FDA's decision to grant an exemption from the requirement of premarket notification for a generic type of class I device will be based upon the existing and reasonably foreseeable characteristics of commercially distributed devices within that generic type. Because FDA cannot anticipate every change or modification to a device, manufacturers of any commercially distributed class I device for which FDA has granted an exemption from the requirement of premarket notification are still required to submit a premarket notification to FDA before introducing a device or delivering it for introduction into commercial distribution when:

(1) The device is intended for a use different from its intended use before May 28, 1976, or the device is intended for a use different from the intended use of a preamendments device or a legally marketed device; e.g., the device is intended for a different medical purpose, or the device is intended for lay use instead of use by health care professionals; or

(2) The modified device operates using a different fundamental scientific technology than used by the device before May 28, 1976; e.g., a surgical instrument cuts tissue with a laser beam rather than with a sharpened metal blade, or an in vitro diagnostic device detects or identifies infectious agents by using a deoxyribonucleic acid (DNA) probe or nucleic acid hybridization technology rather than culture or immunoassay technology.

Such changes or modifications to class I devices that are exempt from premarket notification would mean the exemption would no longer apply. Changes or modifications to devices that are not exempt from premarket notification requirements under any regulation must undergo a more comprehensive assessment to determine the impact of the change or modification on the device's safety and effectiveness. FDA intends to develop guidance clarifying when a change or modification to a device requires submission of a premarket notification as defined in 21 CFR 807.81(a)(3).

On the dates listed in Table I, FDA published final regulations classifying, among others, the devices listed below. When FDA classified these devices, the agency did not exempt them from the requirement of premarket notification. Based on the analysis described above, FDA has now determined that premarket notification with respect to the devices listed below is unnecessary for the protection of the public health and will not advance FDA's public health mission. This approach is consistent with the recommendation in the May 1993 report of the Subcommittee on Oversight and Investigations of the Committee on Energy and Commerce, U.S. House of Representatives, entitled ''Less Than the Sum of its Parts Reforms Needed in the Organization, Management, and Resources of The Food and Drug Administration's Center for Devices and Radiological Health.''

As stated above, earlier this year, the Office of Device Evaluation undertook a risk assessment of all devices in order to ensure the proper allocation of resources in the review process. All of the class II devices listed below were placed in tier 1, the category of devices which have a minimal inherent risk and whose review focuses upon intended use. As stated in the **Federal Register** of July 21, 1994 (59 FR 37378), FDA is now proposing to reclassify 112 class II, tier 1 devices into class I and exempt these devices, along with 12 class I, tier 1 devices, from the requirement of premarket notification, with limitations.

FDA is proposing to exempt from the requirement of premarket notification, with limitations, the 124 generic type of devices (including 12 already classified generic types of class I devices; chromatographic separation material for clinical use (§ 862.2230 (21 CFR 862.2230)); dental floss (§ 872.6390 (21 CFR 872.6390)); acoustic chamber for audiometric testing (§ 874.1060 (21 CFR 874.1060)); ear, nose, and throat bur (§ 874.4140 (21 CFR 874.4140)); nasopharyngeal catheter (§ 874.4175 (21 CFR 874.4175)); otoscope (§ 874.4770 (21 CFR 874.4770)); nonpowered breast pump (§ 884.5150 (21 CFR 884.5150)); unscented menstrual pad (§ 884.5435 (21 CFR 884.5435)); cast removal instrument (§ 888.5960 (21 CFR 888.5960)); flotation cushion (§ 890.3175 (21 CFR 890.3175)); traction accessory (§ 890.5925 (21 CFR 890.5925)); and personnel protective shield (§ 892.6500 (21 CFR 892.6500)) listed below:

TABLE 1

CFR part	Title	Number of devices proposed to be exempt
862	Clinical Chemistry and Clinical Toxicology Devices; May 1, 1987 (52 FR 16102)	1
866	Immunology and Microbiology Devices; November 8, 1982 (47 FR 50814)	5
868	Anesthesiology Devices; July 16, 1982 (47 FR 31130)	40
870	Cardiovascular Devices; February 5, 1980 (45 FR 7904)	10
872	Dental Devices; August 12, 1987 (52 FR 300820); November 20, 1990 (55 FR 484360)	4
874	Ear, Nose, and Throat Devices; November 6, 1986 (51 FR 40378)	6
876	Gastroenterology-Urology Devices; November 23, 1983 (48 FR 53012); June 12, 1989 (54 FR 25042)	11
878	General and Plastic Surgery Devices; June 24, 1988 (53 FR 23856)	4
880	General Hospital and Personal Use Devices; October 21, 1980 (45 FR 69678)	4
882	Neurological Devices; September 4, 1979 (44 FR 51726)	2
884	Obstetrical and Gynecological Devices; February 26, 1980 (45 FR 12682)	11
886	Ophthalmic Devices; September 2, 1987 (52 FR 33346); November 20, 1990 (55 FR 48436)	4
888	Orthopedic Devices; September 4, 1987 (52 FR 33686); November 20, 1990 (55 FR 48436)	3
890	Physical Medicine Devices; November 23, 1983 (48 FR 53032)	12
892	Radiology Devices; January 20, 1988 (53 FR 1554)	7
Total		124