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.

FOR FURTHER INFORMATION CONTACT: Lisa A. Rooney, Center for Devices and Radiological Health (HFZ–84), Food and Drug Administration, 2094 Gaither Rd., Rockville, MD 20850, 301–594–4765, ext. 164.

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.