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.

[FR Doc. 95–18457 Filed 7–27–95; 8:45 am]

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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