DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 862, 864, 866, 868, and 886

[Docket No. 94M–0260]

Medical Devices; Withdrawal of Proposed Exemptions

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule; withdrawal.

SUMMARY: The Food and Drug Administration (FDA) is withdrawing proposals to exempt seven generic types of class I devices from the requirement of premarket notification. Elsewhere in this issue of the **Federal Register**, FDA is publishing a final rule exempting nine generic types of class I devices from the requirement of premarket notification. Also elsewhere in this issue of the **Federal Register**, 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.

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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 which 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 was reconsidering the appropriateness or scope of the proposed exemptions for several of the 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 that 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).

FDA has reviewed the comments and reconsidered the appropriateness or scope of the proposed exemptions for the devices listed above. Upon review and reconsideration, FDA is withdrawing its proposal to exempt six of the devices because the agency has determined that the devices do not meet the criteria for granting such exemptions. These criteria are described in the preamble of the July 21, 1994, proposal. Furthermore, at this time, the agency is withdrawing its proposal to exempt sunglasses (nonprescription) (§ 886.5850) in order to review the large number of comments concerning the proposed limited exemption applicable to this device; however, the agency is continuing to look at ways to appropriately provide an exemption.

The devices for which the proposed exemptions are being withdrawn are listed below.

TABLE 2

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 final rule exempting 9 devices from the requirement of premarket notification and responding to requests to exempt 56 additional generic types of devices.

II. Summary and Analysis of Comments and FDA's Response

A professional association commented that four anesthesia related devices, the breathing mouthpiece (§ 868.5620); the rebreathing device (§ 868.5675); the nonpowered oxygen tent (§ 868.5700); and the anesthetic warmer (§ 872.6100), should not be exempted from the requirement of premarket notification for the reasons stated below.

A. Breathing Mouthpiece (§ 868.5620)

This association commented that it would be inappropriate to exempt this generic type of class I device from the requirement of premarket notification because a ''breathing mouthpiece'' may be interpreted to include certain devices for which FDA endorses standard specifications. According to this comment, these detailed standard specifications were established to provide order to the design, performance, and manufacturing of selected airway devices, connectors, and appropriate related apparatus which may be construed as ''mouthpieces.''

B. Rebreathing Device (§ 868.5675)

This association stated that certain anesthesia machines, volume ventilators, and resuscitation devices are equipped with nonrebreathing and rebreathing devices, used as components within these systems. Certain rebreathing devices have been directly related to death, serious injury, and serious illness resulting from complications caused by their design, performance, use, and misuse. As a result, the comment contends that rebreathing devices should not be exempt from premarket notification requirements.

C. Nonpowered Oxygen Tent (§ 868.5700)

According to this association, the word ''nonpowered'' is confusing and inappropriate to use to specify a type of oxygen tent because, even if electronic controls are not present and electric power is not required, a pneumatic