

## II. Regulatory History of the Device

In the **Federal Register** of December 13, 2002 (67 FR 76706), FDA proposed to reclassify arrhythmia detector and alarm devices from class III to class II (special controls). These devices are used to monitor an electrocardiogram and to produce a visible or audible signal or alarm when an atrial or ventricular arrhythmia occurs. Concurrently, FDA proposed to separate the identification of arrhythmia detectors and alarms from automated external defibrillators (AEDs). FDA decided to address, at a later date, the possible reclassification of AEDs, devices primarily designed for a different intended use (i.e., to correct an arrhythmia) than the arrhythmia detector and alarm. Elsewhere in this issue of the **Federal Register**, FDA is publishing a notice of intent to reclassify AEDs.

Also in the **Federal Register** of December 13, 2002 (67 FR 76749), FDA announced the availability of a guidance document that FDA intended would serve as the special control for arrhythmia detector and alarm devices, if FDA reclassified them. FDA gave interested persons until March 13, 2002, to comment on the proposed regulation and guidance document. FDA did not receive any comments on the proposed regulation, but did receive one comment on the guidance document.

## III. Summary of Final Rule

In accordance with § 860.84(g)(2) (21 CFR 860.84(g)(2)) of the regulations, FDA is reclassifying arrhythmia detector and alarm devices into class II. To ensure clarity, FDA is revising the classification of arrhythmia detector and alarm devices by separating these devices from AEDs and establishing a separate classification regulation for AEDs (§ 870.5310). The guidance document entitled "Class II Special Controls Guidance Document: Arrhythmia Detector and Alarm" will serve as the special control for arrhythmia detector and alarm devices. Elsewhere in this issue of the **Federal Register**, FDA is announcing the availability of this guidance document. Following the effective date of the final classification rule, any firm submitting a 510(k) premarket notification for the device will need to address the issues covered in the special controls guidance. However, the firm need only show that its device meets the recommendations of the guidance or in some other way provides equivalent assurances of safety and effectiveness.

FDA believes that review of performance characteristics and labeling

can ensure that acceptable levels of performance for both safety and effectiveness are addressed before marketing clearance. Thus, persons who intend to market this device must submit to FDA a premarket notification submission before marketing the device.

## IV. Analysis of Comments and FDA's Response

FDA received no comments on the proposed rule. Therefore, FDA is codifying the reclassification and special controls guidance by amending § 870.1025. FDA is also adding a separate regulation for AEDs (§ 870.5310). For the convenience of the reader, FDA is also adding § 870.1 to inform the reader where to find guidance documents referenced in part 870.

## V. Environmental Impact

FDA has determined under 21 CFR 25.34(b) that this reclassification action does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

## VI. Analysis of Impacts

FDA has examined the impacts of the final rule under Executive Order 12866 and the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (Public Law 104–4). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives. If regulation is necessary, a regulatory agency must plot a course that maximizes net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). FDA believes that the final rule is consistent with the regulatory philosophy and principles identified in the Executive order. Additionally, as defined by the Executive order, the final rule does not constitute a significant regulatory action. As a result, the final rule is not subject to review under the Executive order.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Reclassification of this device from class III to class II will relieve all manufacturers of the device of the cost of complying with the premarket approval requirements in section 515 of the act. Manufacturers of class III arrhythmia detectors and alarms currently are required to submit premarket notifications. The guidance

document reflects existing FDA practice in the review of these premarket notifications. FDA expects that manufacturers of cleared arrhythmia detectors and alarms will not have to take any additional action in response to this rule. This rule will help expedite the review process for any new manufacturers of these devices. Because reclassification will reduce regulatory costs with respect to this device, it will impose no significant economic impact on any small entities, and it may permit small potential competitors to enter the marketplace by lowering their costs. The agency therefore certifies that this rule will not have a significant economic impact on a substantial number of small entities. In addition, this rule will not impose costs of \$100 million or more on either the private sector or State, local, and tribal governments in the aggregate, and therefore a summary statement of analysis under section 202(a) of the Unfunded Mandates Reform Act of 1995 is not required.

## VII. Federalism

FDA has analyzed the final rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the rule does not contain policies that have substantial direct effects on the States, on the relationship between the National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, FDA has concluded that the rule does not contain policies that have federalism implications as defined in the Executive order. As a result, a federalism summary impact statement is not required.

## VIII. Paperwork Reduction Act of 1995

FDA concludes that the final rule contains no collections of information. Therefore, clearance by the Office of Management and Budget, according to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520) is not required.

## List of Subjects in 21 CFR Part 870

Medical devices.

■ Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 870 is amended as follows:

## PART 870—CARDIOVASCULAR DEVICES

■ 1. The authority citation for 21 CFR part 870 continues to read as follows:

**Authority:** 21 U.S.C. 351, 360, 360c, 360e, 360j, 371.