DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 862 and 872

[Docket No. 94M–0260]

Medical Devices; 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 exempting nine generic types of class I devices from the requirement of premarket notification. 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. Elsewhere in this issue of the **Federal Register**, FDA is publishing a withdrawal of a proposed rule to grant exemptions from premarket notification for seven other generic types of class I devices. Also, the agency is proposing to exempt an additional 12 generic types of class I devices from the requirement of premarket notification. These actions are being taken under the Medical Device Amendments of 1976.

DATES: Effective August 28, 1995. Beginning on August 28, 1995, 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 Federal Food, Drug, and Cosmetic Act.

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SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of July 21, 1994 (59 FR 37378), FDA issued a proposed rule to exempt 164 generic types of class I devices from the requirement of premarket notification, with limitations. Interested persons were given until October 19, 1994, to comment on the proposed rule.

During the comment period, FDA received comments that questioned the appropriateness of the proposed exemptions for a small number of the devices. FDA also received comments requesting the agency to exempt 56 additional generic types of devices. Furthermore, during this time, FDA reconsidered the appropriateness or scope of the proposed exemptions for several devices included in the proposed rule. In the **Federal Register** of December 7, 1994 (59 FR 63005), FDA issued a final rule exempting from the requirement of premarket notification 148 of the 164 generic types of class I devices included in the July 21, 1994, proposed rule. In the preamble to the final rule, the agency stated that, in a future **Federal Register** notice, it would address the requests concerning the 56 additional devices and that it was deferring action on the following 16 devices in order to review the comments received and to reevaluate whether certain of the devices should be exempted from the requirement of premarket notification. (See Table 1).

TABLE 1

21 CFR	Device
862.2270	Thin-layer chromatography system for clinical use.
862.2310	Clinical sample concentrator.
862.2320	Beta or gamma counter for clinical use.
862.2485	Electrophoresis apparatus for clinical use.
862.2720	Plasma oncometer for clinical use.
862.2800	Refractometer for clinical use.
862.2920	Plasma viscometer for clinical use.
864.2280	Cultured animal and human cells.
866.5570	Lactoferrin immunological test system.
868.5620	Breathing mouthpiece.
868.5675	Rebreathing device.
868.5700	Nonpowered oxygen tent.
872.3740	Retentive and splinting pin.
872.3810	Root canal post.
872.6100	Anesthetic warmer.
886.5850	Sunglasses (nonprescription).

After careful review of the comments and reconsideration of the appropriateness or scope of the proposed exemptions for these devices, the agency has concluded that for 9 of the 16 generic types of class I devices listed in Table 1, 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. These nine devices are listed in Table 2.

TABLE 2

21 CFR	Device
862.2310	Clinical sample concentrator.
862.2320	Beta or gamma counter for clinical use.
862.2485	Electrophoresis apparatus for clinical use.
862.2720	Plasma oncometer for clinical use.
862.2800	Refractometer for clinical use.
862.2920	Plasma viscometer for clinical use.
872.3740	Retentive and splinting pin.
872.3810	Root canal post.
872.6100	Anesthetic warmer.

FDA, upon reconsideration, has determined not to grant the proposed exemptions for the following seven devices. (See Table 3).

TABLE 3

21 CFR	Device
862.2270	Thin-layer chromatography system for clinical use.
864.2280	Cultured animal and human cells.
866.5570	Lactoferrin immunological test system.
868.5620	Breathing mouthpiece.
868.5675	Rebreathing device.
868.5700	Nonpowered oxygen tent.
886.5850	Sunglasses (nonprescription).

Elsewhere in this issue of the **Federal Register**, FDA is publishing a withdrawal of the proposed rule to grant exemptions from the requirement of premarket notification for the seven devices listed above. FDA's reasons for deciding not to exempt those seven devices are given in that withdrawal document.

Furthermore, after reviewing the comments requesting FDA to exempt from the requirement of premarket notification 56 additional generic types of devices, FDA has concluded that 33 of these 56 devices should not be exempted from the requirement. As stated below in this document, 10 of these 56 devices, along with 2 additional class I devices, are being proposed for premarket notification exemption elsewhere in this issue of the **Federal Register**. Thirteen of the 56 devices already are exempted from the requirement of premarket notification.

II. Comments

FDA received 10 comments from trade associations, manufacturer associations, a dental firm, a consumer products manufacturer, a company, and a law firm. A summary of the comments and the agency's response to them is provided below.

A. Comments Addressing Specific Devices

1. One comment opposed the proposed exemptions from the requirement of premarket notification for the retentive and splinting pin (§ 872.3740) and the root canal post (§ 872.3810). According to this comment, premarket notification submissions are necessary to ensure that the material used in these devices are biocompatable in order to prevent toxicity and/or allergic reactions. The comment also stated that, because teeth are delicate, these devices must be designed so that no undue stress will be imparted upon the teeth. According to this comment, exempting these devices from premarket notification would result in substandard products being made available to dental professionals. Another comment in favor of the exemption disagreed, stating that it is the ''method of use and application'' of these devices, not the design or materials used in them that is the determining factor in the safe and effective use of these devices. Moreover, according to this comment, data relating to these devices demonstrate that these devices are well-known, established, safe, and effective.

FDA has concluded that exempting these devices from the requirement of premarket notification will not result in the marketing of substandard devices. First, both devices have a long history of safe use. Second, neither device has a history of adverse events. Third, literature indicates little potential for any danger to public health. Finally, the device identifications clearly describe the material composition of these devices. If devices are made of materials other than those described in the identification, they will be classified into another generic type of device or remain in the same generic type of device, but not be exempt from the requirements of premarket notification.

2. A comment requested that the proposed exemption for carboxymethylcellulose sodium and/or polyvinylmethylether maleic acid calcium-sodium double salt denture adhesive (§ 872.3490) be expanded to include other double salts of polyvinylmethylether maleic acid, specifically salts involving those ions that achieve the same technical effect as calcium and sodium, i.e., iron, magnesium, zinc, and potassium.

FDA disagrees with this comment. Although the comment refers to carboxymethylcellulose sodium and/or polyvinylmethylether maleic acid calcium-sodium double salt denture adhesive (§ 872.3490), a class I device, the comment is actually requesting FDA to exempt another classified dental adhesive device, polyvinylmethylether maleic anhydride (PVM–MA), acid copolymer, and carboxymethylcellulose sodium (NACMC) denture adhesive (§ 872.3500) which is a class III device.

3. FDA received a comment requesting that an endolumina illuminated bougie (EIB) device, a silicone elastomer coated fiberoptic bundle designed to aid in the identification of the esophagus, rectum, rectosigmoid, and other organs during surgical procedures, be added to the list of class II, tier 1 devices to be proposed for exemption from the requirement of premarket notification in a future issue of the **Federal Register**.

FDA disagrees with this comment. As stated in the July 21, 1994, proposal, in early 1994, FDA's Office of Device Evaluation undertook a risk assessment of all devices in order to ensure the proper allocation of resources for the review process. Under this risk assessment, all class I, class II, and class III devices were placed into one of three tiers based upon the inherent risk associated with each device. Tier 3 devices include all first and second of a kind devices utilizing new technology or having new intended uses(s), as well as other devices determined by their inherent risk to require an intensive review. These tier 3 devices require intensive scientific and labeling review by a review team as well as advisory panel input. Tier 2 devices include devices which require routine scientific and labeling review. This tier encompasses the majority of 510(k)'s and select premarket approval applications. Tier 1 devices include, among other things, devices which have a minimal inherent risk and whose review focuses upon intended use.

FDA had found EIB to be substantially equivalent to both the gastroenterology-urology fiberoptic retractor (§ 876.4530), a class I device and the class I transilluminator (§ 886.1945). However, upon further consideration, FDA now believes that EIB would have been more appropriately classified under the fiberoptic light ureteral catheter (§ 876.4020), a class II device, which is also a fiberoptic bundle that emits light, but is inserted into the ureter to enable it to be seen during lower abdominal or pelvic surgery. While the specific indication statement for these two devices are different, their intended uses are the same and, therefore, the devices are substantially equivalent. Like the fiberoptic light ureteral catheter, EIB is used with a high intensity light source, which could produce heating and potential damage of body tissues. Concerns identified at the time of classification of the fiberoptic light ureteral catheter included thermal burns related to the amount of energy transmitted. For this reason, FDA has placed the fiberoptic light ureteral catheter in class II, tier 2. Additionally, endoscopes (which could have been another predicate) and esophageal dilators (which include the esophageal bougie) are also tier 2 devices. Furthermore, retaining the EIB device in class II, tier 2 is justified because EIB is a one-of-a-kind device. FDA has not yet had sufficient experience with this device to justify a tier 1 premarket review, i.e., a focused labeling review for intended use/indications for use. For the reasons stated above, the EIB device will remain a class II, tier 2 device.

B. Comments Requesting FDA to Expand the Exemption from the Requirement of Premarket Notification to Include an Additional 56 Devices

4. A total of eight comments requested that the 56 devices listed in Table 4 also be exempted from the requirement of premarket notification.

TABLE 4

21 CFR	Device
862.2230	Chromatographic separation material for clinical use.
862.2250	Gas liquid chromatography system for clinical use.
866.2600	Wood's fluorescent lamp.
868.1930	Stethoscope head.
872.3310	Coating material for resin fillings.
872.3730	Pantograph.
872.3820	Root canal filling resin.
872.4200	Dental handpiece and accessories.
872.5470	Orthodontic plastic bracket.
872.5500	Extraoral orthodontic headgear.
872.6050	Saliva absorber.
872.6390	Dental floss (including devices made of any inert materials).
872.6770	Cartridge syringe.
874.1060	Acoustic chamber for audiometric testing.
874.4140	Ear, nose, and throat bur.
874.4175	Nasopharyngeal catheter.
874.4770	Otoscope.
874.5220	Ear, nose, and throat drug administration device.
874.5800	External nasal splint.
876.4890	Urological table and accessories (manually powered).
876.5160	Urological clamp for males.
876.5250	Urine collector and accessories (not connected to indwelling catheter).
878.4040	Surgical apparel (except surgical gowns and masks).
878.4460	Surgeon's gloves.
880.5110	Hydraulic adjustable hospital bed.

TABLE 4—Continued

21 CFR	Device
880.5120	Manual adjustable hospital bed.
880.5180	Burn sheet.
880.6250	Patient examination glove.
880.6280	Medical insole.
880.6350	Battery-powered medical examination light.
880.6970	Liquid crystal vein locator.
884.5150	Nonpowered breast pump.
884.5425	Scented or scented deodorized menstrual pad.
884.5435	Unscented menstrual pad.
886.4370	Keratome (AC powered).
888.5960	Cast removal instrument (AC powered).
892.1300	Nuclear rectilinear scanner.
892.1320	Nuclear uptake probe.
892.1330	Nuclear whole body scanner.
892.1410	Nuclear electrocardiograph synchronizer.
892.1610	Diagnostic x-ray beam limiting device.
892.1620	Cine or spot flourographic x-ray camera.
892.1760	Diagnostic x-ray tube housing assembly.
892.1770	Diagnostic x-ray tube mount.
892.1830	Radiographic patient cradle.
892.1850	Radiographic film cassette.
892.1860	Radiographic film/cassette changer.
892.1880	Wall-mounted radiographic cassette holder.
892.1890	Radiographic film illuminator.
892.1910	Radiographic grid.
892.1970	Radiographic ECG/respirator synchronizer.
892.1980	Radiologic table.
892.5770	Powered radiation therapy patient support assembly.
892.5780	Light beam patient position indicator.
892.5930	Therapeutic x-ray tube housing assembly.
892.6500	Personnel protective shield.

FDA has concluded that 18 of the 56 devices listed in Table 4 are not candidates for exemption from the requirement of premarket notification because they are currently classified into class II and/or class III. These devices are listed in Table 5.

TABLE 5

21 CFR	Device
872.3310	Coating material for resin fillings.
872.3820	Root canal filling resin.
872.5470	Orthodontic plastic bracket.
872.5500	Extraoral orthodontic headgear.
872.6770	Cartridge syringe.
884.5425	Scented or scented deodorized menstrual pad.
892.1610	Diagnostic x-ray beam limiting device.
892.1620	Cine or spot flourographic x-ray camera.
892.1760	Diagnostic x-ray tube housing assembly.
892.1770	Diagnostic x-ray tube mount.
892.1830	Radiographic patient cradle.
892.1850	Radiographic film cassette.
892.1860	Radiographic film/cassette changer.
892.1880	Wall-mounted radiographic cassette holder.
892.1980	Radiologic table.
892.5770	Powered radiation therapy patient support assembly.
892.5780	Light beam patient position indicator.
892.5930	Therapeutic x-ray housing assembly.

In accordance with section 513(e)(1) of the act (21 U.S.C. 360c(e)(1)), any interested person may petition FDA to reclassify a device based on new information respecting such a device and to exempt such a device from the requirement of premarket notification. The form and content required for such a petition are set forth in 21 CFR 860.123. The request and reasons supporting the request for exemption from the requirement of premarket notification should be included in the supplemental data sheet. If a device is reclassified into class I, FDA may also exempt the device from the requirement of premarket notification.

Thirteen of the 56 devices listed in Table 4 have already been exempted from premarket notification procedures on the dates listed below. These devices are listed in Table 6.

TABLE 6

Date	Federal Register citation	21 CFR	Device
Nov. 9, 1982	47 FR 50823	866.2600	Wood's fluorescent lamp.
June 12, 1989	54 FR 25042	868.1930	Stethoscope head.
Aug. 12, 1987	52 FR 30082	872.3730	Pantograph.
Apr. 5, 1989	54 FR 13828	872.6050	Saliva absorber.
Dec. 7, 1994	59 FR 63005	874.5220	Ear, nose, and throat drug administration device.
Aug. 25, 1987	52 FR 32110	874.5800	External nasal splint.
June 12, 1989	54 FR 25042	876.4890	Urological table and accessories (manually powered).
June 12, 1989	54 FR 25042	880.5110	Hydraulic adjustable hospital bed.
June 12, 1989	54 FR 25042	880.5120	Manual adjustable hospital bed.
Dec. 7, 1994	59 FR 63005	880.5180	Burn sheet.
June 12, 1989	54 FR 25042	880.6280	Medical insole.
Oct. 21, 1980	45 FR 69682	880.6350	Battery-powered medical examination light.
June 12, 1989	54 FR 25042	880.6970	Liquid crystal vein locator.

Ten of the 56 devices listed in Table 4 are candidates for exemption from the requirement of premarket notification. These devices, which are listed in Table 7, along with the flotation cushion (§ 890.3175) and the traction accessory (§ 890.5925), are being proposed for premarket notification exemption elsewhere in today's issue of the **Federal Register**.

TABLE 7

21 CFR	Device
862.2230	Chromatographic separation material for clinical use.
872.2230	Dental floss (including devices made of inert materials).
874.1060	Acoustic chamber for audiometric testing.
874.4140	Ear, nose, and throat bur.
874.4175	Nasopharyngeal catheter.

TABLE 7—Continued

21 CFR	Device
874.4770	Otoscope.
884.5150	Nonpowered breast pump.
884.5435	Unscented menstrual pad.
888.5960	Cast removal instrument (AC powered).
892.6500	Personnel protective shield.

For fifteen of the 56 devices listed in Table 8, FDA has concluded that these devices are not candidates for exemption from premarket notification procedures because they do not meet the criteria for exemption which is set out below.

TABLE 8

21 CFR	Device
862.2250	Gas liquid chromatography system for clinical use.
872.4200	Dental handpiece and accessories.
876.5160	Urological clamp for males.
876.5250	Urine collector and accessories (not connected to indwelling catheter).
878.4040	Surgical apparel (except surgical gowns and masks).
878.4460	Surgeon's gloves.
880.6250	Patient examination glove.
886.4370	Keratome (AC powered).
892.1300	Nuclear rectilinear scanner.
892.1320	Nuclear uptake probe.
892.1330	Nuclear whole body scanner.
892.1410	Nuclear electrocardiograph synchronizer.
892.1890	Radiographic film illuminator.
892.1910	Radiographic grid.
892.1970	Radiographic ECG/respirator synchronizer.

As stated in the preamble of July 21, 1994, proposal, in order for devices to be exempted from the requirement of premarket notification, they must meet all of the following criteria: (1) The device does not have a significant history of false or misleading claims; (2) the device does not have a significant history of risk; (3) characteristics of the device necessary for its safe and effective performance are well established; (4) anticipated changes in the device that could affect safety and effectiveness will either: (a) be readily detectable by users by visual examination or other means or (b) not materially increase the risk of injury, incorrect diagnosis, or ineffective treatment; and (5) any changes in the device would not be likely to result in a change in the device's classification.

The gas liquid chromatography system for clinical use (§ 862.2250); the urological clamp for males (§ 876.5160); and the urine collector and accessories (§ 876.5250) are class I, tier 2 devices. As stated above, tier 2 devices require review of performance data because characteristics of these devices necessary for their safe and effective performance are not well established.

Characteristics of the dental handpiece and accessories (§ 872.4200) and the nuclear rectilinear scanner (§ 892.1300), which are necessary for their safety and effective performance, are not well established. Moreover, anticipated changes in the devices that could affect safety and effectiveness are not readily detectable visually or by routine testing and could materially increase the risk of injury, incorrect diagnosis, or ineffective treatment.

The keratome (§ 886.4370) is not a candidate for exemption from premarket notification because anticipated changes that could affect the safety and effectiveness of the device are not readily detectable visually or by routine testing.

Surgical apparel (except surgical gowns and masks (§ 878.4040)) and surgeons's gloves (§ 878.4460) are not candidates for exemption from premarket notification procedures because anticipated changes that could affect safety and effectiveness are not readily detectable visually or by routine testing and could materially increase the risk of injury, namely the transmission of blood bourne pathogens.

In the **Federal Register** of January 13, 1989 (53 FR 1604), the exemptions from premarket notification and current good manufacturing practices for patient examination gloves (§ 880.6250) were revoked because of the importance of this device in preventing the transmission between patients and health care workers of human immunodeficiency virus (HIV) that causes acquired immune deficiency syndrome (AIDS).

The nuclear uptake probe (§ 892.1320); the nuclear electrocardiograph synchronizer (§ 892.1410); the nuclear whole body scanner (§ 892.1330); the radiographic film illuminator (§ 892.1890); the radiographic grid (§ 892.1910); and the radiographic ECG/respirator synchronizer (§ 892.1970) are not candidates for exemption from the requirement of premarket notification because anticipated changes that could affect the devices' safety and effectiveness are not readily detectable visually or by routine testing and could materially increase the risk of injury, incorrect diagnosis, or ineffective treatment.

III. 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 nor an environmental impact statement is required.

IV. Analysis of Impact

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 reduces a regulatory burden by exempting manufacturers of devices subject to the final rule from the requirement 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 in 21 CFR Parts 862 and 872

Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR parts 862 and 872 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 862.2310 is amended by revising paragraph (b) to read as follows:

§ 862.2310 Clinical sample concentrator.

* * * * *

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

3. Section 862.2320 is amended by revising paragraph (b) to read as follows:

§ 862.2320 Beta or gamma counter 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.

4. Section 862.2485 is amended by revising paragraph (b) to read as follows:

§ 862.2485 Electrophoresis apparatus 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.

5. Section 862.2720 is amended by revising paragraph (b) to read as follows:

§ 862.2720 Plasma oncometer 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.

6. Section 862.2800 is amended by revising paragraph (b) to read as follows:

§ 862.2800 Refractometer 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.

7. Section 862.2920 is amended by revising paragraph (b) to read as follows:

§ 862.2920 Plasma viscometer 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 872—DENTAL DEVICES

8. 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).

9. Section 872.3740 is amended by revising paragraph (b) to read as follows:

§ 872.3740 Retentive and splinting pin.

* * * * *

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

10. Section 872.3810 is amended by revising paragraph (b) to read as follows:

§ 872.3810 Root canal post.

* * * * *

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

11. Section 872.6100 is amended by revising paragraph (b) to read as follows:

§ 872.6100 Anesthetic warmer.

* * * * *

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

Dated: July 18, 1995.

William B. Schultz,

Deputy Commissioner for Policy.

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