

Dated: October 22, 2003.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 03-27182 Filed 10-23-03; 3:49 pm]

BILLING CODE 4160-01-S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 870

[Docket Nos. 1994N-0418 and 1996P-0276]

Medical Devices: Cardiovascular Devices: Reclassification of the Arrhythmia Detector and Alarm

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is reclassifying arrhythmia detector and alarm devices from class III to class II (special controls). This device is used to monitor an electrocardiogram (ECG) and to produce a visible or audible signal or alarm when an atrial or ventricular arrhythmia occurs. An atrial or ventricular arrhythmia occurs during a premature contraction or ventricular fibrillation. FDA is reclassifying this device based on new information contained in reclassification petitions regarding the device submitted by the Health Industry Manufacturers Association (HIMA) (now known as Advamed), Quinton Instrument Co., and Zymed Medical Instrumentation. Elsewhere in this issue of the **Federal Register**, FDA is announcing the availability of the guidance document that will serve as the special control for this device. FDA is taking this action under the Federal Food, Drug, and Cosmetic Act (the act), as amended by the Medical Device Amendments of 1976 (the 1976 amendments), the Safe Medical Devices Act of 1990 (the SMDA), the Food and Drug Administration Modernization Act of 1997 (the FDAMA), and the Medical Device User Fee and Modernization Act of 2002 (MDUFMA).

DATES: This rule is effective November 28, 2003.

FOR FURTHER INFORMATION CONTACT: Elias Mallis, Center for Devices and Radiological Health (HFZ-450), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301-443-8517, ext. 177.

SUPPLEMENTARY INFORMATION:

I. Background

The act (21 U.S.C. 301 *et. seq.*) established a comprehensive system for the regulation of medical devices intended for human use. Section 513 of the act (21 U.S.C. 360(e)) established three categories (classes) of devices as a function of the regulatory controls needed to provide reasonable assurance of their safety and effectiveness. The three categories of devices are class I (general controls), class II (special controls), and class III (premarket approval).

Under section 513 of the act, FDA refers to devices that were in commercial distribution before May 28, 1976 (the date of enactment of the 1976 amendments), as "preamendments devices." FDA classifies these devices after the agency initiates the following procedures: (1) Receives a recommendation from a device classification panel (an FDA advisory committee), (2) publishes the panel's recommendation for comment, along with a proposed regulation classifying the device, and (3) publishes a final regulation classifying the device. FDA has classified most preamendments devices under these procedures.

FDA refers to devices that were not in commercial distribution before May 28, 1976, as "postamendments devices." These devices are classified automatically by statute (section 513(f) of the act) into class III without any FDA rulemaking process. Those devices remain in class III and require premarket approval, unless FDA initiates the following procedures: (1) Reclassifies the device into class I or II, (2) issues an order classifying the device into class I or II in accordance with section 513(f)(2) of the act, or (3) issues, under section 513(i) of the act, an order finding the device as substantially equivalent to a predicate device that does not require premarket approval. As delineated in section 510(k) of the act (21 U.S.C. 360(k)) and under part 870 of the regulations (21 CFR part 870), FDA determines whether new devices are substantially equivalent to previously offered devices by means of premarket notification procedures. Through premarket notification procedures, a person may, without submission of a premarket approval application (PMA), market a preamendments device that has been classified into class III until FDA issues a final regulation under section 515(b) of the act (21 U.S.C. 360e(b)) requiring premarket approval.

Section 513(e) of the act governs reclassification of classified preamendments devices. This section provides that FDA may, by rulemaking,

reclassify a device based on "new information." Under section 513(e) of the act, FDA can initiate a reclassification or an interested person can petition FDA to reclassify a preamendments device. The term "new information," as used in section 513(e) of the act, includes information developed after the date of the device's original classification. This information could include a reevaluation of the original data or information from the time of the original classification that was not presented, available, or deemed applicable. (See, e.g., *Holland Rantos v. United States Department of Health, Education, and Welfare*, 587 F.2d 1173, 1174 n.1 (D.C. Cir. 1978); *Upjohn v. Finch*, 422 F.2d 944 (6th Cir. 1970); *Bell v. Goddard*, 366 F.2d 177 (7th Cir. 1966).)

Reevaluation of the data previously used by FDA is an appropriate basis for subsequent regulatory action where the reevaluation is made in light of newly available regulatory authority (see *Bell v. Goddard*, *supra*, 366 F.2d at 181; *Ethicon, Inc. v. FDA*, 762 F.Supp. 382, 389-391 (D.D.C. 1991)), or in light of changes in "medical science." (See *Upjohn v. Finch*, *supra*, 422 F.2d at 951.) Whether data before the FDA are past or new data, the "new information" to support reclassification under section 513(e) of the act must be "valid scientific evidence," as defined in section 513(a)(3) of the act and § 860.7(c)(2) (21 CFR 860.7(c)(2)) (See, e.g., *General Medical Co. v. FDA*, 770 F.2d 214 (D.C. Cir. 1985); *Contact Lens Assoc. v. FDA*, 766 F.2d 592 (D.C. Cir.), cert. denied, 474 U.S. 1062 (1985)).

FDA relies upon "valid scientific evidence" in the classification process to determine the level of regulation for devices. When reclassifying a device, FDA can only consider valid scientific evidence that is publicly available. Publicly available information excludes trade secret and confidential commercial information, e.g., the contents of a pending PMA. (See section 520(c) of the act (21 U.S.C. 360j(c).) Section 520(h)(4) of the act provides that 6 years after the date FDA has approved an application FDA may, for reclassification of a device, use certain information contained in a PMA. Useable information includes data from clinical and preclinical tests or studies that demonstrate the safety or effectiveness of the device. This information does not include descriptions of methods of manufacture, product composition, and other trade secrets.