2. Labeling Requirements

The flammability standard became effective on May 1, 1975, and is applicable to sleepwear in sizes 7 through 14 manufactured after that date. Sleepwear in sizes 7 through 14 manufactured before the effective date of the standard is not subject to the standard, and could be sold after May 1, 1975, without violating the standard or the FFA. To help consumers identify sleepwear in sizes 7 through 14 manufactured to comply with the standard, the Commission required complying sleepwear in sizes 7 through 14 manufactured between May 1, 1975, and May 1, 1978, to be labeled with the statement: ''Flame-resistant, U.S. Standard FF 5–74.'' 16 CFR 1616.6(b).

In 1975, the Commission issued regulations for labeling, recordkeeping, and retail display of children's sleepwear in sizes 7 through 14. 16 CFR Part 1616, Subpart B. See the Federal Register notice of April 1, 1975 (40 FR 14584). These regulations required complying sleepwear in sizes 7 through 14 manufactured between May 1, 1975, and May 1, 1978 to be labeled with the statement ''Flame-resistant. U.S. Standard FF 5–74.'' 16 CFR 1616.31(b)(8). This is the same statement required by section 1616.6(b) of the standard.

3. Requirements for Retail Display

The regulations issued in 1975 also included a requirement to segregate complying and noncomplying sleepwear offered for sale at retail stores. The purpose of this requirement was to help consumers distinguish noncomplying sleepwear manufactured before May 1, 1975, from complying sleepwear manufactured after that date.

The Commission required any person who sold noncomplying sleepwear in sizes 7 through 14 to physically segregate it from complying sleepwear in those sizes. 16 CFR 1616.31(c). The Commission also required complying sleepwear in sizes 7 through 14 sold at the same location as noncomplying sleepwear to be identified by a sign stating: ''Flame resistant. Complies with the Standard for the Flammability of Children's Sleepwear (FF 5–74).'' Noncomplying sleepwear in those sizes was required to be identified by a sign stating: ''Flammable. Does Not Meet Standard for the Flammability of Children's Sleepwear (FF 5–74).'' *Id.*

B. Revocation

Since May 1, 1975, all sleepwear in sizes 7 through 14 must be manufactured to comply with the standard. Noncomplying sleepwear in sizes 7 through 14 has not been legally manufactured since that date. The labeling and retail display requirements described above do not apply to sleepwear sold today or that will be sold in the future. Accordingly, the Commission is revoking (i) the labeling requirements in section 1616.6(b) of the standard and in section 1616.31(b)(8) of the enforcement regulations, and (ii) the requirements for retail display of complying and noncomplying sleepwear in section 1616.31(c) of those regulations.

Generally, the Administrative Procedure Act (APA) (5 U.S.C. 553) requires agencies to publish a notice of proposed rulemaking and provide opportunity for public comment before issuing or revoking a regulation. However, the APA provides at 5 U.S.C. 553(b)(B) that the requirement for a notice of proposed rulemaking is not applicable when the agency finds for good cause that notice of proposed rulemaking and public participation are ''impracticable, unnecessary, or contrary to the public interest.''

The Commission finds for good cause that notice of proposed rulemaking and public participation are unnecessary because no sleepwear in sizes 7 through 14 offered for sale now or that will be offered for sale in the future is subject to the requirements of 16 CFR 1616.6(b), 1616.31(b)(8), or 1616.31(c). The rules being revoked have no effect on the rights or duties of any persons who manufacture, sell, or purchase sleepwear in sizes 7 through 14. Providing notice of proposed rulemaking and opportunity for submission of written comments on the proposal would be a meaningless procedure in this case.

The APA also requires at 5 U.S.C. 553(d) that a substantive rule must be published at least 30 days before its effective date unless the agency finds for good cause that such delay is not needed. Again, because no sleepwear in sizes 7 through 14 offered for sale now or in the future is subject to the rules being revoked, the Commission finds for good cause that a delayed effective date is unnecessary. Consequently, this revocation shall become effective immediately.

C. Conclusion

Under the authority of section 553 of the Administrative Procedure Act and sections 4 and 5 of the Flammable Fabrics Act, the Commission hereby amends title 16 of the Code of Federal Regulations, Chapter II, Subchapter D, Part 1616 to read as follows:

PART 1616—[AMENDED]

Subpart A—[Amended]

1. The authority for Part 1616, Subpart A, continues to read as follows:

Authority: Sec. 4, 67 Stat. 112, as amended, 81 Stat. 569–70; 15 U.S.C. 1193.

§ 1616.6 [Removed and reserved]

2. Section 1616.6(b) is revoked, removed and reserved.

Subpart B—[Amended]

3. The authority for Part 1616, Subpart B, continues to read as follows:

Authority: Sec. 5, 67 Stat. 112–13, as amended, 81 Stat. 571; 15 U.S.C. 1194.

§ 1616.3 [Removed and reserved]

4. Sections 1616.31 (b)(6) and (c) are removed and reserved.

(5 U.S.C. 553; 15 U.S.C. 1193, 1194)

Dated: December 15, 1995.

Sadye E. Dunn,

Secretary, Consumer Product Safety Commission.

[FR Doc. 96–421 Filed 1–11–96; 2:00 pm]

BILLING CODE 6355–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 862, 866, 868, 870, 872, 874, 876, 878, 880, 882, 884, 886, 888, 890, and 892

[Docket No. 95N–0139]

RIN 0910–AA65

Medical Devices; Reclassification and Exemption From Premarket Notification for Certain Classified Devices

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is reclassifying 111 generic types of class II devices into class I based on new information respecting such devices. FDA is also exempting the 111 generic types of devices, and 11 already classified generic types of class I devices, from the requirement of premarket notification, with limitations. For the exempted devices, FDA has determined that manufacturers' submissions of premarket notifications are unnecessary for the protection of the public health and that the agency's review of such submissions will not advance its public health mission. The exemptions allow

the agency to make better use of its resources and thus better serve the public. These devices will remain subject to current good manufacturing practice (CGMP) regulations and other general controls. This rulemaking is part of the President's and Vice President's Reinventing Government effort.

DATES: Effective February 15, 1996. Beginning on February 15, 1996, all device manufacturers who have 510(k) submissions pending FDA review for devices falling within a generic category which is subject to this rule, will receive a letter stating that the device is exempt from the premarket notification requirements of the act.

FOR FURTHER INFORMATION CONTACT: Melpomeni K. Jeffries, Center for Devices and Radiological Health (HFZ–404), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–2186.

SUPPLEMENTARY INFORMATION:

I. Background

In the Federal Register of July 28, 1995 (60 FR 38902), FDA issued a proposed rule to reclassify 112 generic types of class II devices into class I based on new information respecting such devices and to exempt the 112 generic types of devices, and 12 already classified generic types of class I devices, from the requirement of premarket notification, with limitations. Interested persons were given until October 11, 1995, to comment on the proposed rule.

II. Comments

During the comment period, FDA received three comments requesting that various devices be added to the list of devices that the agency was proposing to reclassify into class I and/or exempt from the requirement of premarket notification. FDA is considering these comments and will address them in a future issue of the Federal Register.

FDA also received a comment stating that the proposed reclassification and exemption for endoscope and accessories (21 CFR 876.1500) was too narrow. According to this comment, the reclassification and exemption for endoscope and accessories should be expanded to include additional endoscope accessories which the comment felt meets the reclassification and exemption criteria. FDA is finalizing the endoscope and accessories reclassification and exemption as proposed. However, FDA is considering expanding the reclassification and exemption for endoscope and accessories to include additional endoscope accessories and FDA will address this device in a future issue of the Federal Register.

FDA received three comments questioning the appropriateness of the proposed reclassification and exemption for scented or scented deodorized menstrual pads (21 CFR 884.5425) and the proposed exemption for unscented menstrual pads (21 CFR 884.5435). All three comments requested that the ''made from cotton or rayon'' limitation placed upon the proposed reclassification into class I and the exemption from the requirement of premarket notification be revised. In addition, two of the comments questioned the proposed requirements for safety testing. FDA is deferring action on these two devices in order to review these comments more closely and to reevaluate whether the devices should be reclassified and/or exempted from the requirement of premarket notification, with limitations. The agency will address these devices in a future issue of the Federal Register.

III. Conclusion

FDA received no comments opposing the reclassification into class I of 111 of the 112 generic types of devices included in the proposed rule. Moreover, the agency did not receive comments opposing the proposed exemption from the requirements of premarket notification for 111 of these 112 generic types of devices, and 11 already classified generic types of class I devices. For 111 of the 112 devices proposed for reclassification into class I, the agency has concluded, based on new information respecting such devices as described in the proposed rule, that general controls will provide reasonable assurance of the safety and effectiveness of these devices. For 122 of the 124 devices for which exemptions have been proposed (including the 111 device types being reclassified), FDA has concluded that manufacturers' submissions of premarket notifications are unnecessary for the protection of the public health and that the agency's review of such submissions will not advance its public health mission. Thus, FDA is finalizing the reclassification of 111 devices and the exemption from premarket notification for 122 devices, including the 111 devices being reclassified and 11 of the devices already classified in class I. All of these devices remain subject to CGMP requirements and other general controls under the statute.

IV. Environmental Impact

The agency has determined under 21 CFR 25.24(e)(2) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment or an environmental impact statement is required.

V. Analysis of Impacts

FDA has examined the impacts of the final rule under Executive Order 12866 and the Regulatory Flexibility Act (Pub. L. 96–354). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The agency believes that this final rule is consistent with the regulatory philosophy and principles identified in the Executive Order. In addition, the final rule is not a significant regulatory action as defined by the Executive Order and so is not subject to review under the Executive Order.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because this final rule would reduce a regulatory burden by exempting manufacturers of devices subject to the rule from the requirements of premarket notification, the agency certifies that the final rule will not have a significant economic impact on a substantial number of small entities. Therefore, under the Regulatory Flexibility Act, no further analysis is required.

List of Subjects

21 CFR Parts 862, 868, 870, 872, 874, 876, 878, 880, 882, 884, 888, and 890

Medical devices.

21 CFR Part 866

Biologics, Laboratories, Medical devices.

21 CFR Part 886

Medical devices, Ophthalmic goods and services.

21 CFR Part 892

Medical devices, Radiation protection, X-rays.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR parts 862, 866, 868, 870, 872, 874, 876, 878, 880, 882, 884, 886, 888, 890, and 892 are amended as follows:

PART 862—CLINICAL CHEMISTRY AND CLINICAL TOXICOLOGY DEVICES

1. The authority citation for 21 CFR part 862 continues to read as follows:

Authority: Secs. 501, 510, 513, 515, 520, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351, 360, 360c, 360e, 360j, 371).

2. Section 862.2230 is amended by revising paragraph (b) to read as follows:

§ 862.2230 Chromatographic separation material for clinical use.

* * * * *

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

PART 866—IMMUNOLOGY AND MICROBIOLOGY DEVICES

3. The authority citation for 21 CFR part 866 continues to read as follows:

Authority: Secs. 501, 510, 513, 515, 520, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351, 360, 360c, 360e, 360j, 371).

4. Section 866.2160 is amended by revising paragraph (b) to read as follows:

§ 866.2160 Coagulase plasma.

* * * * *

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

5. Section 866.3720 is amended by revising paragraph (b) to read as follows:

§ 866.3720 Streptococcus spp. exoenzyme reagents.

* * * * *

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

6. Section 866.5520 is amended by revising paragraph (b) to read as follows:

§ 866.5520 Immunoglobulin G (Fab fragment specific) immunological test system.

* * * * *

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

7. Section 866.5530 is amended by revising paragraph (b) to read as follows:

§ 866.5530 Immunoglobulin G (Fc fragment specific) immunological test system.

* * * * *

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

8. Section 866.5860 is amended by revising paragraph (b) to read as follows:

§ 866.5860 Total spinal fluid immunological test system.

* * * * *

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

PART 868—ANESTHESIOLOGY DEVICES

9. The authority citation for 21 CFR part 868 continues to read as follows:

Authority: Secs. 501, 510, 513, 515, 520, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351, 360, 360c, 360e, 360j, 371).

10. Section 868.1100 is amended by revising paragraph (b) to read as follows:

§ 868.1100 Arterial blood sampling kit.

* * * * *

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

11. Section 868.1575 is amended by revising paragraph (b) to read as follows:

§ 868.1575 Gas collection vessel.

* * * * *

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

12. Section 868.1870 is amended by revising paragraph (b) to read as follows:

§ 868.1870 Gas volume calibrator.

* * * * *

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

13. Section 868.1975 is amended by revising paragraph (b) to read as follows:

§ 868.1975 Water vapor analyzer.

* * * * *

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

14. Section 868.2300 is amended by revising paragraph (b) to read as follows:

§ 868.2300 Bourdon gauge flowmeter.

* * * * *

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

15. Section 868.2320 is amended by revising paragraph (b) to read as follows:

§ 868.2320 Uncompensated thorpe tube flowmeter.

* * * * *

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

16. Section 868.2340 is amended by revising paragraph (b) to read as follows:

§ 868.2340 Compensated thorpe tube flowmeter.

* * * * *

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

17. Section 868.2350 is amended by revising paragraph (b) to read as follows:

§ 868.2350 Gas calibration flowmeter.

* * * * *

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

18. Section 868.2610 is amended by revising paragraph (b) to read as follows:

§ 868.2610 Gas pressure gauge.

* * * * *

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

19. Section 868.2620 is amended by revising paragraph (b) to read as follows:

§ 868.2620 Gas pressure calibrator.

* * * * *

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

20. Section 868.2700 is amended by revising paragraph (b) to read as follows:

§ 868.2700 Pressure regulator.

* * * * *

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

21. Section 868.2875 is amended by revising paragraph (b) to read as follows:

§ 868.2875 Differential pressure transducer.

* * * * *

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

22. Section 868.2885 is amended by revising paragraph (b) to read as follows:

§ 868.2885 Gas flow transducer.

* * * * *

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

23. Section 868.2900 is amended by revising paragraph (b) to read as follows:

§ 868.2900 Gas pressure transducer.

* * * * *

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

24. Section 868.5100 is amended by revising paragraph (b) to read as follows:

§ 868.5100 Nasopharyngeal airway.

* * * * *

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

25. Section 868.5110 is amended by revising paragraph (b) to read as follows:

§ 868.5110 Oropharyngeal airway.

* * * * *

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

26. Section 868.5240 is amended by revising paragraph (b) to read as follows:

§ 868.5240 Anesthesia breathing circuit.

* * * * *

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

27. Section 868.5300 is amended by revising paragraph (b) to read as follows:

§ 868.5300 Carbon dioxide absorbent.

* * * * *

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

28. Section 868.5310 is amended by revising paragraph (b) to read as follows:

§ 868.5310 Carbon dioxide absorber.

* * * * *

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

29. Section 868.5320 is amended by revising paragraph (b) to read as follows:

§ 868.5320 Reservoir bag.

* * * * *

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

30. Section 868.5375 is amended by revising paragraph (b) to read as follows:

§ 868.5375 Heat and moisture condenser (artificial nose).

* * * * *

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

31. Section 868.5460 is amended by revising paragraph (b) to read as follows:

§ 868.5460 Therapeutic humidifier for home use.

* * * * *

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

32. Section 868.5530 is amended by revising paragraph (b) to read as follows:

§ 868.5530 Flexible laryngoscope.

* * * * *

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

33. Section 868.5540 is amended by revising paragraph (b) to read as follows:

§ 868.5540 Rigid laryngoscope.

* * * * *

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

34. Section 868.5550 is amended by revising paragraph (b) to read as follows:

§ 868.5550 Anesthetic gas mask.

* * * * *

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

35. Section 868.5570 is amended by revising paragraph (b) to read as follows:

§ 868.5570 Nonrebreathing mask.

* * * * *

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

36. Section 868.5580 is amended by revising paragraph (b) to read as follows:

§ 868.5580 Oxygen mask.

* * * * *

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

37. Section 868.5590 is amended by revising paragraph (b) to read as follows:

§ 868.5590 Scavenging mask.

* * * * *

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

38. Section 868.5600 is amended by revising paragraph (b) to read as follows:

§ 868.5600 Venturi mask.

* * * * *

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

39. Section 868.5770 is amended by revising paragraph (b) to read as follows:

§ 868.5770 Tracheal tube fixation device.

* * * * *

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

40. Section 868.5780 is amended by revising paragraph (b) to read as follows:

§ 868.5780 Tube introduction forceps.

* * * * *

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

41. Section 868.5790 is amended by revising paragraph (b) to read as follows:

§ 868.5790 Tracheal tube stylet.

* * * * *

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

42. Section 868.5810 is amended by revising paragraph (b) to read as follows:

§ 868.5810 Airway connector.

* * * * *

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

43. Section 868.5820 is amended by revising paragraph (b) to read as follows:

§ 868.5820 Dental protector.

* * * * *

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

44. Section 868.5860 is amended by revising paragraph (b) to read as follows:

§ 868.5860 Pressure tubing and accessories.

* * * * *

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

45. Section 868.5975 is amended by revising paragraph (b) to read as follows:

§ 868.5975 Ventilator tubing.

* * * * *

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

46. Section 868.5995 is amended by revising paragraph (b) to read as follows:

§ 868.5995 Tee drain (water trap).

* * * * *

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

47. Section 868.6400 is amended by revising paragraph (b) to read as follows:

§ 868.6400 Calibration gas.

* * * * *

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

48. Section 868.6820 is amended by revising paragraph (b) to read as follows:

§ 868.6820 Patient position support.

* * * * *

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

49. Section 868.6885 is amended by revising paragraph (b) to read as follows:

§ 868.6885 Medical gas yoke assembly.

* * * * *

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

PART 870—CARDIOVASCULAR DEVICES

50. The authority citation for 21 CFR part 870 continues to read as follows:

Authority: Secs. 501, 510, 513, 515, 520, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351, 360, 360c, 360e, 360j, 371).

51. Section 870.2390 is amended by revising paragraph (b) to read as follows:

§ 870.2390 Phonocardiograph.

* * * * *

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

52. Section 870.2600 is amended by revising paragraph (b) to read as follows:

§ 870.2600 Signal isolation system.

* * * * *

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

53. Section 870.2620 is amended by revising paragraph (b) to read as follows:

§ 870.2620 Line isolation monitor.

* * * * *

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

54. Section 870.2640 is amended by revising paragraph (b) to read as follows:

§ 870.2640 Portable leakage current alarm.

* * * * *

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

55. Section 870.2810 is amended by revising paragraph (b) to read as follows:

§ 870.2810 Paper chart recorder.

* * * * *

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

56. Section 870.3650 is amended by revising paragraph (b) to read as follows:

§ 870.3650 Pacemaker polymeric mesh bag.

* * * * *

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

57. Section 870.3670 is amended by revising paragraph (b) to read as follows:

§ 870.3670 Pacemaker charger.

* * * * *

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

58. Section 870.3690 is amended by revising paragraph (b) to read as follows:

§ 870.3690 Pacemaker test magnet.

* * * * *

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

59. Section 870.3935 is amended by revising paragraph (b) to read as follows:

§ 870.3935 Prosthetic heart valve holder.

* * * * *

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

60. Section 870.3945 is amended by revising paragraph (b) to read as follows:

§ 870.3945 Prosthetic heart valve sizer.

* * * * *

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

PART 872—DENTAL DEVICES

61. The authority citation for 21 CFR part 872 continues to read as follows:

Authority: Secs. 501, 510, 513, 515, 520, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351, 360, 360c, 360e, 360j, 371).

62. Section 872.1840 is amended by revising paragraph (b) to read as follows:

§ 872.1840 Dental X-ray position indicating device.

* * * * *

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

63. Section 872.1850 is amended by revising paragraph (b) to read as follows:

§ 872.1850 Lead-lined position indicator.

* * * * *

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

64. Section 872.4630 is amended by revising paragraph (b) to read as follows:

§ 872.4630 Dental operating light.

* * * * *

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

65. Section 872.6390 is amended by revising paragraph (b) to read as follows:

§ 872.6390 Dental floss.

* * * * *

(b) *Classification*. Class I. If the device is made of inert materials and is not coated or impregnated with chemicals intended to provide a therapeutic benefit or interact with tissues of the oral cavity, it is exempt from the premarket notification procedures in Subpart E of Part 807 of this chapter.

PART 874—EAR, NOSE, AND THROAT DEVICES

66. The authority citation for 21 CFR part 874 continues to read as follows:

Authority: Secs. 501, 510, 513, 515, 520, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351, 360, 360c, 360e, 360j, 371).

67. Section 874.1060 is amended by revising paragraph (b) to read as follows:

§ 874.1060 Acoustic chamber for audiometric testing.

* * * * *

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

68. Section 874.1080 is amended by revising paragraph (b) to read as follows:

§ 874.1080 Audiometer calibration set

* * * * *

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

69. Section 874.4140 is amended by revising paragraph (b) to read as follows:

§ 874.4140 Ear, nose, and throat bur.

* * * * *

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

70. Section 874.4175 is amended by revising paragraph (b) to read as follows:

§ 874.4175 Nasopharyngeal catheter.

* * * * *

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

71. Section 874.4350 is amended by revising paragraph (b) to read as follows:

§ 874.4350 Ear, nose, and throat fiberoptic light source and carrier.

* * * * *

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

72. Section 874.4770 is amended by revising paragraph (b) to read as follows:

§ 874.4770 Otoscope.

* * * * *

(b) *Classification*. Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter only when used in the external ear canal.

PART 876—GASTROENTEROLOGY-UROLOGY DEVICES

73. The authority citation for 21 CFR part 876 is revised to read as follows:

Authority: Secs. 501, 510, 513, 515, 520, 522, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351, 360, 360c, 360e, 360j, 360l, 371).

74. Section 876.1075 is amended by revising paragraph (b) to read as follows:

§ 876.1075 Gastroenterology-urology biopsy instrument.

* * * * *

(b) *Classification*. (1) Class II (performance standards).

(2) Class I for the biopsy forceps cover and the non-electric biopsy forceps. The devices subject to this paragraph (b)(2) are exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

75. Section 876.1400 is amended by revising paragraph (b) to read as follows:

§ 876.1400 Stomach pH electrode.

* * * * *

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

76. Section 876.1500 is amended by revising paragraph (b) to read as follows:

§ 876.1500 Endoscope and accessories.

* * * * *

(b) *Classification*. (1) Class II (performance standards).

(2) Class I for the photographic accessories for endoscope, miscellaneous bulb adapter for endoscope, binocular attachment for endoscope, eyepiece attachment for prescription lens, teaching attachment, inflation bulb, measuring device for panendoscope, photographic equipment for physiologic function monitor, special lens instrument for endoscope, smoke removal tube, rechargeable battery box, pocket battery box, bite block for endoscope, and cleaning brush for endoscope. The devices subject to this paragraph (b)(2) are exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

77. Section 876.1800 is amended by revising paragraph (b) to read as follows:

§ 876.1800 Urine flow or volume measuring system.

* * * * *

(b) *Classification*. (1) Class II (performance standards).

(2) Class I for the disposable, nonelectrical urine flow rate measuring device, and nonelectrical urinometer. The devices subject to this paragraph (b)(2) are exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

78. Section 876.4590 is amended by revising paragraph (b) to read as follows:

§ 876.4590 Interlocking urethral sound.

* * * * *

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

79. Section 876.4890 is amended by revising paragraph (b) to read as follows:

§ 876.4890 Urological table and accessories.

* * * * *

(b) *Classification*. (1) Class II (performance standards) for the electrically powered urological table and accessories.

(2) Class I for the manually powered table and accessories, and for stirrups for electrically powered table. The device subject to this paragraph (b)(2) is exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

80. Section 876.5090 is amended by revising paragraph (b) to read as follows:

§ 876.5090 Suprapubic urological catheter and accessories.

* * * * *

(b) *Classification*. (1) Class II (performance standards).

(2) Class I for the catheter punch instrument, nondisposable cannula and trocar, and gastro-urological trocar. The devices subject to this paragraph (b)(2) are exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

81. Section 876.5130 is amended by revising paragraph (b) to read as follows:

§ 876.5130 Urological catheter and accessories.

* * * * *

(b) *Classification*. (1) Class II (performance standards).

(2) Class I for the ureteral stylet (guidewire), stylet for gastro-urological catheter, ureteral catheter adapter, ureteral catheter connector, and ureteral catheter holder. The devices subject to this paragraph (b)(2) are exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

82. Section 876.5450 is amended by revising paragraph (b) to read as follows:

§ 876.5450 Rectal dilator.

* * * * *

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

83. Section 876.5520 is amended by revising paragraph (b) to read as follows:

§ 876.5520 Urethral dilator.

* * * * *

(b) *Classification*. (1) Class II (performance standards).

(2) Class I for the urethrometer, urological bougie, filiform and filiform follower, and metal or plastic urethral sound. The devices subject to this paragraph (b)(2) are exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

84. Section 876.5540 is amended by revising paragraphs (b)(3) and by adding new paragraph (b)(4) to read as follows:

§ 876.5540 Blood access device and accessories.

* * * * *

(b) *Classification*. * * *

(3) Class II (performance standards) for accessories for both the implanted and the nonimplanted blood access devices not listed in paragraph (b)(4) of this section.

(4) Class I for the cannula clamp, disconnect forceps, crimp plier, tube plier, crimp ring, and joint ring, accessories for both the implanted and nonimplanted blood access device. The devices subject to this paragraph (b)(4) are exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

PART 878—GENERAL AND PLASTIC SURGERY DEVICES

85. The authority citation for 21 CFR part 878 continues to read as follows:

Authority: Secs. 501, 510, 513, 515, 520, 522, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351, 360, 360c, 360e, 360j, 360l, 371).

86. Section 878.4450 is amended by revising paragraph (b) to read as follows:

§ 878.4450 Nonabsorbable gauze for internal use.

* * * * *

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

87. Section 878.4810 is amended by revising paragraph (b) to read as follows:

§ 878.4810 Laser surgical instrument for use in general and plastic surgery and in dermatology.

* * * * *

(b) *Classification*. (1) Class II.

(2) Class I for special laser gas mixtures used as a lasing medium for this class of lasers. The devices subject to this paragraph (b)(2) are exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

88. Section 878.5350 is amended by revising paragraph (b) to read as follows:

§ 878.5350 Needle-type epilator.

* * * * *

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

89. Section 878.5910 is amended by revising paragraph (b) to read as follows:

§ 878.5910 Pneumatic tourniquet.

* * * * *

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

PART 880—GENERAL HOSPITAL AND PERSONAL USE DEVICES

90. The authority citation for 21 CFR 880 continues to read as follows:

Authority: Secs. 501, 510, 513, 515, 520, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351, 360, 360c, 360e, 360j, 371).

91. Section 880.2720 is amended by revising paragraph (b) to read as follows:

§ 880.2720 Patient scale.

* * * * *

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

92. Section 880.2900 is amended by revising paragraph (b) to read as follows:

§ 880.2900 Clinical color change thermometer.

* * * * *

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

93. Section 880.5560 is amended by revising paragraph (b) to read as follows:

§ 880.5560 Temperature regulated water mattress.

* * * * *

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

94. Section 880.6320 is amended by revising paragraph (b) to read as follows:

§ 880.6320 AC-powered medical examination light.

* * * * *

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

PART 882—NEUROLOGICAL DEVICES

95. The authority citation for 21 CFR part 882 continues to read as follows:

Authority: Secs. 501, 510, 513, 515, 520, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351, 360, 360c, 360e, 360j, 371).

96. Section 882.1410 is amended by revising paragraph (b) to read as follows:

§ 882.1410 Electroencephalograph electrode/lead tester.

* * * * *

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

97. Section 882.4325 is amended by revising paragraph (b) to read as follows:

§ 882.4325 Cranial drill handpiece (brace).

* * * * *

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

PART 884—OBSTETRICAL AND GYNECOLOGICAL DEVICES

98. The authority citation for 21 CFR part 884 continues to read as follows:

Authority: Secs. 501, 510, 513, 515, 520, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351, 360, 360c, 360e, 360j, 371).

99. Section 884.1550 is revised to read as follows:

§ 884.1550 Amniotic fluid sampler (amniocentesis tray).

(a) *Identification*. The amniotic fluid sampler (amniocentesis tray) is a collection of devices used to aspirate amniotic fluid from the amniotic sac via a transabdominal approach. Components of the amniocenteses tray include a disposable 3 inch 20 gauge needle with stylet and a 30 cc. syringe, as well as the various sample collection accessories, such as vials, specimen containers, medium, drapes, etc. The device is used at 16–18 weeks gestation for antepartum diagnosis of certain congenital abnormalities or anytime after 24 weeks gestation when used to assess fetal maturity.

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

100. Section 884.1640 is amended by revising paragraph (b) to read as follows:

§ 884.1640 Culdoscope and accessories.

* * * * *

(b) *Classification*. (1) Class II (performance standards).

(2) Class I for culdoscope accessories that are not part of a specialized instrument or device delivery system; do not have adapters, connectors, channels, or do not have portals for electrosurgical, laser, or other power sources. Such culdoscope accessory instruments include: lens cleaning brush, biopsy brush, clip applier (without clips), applicator, cannula (without trocar or valves), ligature carrier/needle holder, clamp/hemostat/grasper, curette, instrument guide, ligature passing and knotting instrument, suture needle (without suture), retractor, mechanical (noninflatable), snare, stylet, forceps, dissector, mechanical (non-inflatable) scissors, and suction/irrigation probe. The devices subject to this paragraph (b)(2) are exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

101. Section 884.1690 is amended by revising paragraph (b) to read as follows:

§ 884.1690 Hysteroscope and accessories.

* * * * *

(b) *Classification*. (1) Class II (performance standards).

(2) Class I for hysteroscope accessories that are not part of a specialized instrument or device delivery system; do not have adapters, connectors, channels, or do not have portals for electrosurgical, laser, or other power sources. Such hysteroscope accessory instruments include: lens cleaning brush, cannula (without trocar or valves), clamp/hemostat/grasper,

curette, instrument guide, forceps, dissector, mechanical (noninflatable), and scissors. The devices subject to this paragraph (b)(2) are exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

102. Section 884.1700 is amended by revising paragraph (b) to read as follows:

§ 884.1700 Hysteroscopic insufflator.

* * * * *

(b) *Classification*. (1) Class II (performance standards).

(2) Class I for tubing and tubing/filter fits which only include accessory instruments which are not used to effect intrauterine access e.g. hysteroscopic introducer sheaths, etc.; and single-use tubing kits used for only intrauterine insufflation. The devices subject to this paragraph (b)(2) are exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

103. Section 884.1720 is amended by revising paragraph (b) to read as follows:

§ 884.1720 Gynecologic laparoscope and accessories.

* * * * *

(b) *Classification*. (1) Class II (performance standards).

(2) Class I for gynecologic laparoscope accessories that are not part of a specialized instrument or device delivery system, do not have adapters, connector channels, or do not have portals for electrosurgical, lasers, or other power sources. Such gynecologic laparoscope accessory instruments include: the lens cleaning brush, biopsy brush, clip applier (without clips), applicator, cannula (without trocar or valves), ligature carrier/needle holder, clamp/hemostat/grasper, curette, instrument guide, ligature passing and knotting instrument, suture needle (without suture), retractor, mechanical (noninflatable), snare, stylet, forceps, dissector, mechanical (noninflatable), scissors, and suction/irrigation probe. The devices subject to this paragraph (b)(2) are exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

104. Section 884.1730 is amended by revising paragraph (b) to read as follows:

§ 884.1730 Laparoscopic insufflator.

* * * * *

(b) *Classification*. (1) Class II (performance standards).

(2) Class I for tubing and tubing/filter kits which include accessory instruments which are not used to effect intra-abdominal access, Verres needles etc.; and single-use tubing kits used for only intra-abdominal insufflation (pneumoperitoneum). The devices subject to this paragraph (b)(2) are exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

105. Section 884.4530 is amended by revising paragraph (b) to read as follows:

§ 884.4530 Obstetric-gynecological specialized manual instrument.

* * * * *

(b) *Classification*. (1) Class II (performance standards).

(2) Class I for the amniotome, uterine curette, cervical dilator (fixed-size bougies), cerclage needle, IUD remover, uterine sound, and gynecological biopsy forceps. The devices subject to this paragraph (b)(2) are exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

106. Section 884.5150 is amended by revising paragraph (b) to read as follows:

§ 884.5150 Nonpowered breast pump.

* * * * *

(b) *Classification*. Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter if the device is using either a bulb or telescoping mechanism which does not develop more than 250 mm Hg suction, and the device materials that contact breast or breast milk do not produce cytotoxicity, irritation, or sensitization effects.

107. Section 884.5900 is amended by revising paragraph (b) to read as follows:

§ 884.5900 Therapeutic vaginal douche apparatus.

* * * * *

(b) *Classification*. (1) Class II (performance standards).

(2) Class I if the device is operated by gravity feed. Devices subject to this paragraph (b)(2) are exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

PART 886—OPHTHALMIC DEVICES

108. The authority citation for 21 CFR 886 continues to read as follows:

Authority: Secs. 501, 510, 513, 515, 520, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351, 360, 360c, 360e, 360j, 371).

109. Section 886.1405 is amended by revising paragraph (b) to read as follows:

§ 886.1405 Ophthalmic trial lens set.

* * * * *

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

110. Section 886.1750 is amended by revising paragraph (b) to read as follows:

§ 886.1750 Skiascopic rack.

* * * * *

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

111. Section 886.1760 is amended by revising paragraph (b) to read as follows:

§ 886.1760 Ophthalmic refractometer.

* * * * *

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

112. Section 886.3200 is revised to read as follows:

§ 886.3200 Artificial eye.

(a) *Identification*. An artificial eye is a device resembling the anterior portion of the eye, usually made of glass or plastic, intended to be inserted in a patient's eye socket anterior to an orbital implant, or the eviscerated eyeball, for cosmetic purposes. The device is not intended to be implanted.

(b) *Classification*. Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter if the device is made from the same materials, has the same chemical composition, and uses the same manufacturing processes as currently legally marketed devices.

PART 888—ORTHOPEDIC DEVICES

113. The authority citation for 21 CFR part 888 continues to read as follows:

Authority: Secs. 501, 510, 513, 515, 520, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351, 360, 360c, 360e, 360j, 371).

114. Section 888.1100 is amended by revising paragraph (b) to read as follows:

§ 888.1100 Arthroscope.

* * * * *

(b) *Classification*. (1) Class II (performance standards).

(2) Class I for the following manual arthroscopic instruments: cannulas, currettes, drill guides, forceps, gouges, graspers, knives, obturators, osteotomes, probes, punches, rasps, retractors, rongeurs, suture passers, suture knotpushers, suture punches, switching rods, and trocars. The devices subject to this paragraph (b)(2) are exempt from the premarket notification procedures in subpart E of part 807 of this chapter.

115. Section 888.3000 is amended by revising paragraph (b) to read as follows:

§ 888.3000 Bone cap.

* * * * *

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

116. Section 888.5960 is amended by revising paragraph (b) to read as follows:

§ 888.5960 Cast removal instrument.

* * * * *

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

PART 890—PHYSICAL MEDICINE DEVICES

117. The authority citation for 21 CFR part 890 continues to read as follows:

Authority: Secs. 501, 510, 513, 515, 520, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351, 360, 360c, 360e, 360j, 371).

118. Section 890.1575 is amended by revising paragraph (b) to read as follows:

§ 890.1575 Force-measuring platform.

* * * * *

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

119. Section 890.1600 is amended by revising paragraph (b) to read as follows:

§ 890.1600 Intermittent pressure measurement system.

* * * * *

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

120. Section 890.1615 is amended by revising paragraph (b) to read as follows:

§ 890.1615 Miniature pressure transducer.

* * * * *

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

121. Section 890.3175 is amended by revising paragraph (b) to read as follows:

§ 890.3175 Flotation cushion.

* * * * *

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

122. Section 890.3760 is amended by revising paragraph (b) to read as follows:

§ 890.3760 Powered table.

* * * * *

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

123. Section 890.5380 is amended by revising paragraph (b) to read as follows:

§ 890.5380 Powered exercise equipment.

* * * * *

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

124. Section 890.5410 is amended by revising paragraph (b) to read as follows:

§ 890.5410 Powered finger exerciser.

* * * * *

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

125. Section 890.5660 is amended by revising paragraph (b) to read as follows:

§ 890.5660 Therapeutic massager.

* * * * *

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

126. Section 890.5925 is amended by revising paragraph (b) to read as follows:

§ 890.5925 Traction accessory.

* * * * *

(b) *Classification*. Class I. The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter. The device is also exempt from the current good manufacturing practice regulations in part 820 of this chapter, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

127. Section 890.5940 is amended by revising paragraph (b) to read as follows:

§ 890.5940 Chilling unit.

* * * * *

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

128. Section 890.5950 is amended by revising paragraph (b) to read as follows:

§ 890.5950 Powered heating unit.

* * * * *

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

129. Section 890.5975 is amended by revising paragraph (b) to read as follows:

§ 890.5975 Therapeutic vibrator.

* * * * *

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

PART 892—RADIOLOGY DEVICES

130. The authority citation for 21 CFR part 892 continues to read as follows:

Authority: Secs. 501, 510, 513, 515, 520, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351, 360, 360c, 360e, 360j, 371).

131. Section 892.1700 is amended by revising paragraph (b) to read as follows:

§ 892.1700 Diagnostic X-ray high voltage generator.

* * * * *

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

132. Section 892.1760 is amended by revising paragraph (b) to read as follows:

§ 892.1760 Diagnostic X-ray tube housing assembly.

* * * * *

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

133. Section 892.1770 is amended by revising paragraph (b) to read as follows:

§ 892.1770 Diagnostic X-ray tube mount.

* * * * *

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

134. Section 892.1830 is amended by revising paragraph (b) to read as follows:

§ 892.1830 Radiologic patient cradle.

* * * * *

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

135. Section 892.1880 is amended by revising paragraph (b) to read as follows:

§ 892.1880 Wall-mounted radiographic cassette holder.

* * * * *

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

136. Section 892.5780 is amended by revising paragraph (b) to read as follows:

§ 892.5780 Light beam patient position indicator.

* * * * *

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

137. Section 892.6500 is amended by revising paragraph (b) to read as follows:

§ 892.6500 Personnel protective shield.

* * * * *

(b) *Classification*. Class I. If the device's labeling specifies the lead equivalence, it is exempt from the

premarket notification procedures in subpart E of part 807 of this chapter.

Dated: January 5, 1996.

William B. Schultz,

Deputy Commissioner for Policy.

[FR Doc. 96–418 Filed 1–11–96; 2:00 pm]

BILLING CODE 4160–01–F

PENSION BENEFIT GUARANTY CORPORATION

29 CFR Parts 2610 and 2622

Late Premium Payments and Employer Liability Underpayments and Overpayments; Interest Rate for Determining Variable Rate Premium; Amendments to Interest Rates

AGENCY: Pension Benefit Guaranty Corporation.

ACTION: Final rule.

SUMMARY: This document notifies the public of the interest rate applicable to late premium payments and employer liability underpayments and overpayments for the calendar quarter beginning January 1, 1996. This interest rate is established quarterly by the Internal Revenue Service. This document also sets forth the interest rates for valuing unfunded vested benefits for premium purposes for plan years beginning in November 1995 through January 1996. These interest rates are established pursuant to section 4006 of the Employee Retirement Income Security Act of 1974, as amended. The effect of these amendments is to advise plan sponsors and pension practitioners of these new interest rates.

EFFECTIVE DATE: January 1, 1996.

FOR FURTHER INFORMATION CONTACT: Harold J. Ashner, Assistant General Counsel, Office of the General Counsel, Pension Benefit Guaranty Corporation, 1200 K Street, NW., Washington, DC 20005–4026; telephone 202–326–4024 (202–326–4179 for TTY and TTD). These are not toll-free numbers.

SUPPLEMENTARY INFORMATION: As part of title IV of the Employee Retirement Income Security Act of 1974, as amended, the Pension Benefit Guaranty Corporation collects premiums from ongoing plans to support the single-employer and multiemployer insurance programs. Under the single-employer program, the PBGC also collects employer liability from those persons described in ERISA section 4062(a). Under ERISA section 4007 and 29 CFR § 2610.7, the interest rate to be charged on unpaid premiums is the rate established under section 6601 of the Internal Revenue Code (''Code''). Similarly, under 29 CFR § 2622.7, the interest rate to be credited or charged with respect to overpayments or underpayments of employer liability is the section 6601 rate. These interest rates are published by the PBGC in appendix A to the premium regulation and appendix A to the employer liability regulation.

The Internal Revenue Service has announced that for the quarter beginning January 1, 1996, the interest charged on the underpayment of taxes will be at a rate of 9 percent. Accordingly, the PBGC is amending appendix A to 29 CFR part 2610 and appendix A to 29 CFR part 2622 to set forth this rate for the January 1, 1996, through March 31, 1996, quarter.

Under ERISA section 4006(a)(3)(E)(iii)(II), in determining a single-employer plan's unfunded vested benefits for premium computation purposes, plans must use an interest rate equal to 80% of the annual yield on 30-year Treasury securities for the month preceding the beginning of the plan year for which premiums are being paid. Under § 2610.23(b)(1) of the premium regulation, this value is determined by reference to 30-year Treasury constant maturities as reported in Federal Reserve Statistical Releases G.13 and H.15. The PBGC publishes these rates in appendix B to the regulation.

The PBGC publishes these monthly interest rates in appendix B on a quarterly basis to coincide with the publication of the late payment interest rate set forth in appendix A. (The PBGC publishes the appendix A rates every quarter, regardless of whether the rate has changed.) Unlike the appendix A rate, which is determined prospectively, the appendix B rate is not known until a short time after the first of the month for which it applies. Accordingly, the PBGC is hereby amending appendix B to part 2610 to add the vested benefits valuation rates for plan years beginning in November of 1995 through January of 1996.

The appendices to 29 CFR parts 2610 and 2622 do not prescribe the interest rates under these regulations. Under both regulations, the appendix A rates are the rates determined under section 6601(a) of the Code. The interest rates in appendix B to part 2610 are prescribed by ERISA section 4006(a)(3)(E)(iii)(II) and § 2610.23(b)(1) of the regulation. These appendices merely collect and republish the interest rates in a convenient place. Thus, the interest rates in the appendices are informational only. Accordingly, the PBGC finds that notice of and public comment on these amendments would be unnecessary and contrary to the public interest. For the above reasons, the PBGC also believes that good cause exists for making these amendments effective immediately.

The PBGC has determined that none of these actions is a ''significant regulatory action'' under the criteria set forth in Executive Order 12866.

Because no general notice of proposed rulemaking is required for these amendments, the Regulatory Flexibility Act of 1980 does not apply. See 5 U.S.C. 601(2).

List of Subjects

29 CFR Part 2610

Employee benefit plans, Penalties, Pension insurance, Pensions, and Reporting and recordkeeping requirements.

29 CFR Part 2622

Business and industry, Employee benefit plans, Pension insurance, Pensions, Reporting and recordkeeping requirements, and Small businesses.

In consideration of the foregoing, part 2610 and part 2622 of chapter XXVI of title 29, Code of Federal Regulations, are hereby amended as follows:

PART 2610—PAYMENT OF PREMIUMS

1. The authority citation for part 2610 continues to read as follows:

Authority: 29 U.S.C. 1302(b)(3), 1306, 1307.

2. Appendix A to part 2610 is amended by adding a new entry for the quarter beginning January 1, 1996, to read as follows. The introductory text is republished for the convenience of the reader and remains unchanged.

Appendix A to Part 2610—Late Payment Interest Rates

The following table lists the late payment interest rates under § 2610.7(a) for the specified time periods:

From—	Through—	Interest rate (percent)
* *	* *	*
January 1, 1996.	March 31, 1996 .	9.00

3. Appendix B to part 2610 is amended by adding to the table of interest rates new entries for premium payment years beginning in November of 1995 through January of 1996, to read as follows. The introductory text is republished for the convenience of the reader and remains unchanged.