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.

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 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

system will ''power'' an oxygen delivery tent. The association stated that such a pneumatic powered oxygen tent falls within the classification of an oxygen administration system which must satisfy certain criteria and specifications. According to the association, review of premarket notification submissions is the only way to ensure that these devices conform to these criteria and specifications. Thus, the association concluded, these devices should not be exempt from the premarket notification requirements.

D. Anesthetic Warmer (§ 872.6100)

This comment was concerned that the words ''anesthetic warmer'' could be applied literally to refer to certain anesthesiology devices associated with known cases of injury, device failure, and misuse. Further, the comment stated that ''anesthetic warmer'' could be applied to anesthesiology devices which are required to follow performance and/or safety specifications.

FDA agrees that the breathing mouthpiece (§ 868.5620); the rebreathing device (§ 868.5675); and the nonpowered oxygen tent (§ 868.5700) should not be exempt from the requirement of premarket notification. Thus, the agency is withdrawing the proposed exemptions for these devices because these devices have a significant history of risk and/or characteristics of the devices necessary for their safe and effective performance are not well established. However, FDA has concluded that the anesthetic warmer (§ 872.6100) should be exempt from the requirement of premarket notification. Moreover, FDA believes that the identification of this device is sufficiently clear to exclude the devices referred to in the comment.

III. Reconsideration of the Appropriateness or Scope of the Exemptions

FDA reconsidered the appropriateness of exempting cultured animal and human cells (§ 864.2280) from the requirement of premarket notification.

FDA is withdrawing the proposed exemption for this device because, upon reconsideration, the agency has determined that the device does not meet the exemption criteria. The device is comprised of either continuous cell or primary cell lines for the isolation and identification of various pathogenic organisms. If the cells are continuous lines, it must be assured that a mechanism is in place for the manufacturer to determine that the cell line has not changed from the original cell type. After prolonged passages cell lines will deviate from the original cell line and the sensitivity for isolation of organisms is decreased. On the other hand, if the cell line is primary, there must be assurance that the cell line is not contaminated with adventitious organisms which may preclude the isolation or identification of the pathogen from the patient. Sometimes it is not readily apparent whether the cells are contaminated with adventitious organisms. Furthermore, with the advent of genetically engineered cell lines for identification of specific organisms, information must be reviewed to determine whether the genetically engineered cell lines will function as claimed. Also, it must be assured that the labeling is consistent with the effectiveness and use of the specific cell. If an applicant wishes to make effectiveness or use claims which are not supported in the literature, appropriate studies are required to validate these claims. If the device is inappropriately labeled, the risk of incorrect diagnosis or ineffective treatment may be increased.

Upon reconsideration, FDA is withdrawing the proposed exemption for the lactoferrin immunological test system (§ 886.5570) because it is anticipated that there may be significant changes to this device that could affect its safety and effectiveness. Such changes could involve new intended uses and new matrices for which the agency has no information or data. The device is not well characterized and any anticipated changes that could affect safety or effectiveness are not readily detectable by any means and could increase the risk of incorrect diagnosis. Similarly, it must be assured that the labeling for the device is appropriate and accurate for the proposed claims. If the device is not appropriately labeled and the performance established, there may be an increased risk of misdiagnosis.

FDA is also withdrawing the proposed exemption for the thin-layer chromatography system for clinical use (§ 862.2270). Upon further review, FDA has determined that any anticipated changes that could affect the safety and effectiveness of the device are not readily detectable by any means and could materially increase the risk of incorrect diagnosis.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513 and 701(a) (21 U.S.C. 360c and 371(a)) and under 21 CFR 5.10, the proposed rule published in the **Federal Register** of July 21, 1994, is withdrawn with respect to the 7 devices cited in Table 2 of this document.

Dated: July 18, 1995.

William B. Schultz,

Deputy Commissioner for Policy.

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

[Docket No. 95N–0139]

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

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to reclassify 112 generic types of class II devices into class I based on new information respecting such devices. FDA is also proposing 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. For the devices for which exemptions are being proposed, 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. Granting the exemptions will allow the agency to make better use of its resources and thus better serve the public.

DATES: Submit written comments by October 11, 1995. For the devices the agency is proposing to reclassify into class I and exempt from the requirement of premarket notification, FDA is proposing that any final rule that may issue based on this proposed rule become effective August 28, 1995.

ADDRESSES: Written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, rm. 1–23, 12420 Parklawn Dr., Rockville, MD 20857.

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

The Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 321 *et. seq.*), as amended by the Medical Devices