt from the current good manufacturing practice requirements of the quality management system regulation in part 820 of this chapter, except for requirements concerning records and complaint files under § 820.35 of this chapter.

■ 174. In § 890.3420, revise paragraph (b) to read as follows:

§ 890.3420 External limb prosthetic component.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 890.9. The device is also exempt from the current good manufacturing practice requirements of the quality management system regulation in part 820 of this chapter, except for requirements concerning records and complaint files under § 820.35 of this chapter.

■ 175. In § 890.3475, revise paragraph (b) to read as follows:

§ 890.3475 Limb orthosis.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 890.9. The device is also exempt from the current good manufacturing practice requirements of the quality management system regulation in part 820 of this chapter, except for requirements concerning records and complaint files under § 820.35 of this chapter.

■ 176. In § 890.3490, revise paragraph (b) to read as follows:

§ 890.3490 Truncal orthosis.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 890.9. The device is also exempt from the current good manufacturing practice requirements of the quality management system regulation in part 820 of this chapter, except for requirements concerning records and complaint files under § 820.35 of this chapter.

■ 177. In § 890.3520, revise paragraph (b) to read as follows:

§ 890.3520 Plinth.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 890.9. The device is also exempt from the current good manufacturing practice requirements of the quality management system regulation in part 820 of this chapter, except for requirements concerning records and complaint files under § 820.35 of this chapter.

■ 178. In § 890.3640, revise paragraph (b) to read as follows:

§ 890.3640 Arm sling.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 890.9. The device is also exempt from the current good manufacturing practice requirements of the quality management system regulation in part 820 of this chapter, except for requirements concerning records and complaint files under § 820.35 of this chapter.

■ 179. In § 890.3665, revise paragraph (b) to read as follows:

§ 890.3665 Congenital hip dislocation abduction splint.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 890.9. The device is also exempt from the current good manufacturing practice requirements of the quality management system regulation in part 820 of this chapter, except for requirements concerning records and complaint files under § 820.35 of this chapter.

■ 180. In § 890.3675, revise paragraph (b) to read as follows:

§ 890.3675 Denis Brown splint.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 890.9. The device is also exempt from the current good manufacturing practice requirements of the quality management system regulation in part 820 of this chapter, except for requirements concerning records and complaint files under § 820.35 of this chapter.

■ 181. In § 890.3700, revise paragraph (b) to read as follows:

§ 890.3700 Nonpowered communication system.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 890.9. The device is also exempt from the current good manufacturing practice requirements of the quality management system regulation in part 820 of this chapter, except for requirements concerning records and complaint files under § 820.35 of this chapter.

■ 182. In § 890.3790, revise paragraph (b) to read as follows:

§ 890.3790 Cane, crutch, and walker tips and pads.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 890.9. The device is also exempt from the current good manufacturing practice requirements of the quality management system regulation in part 820 of this chapter, except for requirements concerning records and complaint files under § 820.35 of this chapter.

■ 183. In § 890.3825, revise paragraph (b) to read as follows:

§ 890.3825 Mechanical walker.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 890.9. The device is also exempt from the current good manufacturing practice requirements of the quality management system regulation in part 820 of this chapter, except for requirements concerning records and complaint files under § 820.35 of this chapter.

■ 184. In § 890.3910, revise paragraph (b) to read as follows:

§ 890.3910 Wheelchair accessory.

* * * * *

(b) *Classification.* Class I (general controls). If the device is not intended for use as a protective restraint as defined in § 880.6760 of this chapter, it is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the

limitations in § 890.9. The device is also exempt from the current good manufacturing practice requirements of the quality management system regulation in part 820 of this chapter, except for requirements concerning records and complaint files under § 820.35 of this chapter.

■ 185. In § 890.3940, revise paragraph (b) to read as follows:

§ 890.3940 Wheelchair platform scale.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 890.9. The device is also exempt from the current good manufacturing practice requirements of the quality management system regulation in part 820 of this chapter, except for requirements concerning records and complaint files under § 820.35 of this chapter.

■ 186. In § 890.5050, revise paragraph (b) to read as follows:

§ 890.5050 Daily activity assist device.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 890.9. If the device is not labeled or otherwise represented as sterile, the device is also exempt from the current good manufacturing practice requirements of the quality management system regulation in part 820 of this chapter, except for requirements concerning records and complaint files under § 820.35 of this chapter.

■ 187. In § 890.5125, revise paragraph (b) to read as follows:

§ 890.5125 Nonpowered sitz bath.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 890.9. The device is also exempt from the current good manufacturing practice requirements of the quality management system regulation in part 820 of this chapter, except for requirements concerning records and complaint files under § 820.35 of this chapter.

■ 188. In § 890.5350, revise paragraph (b) to read as follows:

§ 890.5350 Exercise component.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 890.9. The device is also exempt from the current good manufacturing practice requirements of the quality management system regulation in part 820 of this chapter, except for requirements concerning records and complaint files under § 820.35 of this chapter.

■ 189. In § 890.5370, revise paragraph (b) to read as follows:

§ 890.5370 Nonmeasuring exercise equipment.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 890.9. The device is also exempt from the current good manufacturing practice requirements of the quality management system regulation in part 820 of this chapter, except for requirements concerning records and complaint files under § 820.35 of this chapter.

■ 190. In § 890.5700, revise paragraph (b) to read as follows:

§ 890.5700 Cold pack.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807. The device also is exempt from the current good manufacturing practice requirements of the quality management system regulation in part 820, except for requirements concerning records and complaint files under § 820.35 of this chapter.

■ 191. In § 890.5730, revise paragraph (b) to read as follows:

§ 890.5730 Moist heat pack.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 890.9. The device is also exempt from the current good manufacturing practice requirements of the quality management system regulation in part 820 of this chapter, except for requirements concerning records and complaint files under § 820.35 of this chapter.

■ 192. In § 890.5925, revise paragraph (b) to read as follows:

§ 890.5925 Traction accessory.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 890.9. The device is also exempt from the current good manufacturing practice requirements of the quality management system regulation in part 820 of this chapter, except for requirements concerning records and complaint files under § 820.35 of this chapter.

PART 892—RADIOLOGY DEVICES

■ 193. The authority citation for part 892 continues to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 360*l,* 371.

■ 194. In § 892.1920, revise paragraph (b) to read as follows:

§ 892.1920 Radiographic head holder.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 892.9. The device is also exempt from the current good manufacturing practice requirements of the quality management system regulation in part 820 of this chapter, except for requirements concerning records and complaint files under § 820.35 of this chapter.

■ 195. In § 892.1940, revise paragraph (b) to read as follows:

§ 892.1940 Radiologic quality assurance instrument.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 892.9. The device is also exempt from the current good manufacturing practice requirements of the quality management system regulation in part 820 of this chapter, except for requirements concerning records and complaint files under § 820.35 of this chapter.

■ 196. In § 892.1950, revise paragraph (b) to read as follows:

§ 892.1950 Radiographic anthropomorphic phantom.

* * * * *

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter, subject to the limitations in § 892.9. The device is also exempt from the current good manufacturing practice requirements of the quality management system regulation in part 820 of this chapter, except for requirements concerning records and complaint files under § 820.35 of this chapter.

■ 197. In § 892.5725, revise paragraph (b)(2) to read as follows:

§ 892.5725 Absorbable perirectal spacer.

* * * * *

(b) * * *

(2) The risk management activities performed as part of the manufacturer's § 820.10(c) of this chapter design and development activities must document an appropriate end user initial training program which will be offered as part of efforts to mitigate the risk of failure to correctly operate the device, including, but not limited to, documentation of an appropriate end user initial training program on the proper spacer deployment technique.

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Lowell M. Zeta,

Acting Deputy Commissioner for Policy, Legislation, and International Affairs.

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