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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 870

[Docket No. 94N–0418 and 96P–0276]

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

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to reclassify the arrhythmia detector and alarm from class III (premarket approval) to class II (special controls) based on new information regarding the device. FDA is also proposing to revise the identification of the arrhythmia detector and alarm to separate the automated external defibrillator (AED) from the identification of the arrhythmia detector and alarm. FDA intends to propose the reclassification of the AED at a later time. FDA is taking this action in response to petitions submitted under the Federal Food, Drug, and Cosmetic Act (the act), as amended by the Medical Device Amendments of 1976 (the 1976 amendments) and the Safe Medical Devices Act of 1990 (the SMDA), and the Food and Drug Administration Modernization Act of 1997 (FDAMA).

DATES: Submit written or electronic comments by [*insert date 90 days after date of publication in the* **Federal Register**].

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to: http://www.fda.gov/dockets/ecomments.

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FOR FURTHER INFORMATION CONTACT: Carole C. Carey, Center for Devices and Radiological Health (HFZ–450), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–443–8609.

SUPPLEMENTARY INFORMATION:

I. Regulatory Authorities

The act, as amended by the 1976 amendments (Public Law 94–295), the SMDA (Public Law 101–629), and FDAMA (Public Law 105–115), establishes a comprehensive system for the regulation of medical devices intended for human use. Section 513 of the act (21 U.S.C. 360c) established three categories (classes) of devices, depending on 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, devices that were in commercial distribution before May 28, 1976 (the date of enactment of the amendments), generally referred to as preamendments devices, are classified after FDA has: (1) Received a recommendation from a device classification panel (an FDA advisory committee); (2) published the panel's recommendation for comment, along with a proposed regulation classifying the device; and (3) published a final regulation classifying the device. FDA has classified most preamendments devices under these procedures.

Devices that were not in commercial distribution prior to May 28, 1976, generally referred to as postamendment 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 and until the device is reclassified into class I or II or FDA issues an order finding the device to be substantially equivalent, in accordance with section 513(i) of the act, to a predicate device that does not require premarket approval. The agency determines whether new devices are substantially equivalent to previously offered devices by means of premarket notification procedures in section 510(k) of the act (21 U.S.C. 360(k)) and 21 CFR part 807 of the regulations.

A preamendments device that has been classified into class III may be marketed, by means of premarket notification (510(k)) procedures, without submission of a premarket approval application until FDA issues a final regulation under section 515(b) of the act (21 U.S.C. 360e(b)) requiring premarket approval.

The SMDA added section 515(i) to the act. This section requires FDA to issue an order to manufacturers of preamendment class III devices and substantially equivalent postamendments devices for which no final regulation requiring the submission of premarket approval applications (PMAs) has been issued. This order requires such manufacturers to submit to the agency a summary of, and a citation to, any information known or otherwise available to them respecting such devices, including adverse safety and effectiveness information that has not been submitted under section 519 of the act (21 U.S.C. 360i). Section 519 of the act requires manufacturers, importers, distributors, and device user facilities to submit adverse event reports of certain device-related events and reports of certain corrective actions taken. Section 515(i) of the act also directs FDA to either revise the classification of the device into class I or class II or require the device to remain in class III and establish a

schedule for the promulgation of a rule requiring the submission of PMAs for those devices remaining in class III.

In the **Federal Register** of May 6, 1994 (59 FR 23731), FDA announced the availability of a document setting forth its strategy for implementing the provisions of the SMDA that require FDA to review the classification of preamendments class III devices. Under this plan, the agency divided preamendment class III devices into the following three groups: (1) Group 1 devices are devices that FDA believes raise significant questions of safety and/ or effectiveness, but are no longer used or are in very limited use; (2) group 2 devices are devices that FDA believes have a high potential for being reclassified into class II; and group 3 devices are devices that FDA believes are currently in commercial distribution and are not likely candidates for reclassification. FDA also announced its intention to call for submission of PMAs for the 15 highest priority devices in group 3, and for all group 1 devices. The agency also announced its intention to issue an order under section 515(i) of the act for the remaining group 3 devices and for all of the group 2 devices.

In the **Federal Register** of August 14, 1995 (60 FR 41984 and 60 FR 41986), FDA published two orders for certain class III devices requiring the submission of safety and effectiveness information in accordance with the preamendments class III strategy for implementing section 515(i) of the act. FDA published two updated orders in the **Federal Register** of June 13, 1997 (62 FR 32352 and 32355). The orders describe in detail the format for submitting the type of information required by section 515(i) of the act so that the information submitted would clearly support either reclassification or indicate that a device should be retained in class III. The orders also scheduled the required submissions in groups, at 6-month intervals, beginning with August 14, 1996.

The device proposed in this regulation for reclassification was included in group 3.

Reclassification of classified preamendments devices is governed by section 513(e) of the act. This section provides that FDA may, by rulemaking, reclassify a device based upon "new information." The reclassification can be initiated by FDA or by the petition of an interested person.

The term "new information," as used in section 513(e) of the act, includes information developed as a result of a reevaluation of the data before the agency when the device was originally classified, as well as information not presented, not available, or not developed at that time. (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); and *Bell* v. *Goddard*, 366 F.2d 177 (7th Cir. 1966).)

Reevaluation of the data previously before the agency is an appropriate basis for subsequent regulatory action where the reevaluation is made in light of changes in "medical science."

(See *Upjohn* v. *Finch*, supra, 422 F.2d at 951), or in light of newly available regulatory controls (cf. *Ethicon, Inc.*, v. *FDA*, 762 F. Supp. 382, 388–389 (D.D.C. 1991)), such as special controls or design controls. However, regardless of whether data before the agency are past or new data, the "new information" on which any reclassification is based is required to consist of "valid scientific evidence" as defined in section 513(a)(3) of the act and 21 CFR 860.7(c)(2). FDA relies upon "valid scientific evidence" in the classification process to determine the level of regulation for devices.

II. Regulatory History of the Device

The arrhythmia detector and alarm subject to this proposal was classified in part 870 (21 CFR part 870) by a final rule published in the **Federal Register** of February 5, 1980 (45 FR 7907) at § 870.1025. In the proposed rule upon which the final rule was based (March 9, 1979 (44 FR 13284)), FDA considered the recommendations of the Cardiovascular Device Classification Panel. Subsequently, FDA classified the arrhythmia detector and alarm into class III, because there was insufficient information to determine that class I or class II controls could provide reasonable assurance of the safety and effectiveness of the device.

FDA is addressing three petitions to reclassify arrhythmia detectors and alarms from the Health Industry Manufacturers Association (HIMA) (now known as Advamed); Quinton Instrument Co.; and Zymed Medical Instrumentation (Refs. 1 through 3) and safety and effectiveness information ("515(i) submissions") submitted by Datascope Corp.; Hogan and Harton L.L.P.; Life Sensing Instrument Co.; Inc.; Medical Data Electronics; Mennen Medical Ltd.; Mortara Instrument; and, Olsson, Frank and Weeda, P.C. (Refs. 4 through 10).

FDA is not addressing at this time the petitions submitted by HIMA (Advamed) to reclassify automated external defibrillators (AEDs) from class III to class II. This device is primarily designed for a different intended use than the arrhythmia detector and alarm. An AED has a shock advisory algorithm, automatically detects a shockable cardiac rhythm, and automatically delivers an electric shock (fully automated device) or delivers a shock when activated by the operator (semi-automated device). Defibrillators are preamendment class II devices under § 870.5300. Arrhythmia detectors and alarms are

preamendment class III devices under § 870.1025. AEDs are devices found substantially equivalent to the class III arrhythmia detector and alarm (§ 870.1025) in response to a 510(k) because they are a combination of the class II defibrillator and the class III arrhythmia detector and alarm. FDA, therefore, found them equivalent to the higher class of the combined devices. In a future issue of the **Federal Register**, FDA will publish a notice of a panel meeting that will discuss the possible reclassification of AEDs.

III. Proposed Addition of Identification for AEDs

FDA is proposing to add a new identification of the AEDs to read as follows:

An automated external defibrillator is a low-energy device with a rhythm recognition detection system that delivers into a 50 ohm test load an electrical shock of a maximum of 360 joules of energy used for defibrillating (restoring normal heart rhythm) the atria or ventricles of the heart. The device analyzes the patient's electrocardiogram, interprets the cardiac rhythm and automatically delivers an electrical shock (fully automated AED), or advises the user to deliver the shock (semi-automated or shock advisory AED) to treat ventricular fibrillation or pulseless ventricular tachycardia.

The name of the classification regulation, arrhythmia detector and alarm and the identification of these devices will remain unchanged.

IV. Proposed Reclassification

FDA is proposing that the arrhythmia detector and alarm be reclassified from class III to class II. FDA believes that the guidance document identified in section VIII of this document as the special control would provide reasonable assurance of the safety and effectiveness of the device. Therefore,

in accordance with sections 513(e) and 515(i) of the act and 21 CFR 860.130, based on new information with respect to the device, FDA is proposing to reclassify the arrhythmia detector and alarm preamendment class III device into class II.

The agency does not intend to exempt this proposed class II device from premarket notification (510(k)) submissions as permitted by section 510(m) of the act.

FDA believes that it needs to review the information to address the risks identified in the guidance document in order to assure that a new device is at least as safe and effective as legally marketed devices.

V. Risks to Health

After considering the information discussed by the panel during the original classification proceedings, as well as published literature, medical device reports (MDR), and section 515(i) of the act submissions of safety and effectiveness information, FDA has evaluated the risks associated with the arrhythmia detector and alarm. FDA now believes that the following are the risks to health associated with the use of the arrhythmia detector and alarm:

A. Misdiagnosis

Inaccurate electrocardiogram (ECG) waveform measurement and analysis can lead to misdiagnosis and could result in failure-to-alarm in the case of life threatening arrhythmias or cause false alarms to be activated. Conditions exist under which an algorithm may misclassify portions of the ECG waveform. Inadequate design and poor signal processing techniques in the presence of artifact or noise can also result in miscounting of heart rate and misclassification of arrhythmias. Noise degrades signal quality and is affected

by patient motion, electromagnetic interference, and improper electrode placement. It may distort the signal to the point the data are invalid or cannot be analyzed.

Although the algorithm in most commercially available devices today has improved accuracy in both beat detection and beat classification with enhanced noise reduction techniques, it is extremely difficult to design a system that accurately analyzes 100 percent of all arrhythmias. Algorithm accuracy is a potential safety and effectiveness issue; however, it is not frequently reported as an adverse event. Approximately 6 percent of the MDR and complaint data are attributed to algorithm accuracy (Ref. 1). The ability of ST-segment measurement algorithm performance to predict clinical conditions has not been completely validated. Literature indicates that this capability is helpful for patients who have the potential of experiencing ischemic episodes and some clinicians believe changes in the ST segment can be indicative of myocardial ischemia (Refs. 11 through 15).

The performance of an automated, computerized, arrhythmia monitor system is dependent on the accuracy of the arrhythmia detection and identification algorithm. If inaccurate diagnostic data are used in managing the patient, the physician may prescribe a course of treatment that places the patient at risk.

B. Incorrect Pacemaker Pulse Detection

Many patients on ECG monitoring systems also have pacemakers. This condition poses a particular problem as the detection of pacemaker pulse artifact during "loss of capture" (heart does not respond to the pacing pulse stimulus), may inappropriately be interpreted as a normal beat. Failure of a heart rate alarm to occur during loss of capture compromises the patient's

condition and may result in death. In the early 1990s, Emergency Care Research Institute (ECRI) investigated the difficulties in monitoring pacemaker patients (Ref. 16). Their initial testing of the patient monitors demonstrated the devices' limited ability to reliably reject simulated pacemaker signals. A subsequent 1994 publication reported concerns about the ability of telemetry arrhythmia monitoring systems to accurately and reliably identify pacemaker pulses (Ref. 17). Another type of problem encountered when monitoring patients with pacemakers is a false alarm due to a "no detect" time window (a brief period when the device is not sensing the patient's ECG) that occurs when the monitor sees the pacemaker spike, but fails to see the patient's own ECG signal. Although the potential risk associated with pacemakers is high, the incidence of incorrect pacemaker pulse detection is low based on the relatively small number of reports. A review of manufacturers' MDRs between 1984 and 1995 showed that approximately 14 percent of MDRs were attributed to pace pulse detection capability (Ref. 1).

C. Delayed Response to Life Threatening Arrhythmias Due to User Error, Improper Training, and Unattended Monitors

The level of training and quality of user training greatly affect the safe and effective operation of arrhythmia monitoring systems. An unattended monitor, or use by untrained or improperly trained clinical staff, can adversely affect system performance. In a system where excessive false alarms occur (from causes described in previous paragraphs), this may result in user failure to respond promptly to critical alarms. Furthermore, caregivers could develop a negative attitude from the false alarms, eroding user confidence in the device and resulting in deactivation of the alarm or failure to reset the alarm. HIMA (Advamed) indicated that approximately 15 percent (9 of 59) of the MDRs from

1984 to 1995 were attributed to alarm functionality (i.e., alarms turned off by the staff) (Ref. 1). Other device performance concerns are difficulty in using the device and the device taking too much time to use (i.e., setting up the patient and ensuring that the algorithm has learned the appropriate rhythms) (Ref. 18).

D. Loss of Alarm at Central Station or Bedside

Loss of alarm at central station or bedside may occur due to software crash, hardware failure preventing communication, and/or the inability of central station to receive data/alarms from the bedside monitor.

E. Excessive Patient Leakage Current

Excessive patient leakage current may result in electrically induced cardiac arrhythmias.

VI. Summary of the Reasons for Reclassification

After considering the data and information contained in the petitions, 515(i) submissions of safety and effectiveness information, published literature, and over 20 years of device experience in the clinical environment, FDA believes that the arrhythmia detector and alarm can be reclassified into class II. Special controls, in addition to general controls, can address the risks described above and provide reasonable assurance of the safety and effectiveness of the device. FDA believes there is sufficient information to establish special controls to provide such assurance.

VII. Summary of Data Upon Which the Reclassification is Based

In addition to the potential risks of the arrhythmia detector and alarm described in section V of this document, there is reasonable knowledge of the

benefits of the device. Specifically, arrhythmia detector and alarm monitoring systems allow cardiac monitoring of patients who are at significant risk of immediate life-threatening arrhythmias, such as patients suspected of having acute myocardial infarction, patients who have been recently resuscitated from cardiac arrest, and patients with unstable angina (Ref. 19). When monitoring for evidence of cardiac ischemia, the ST-segment monitoring feature in the arrhythmia detector and alarm devices allows timely notification of ST-segment changes. The integrated alarm system alerts caregivers to any life threatening arrhythmias that require their immediate attention and assessment of the patient's condition before treatment intervention. In addition to patient cardiac monitoring in critical areas, it is also frequently used in noncritical settings to improve patient care management and serve as a labor saving device. The computerized documentation or trending of arrhythmia events is far more efficient than piecing together pages of ECG strips.

Based on the available information, FDA believes that the special controls discussed in section VII of thus document are capable of providing reasonable assurance of the safety and effectiveness of the arrhythmia detector and alarm with regard to the identified risks to health of this device.

VIII. Proposed Special Controls

FDA believes that the special control guidance document entitled "Class II Special Controls Guidance Document: Arrhythmia Detector and Alarm; Draft Guidance for Industry and FDA," in addition to general controls, can address the risks to health described in section V of this document. Elsewhere in this issue of the **Federal Register**, FDA is announcing the availability of this guidance document. FDA is also revising § 870.1 to inform the reader as to the availability of the guidance document.

If adopted, following the effective date of a final rule classifying the device, any firm submitting a 510(k) premarket notification for the device would need to address the issues covered in the special control guidance. However, the firm would need to show only that its device meets the recommendations of the guidance or in some other way provides equivalent assurances of safety and effectiveness.

The guidance document contains specific recommendations with regard to the information and testing in the premarket notification application. Particular sections of the guidance document address the following topics:

- Safety testing (software validation, electrical safety and environmental handling testing, electromagnetic compatibility),
- Performance testing, and
- Labeling.

A. Safety Testing

Safety testing as described in the guidance document includes software validation, electrical safety and environmental handling testing, and electromagnetic compatibility. The in vitro safety testing can help control the risks of incorrect pacemaker pulse detection and other risks associated with the use of the device, such as loss of alarm at central station or bedside monitor, excessive patient leakage current, injury to patient's skin, and electrical shock to the operator. Proper design can improve the paced patient algorithm performance. For example, the pace pulse detection should be implemented on the unfiltered ECG signal prior to processing of the waveform by the QRS beat detector. Most of the other concerns addressed in this section of the guidance are well known and are generic to microprocessor-controlled, software-driven, electromedical devices. This section of the guidance makes

recommendations on the qualification testing to evaluate the device electrical safety requirements, its ability to function after exposure to environmental hazards, electromagnetic compatibility in the intended environment of use, and software validation based on the use of relevant consensus standards and/ or other FDA guidance documents.

B. Performance Testing

The section on performance testing of the guidance document can help control the risks of misdiagnosis from inaccurate ECG signal measurement and misclassified waveforms. The availability of annotated arrhythmia databases has allowed detection algorithms to be tested on the same data. It is recommended that manufacturers properly test the accuracy of the automated arrhythmia detection and ST-segment measurement algorithms, and disclose the results of those tests. This section of the guidance document also emphasizes testing to demonstrate conformance to relevant ECG standards, testing alarm accuracy within a few seconds of the onset of critical life threatening arrhythmias, and testing other alarms functions including those related to system tasks. The guidance also recommends comparative testing to a legally marketed predicate device. If the device incorporates significant new features, additional testing may be necessary. These tests may be conducted in the laboratory and/or clinical settings.

C. Labeling

As described in the guidance, labeling can help control the delayed responses to life threatening arrhythmias due to user error, improper training, and unattended monitors. In addition to conformance to the labeling regulations at 21 CFR part 801, the user (operator) manual should contain detailed operating instructions designed to reduce risks from user error with

the device. Furthermore, the device should be operated only by persons with specific training in the use of the device.

IX. FDA's Tentative Findings

FDA believes that the arrhythmia detector and alarm can be reclassified into class II because special controls, in addition to general controls, would provide reasonable assurance of the safety and effectiveness of the device, and there is sufficient information to establish special controls to provide such assurance.

X. Environmental Impact

The agency has determined under 21 CFR 25.34(b) that this proposed classification action is of a type that 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.

XI. Analysis of Impacts

FDA has examined the impacts of the proposed 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 and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety and other advantages, distributive impacts, and equity). The agency believes that this proposed rule is consistent with the regulatory philosophy and principles identified in the Executive order. In addition, the proposed rule is not a significant regulatory action as defined

by the Executive order and so 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, if FDA finalizes 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 proposed rule, if issued, will not have a significant economic impact on a substantial number of small entities. In addition, this proposed 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.

XII. Submission of Comments and Proposed Dates

Interested persons may submit to the Dockets Management Branch (see **ADDRESSES**) written comments regarding this proposal by (see **DATES**). Two

copies of any comments are to be submitted except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday. FDA proposes that any find regulation based on this proposed rule become effective 30 days after its date of publication in the **Federal Register**.

XIII. References

The following references have been placed on display in the Dockets Management Branch (see **ADDRESSES**) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. HIMA (Health Industry Manufacturers Association), reclassification petition, Docket No. 94N–0418, vol. 1–7, Washington, DC, August 14, 1996.

2. Quinton Instrument Co., reclassification petition, Docket No. 94N–0418, vol. 1, WA, August 14, 1996.

3. Zymed Medical Instrumentation, reclassification petition, Docket No. 96P–0276/CCP 1, vol. 1, CA, August 7, 1996.

4. Datascope Corp., submission of safety and effectiveness information, Docket No. 94N–0418, vol. 1, NJ, October 2, 1996.

5. Hogan and Hartson L. L. P. for Cardiac Telecom Corp., submission of safety and effectiveness information, Docket No. 94N–0418, vol. 1, Washington, DC, August 14, 1996.

6. Life Sensing Instrument Co., Inc., submission of safety and effectiveness information, Docket No. 94N–0418, vol. 1, TN, July 15, 1996.

7. Medical Data Electronics, Inc., submission of safety and effectiveness information, Docket No. 94N–0418, vol. 1, CA, August 14, 1996.

8. Mennen Medical Ltd., submission of safety and effectiveness information, Docket No. 94N–0418, vol. 1, October 25, 1996.

9. Mortara Instrument, Inc., submission of safety and effectiveness information, Docket No. 94N–0418, vol. 1, WI, August 14, 1996.

10. Olsson, Frank and Weeda, P. C. for QMED, Inc., submission of safety and effectiveness information, Docket No. 94N–0418, vol. 1, Washington, DC, August 15, 1996.

11. Ellis, J. et al., "Comparison of Two Automated ST-Segment Analysis Systems, EKG (Including T Wave Inversion Analysis), and Transesophageal Echocardiography for the Diagnosis of Intraoperative Myocardial Ischemia," abstract (included in Ref. 1).

12. Gottlieb, S. et al., "Silent Ischemia on Holter Monitoring Predicts Mortality in High-Risk Postinfarction Patients," *Journal of the American Medical Association*, vol. 259, pp. 1030–1035, 1988 (included in Ref. 1).

13. Krucoff, M., "Identification of High Risk Patients with Silent Myocardial Ischemia After Percutaneous Transluminal Coronary Angioplasty by Multilead Monitoring," *American Journal of Cardiology,* vol. 61, pp. 29F–24F, 1988 (included in Ref. 1).

14. Muller, J. and Barash, P., "Automated ST-Segment Monitoring," *International Anesthesioogy Clinics*, vol. 31, pp. 45–55, 1993 (included in Ref. 1).

15. Nademanee, K. et al., "Characteristics and Clinical Significance of Silent Myocardial Ischemia in Unstable Angina," *American Journal of Cardiology,* vol. 58, pp. 26B–33B, 1986 (included in Ref. 1).

16. ECRI, "Physiologic Patient Monitors," update, *Health Devices*, vol. 21, Nos. 3–4, pp. 123–128, March-April 1992.

17. ECRI, "Ambulatory Telemetry Arrhythmia Monitoring Systems (including Guidance Section: Implementation and Effective Use of Telemetry Arrhythmia Monitoring Systems," *Health Devices*, vol. 23, No. 7, pp. 267–305, July 1994.

18. Badura, F., "Nurse Acceptance of a Computerized Arrhythmia Monitoring System," *Instrumentation for Critical Care*, vol. 9, pp. 1044–48, 1980 (included in Ref. 1).

19. Emergency Cardiac Care Committee of the American College of Cardiology, "Recommended Guidelines for In-Hospital Cardiac Monitoring of Adults for Detection of Arrhythmias," *Journal American of College Cardiology*, vol. 18, pp. 1431–1433, 1991 (included in Refs. 1 and 8).

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, it is proposed that 21 CFR part 870 be amended 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.

2. Section 870.1 is amended by adding paragraph (e) to read as follows:

§ 870.1 Scope.

* * * * *

(e) Guidance documents referenced in this part are available on the Internet at http://www.fda.gov/cdrh/guidance.html.

2. Section 870.1025 is revised to read as follows:

§ 870.1025 Arrhythmia detector and alarm.

(a) Arrhythmia detector and alarm (including ST-segment measurement and alarm)—(1) *Identification.* An arrhythmia detector and alarm is system that monitors the electrocardiogram and is designed to produce a visible or

audible signal or alarm when an atrial or ventricular arrhythmia, such as a premature contraction or ventricular fibrillation, exists.

(2) *Classification.* Class II (special controls). The special control for this device is the FDA guidance document entitled "Class II Special Controls Guidance Document: Arrhythmia Detector and Alarm; Guidance for Industry and FDA." See § 870.1 for the availability of this guidance document.

(b) *Automated external defibrillator*— (1) *Identification.* An automated external defibrillator is a low-energy device with a rhythm recognition detection system that delivers into a 50 ohm test load an electrical shock of a maximum of 360 joules of energy used for defibrillating (restoring normal heart rhythm) the atria or ventricles of the heart. The device analyzes the patient's electrocardiogram, interprets the cardiac rhythm and automatically delivers an electrical shock (fully automated AED), or advises the user to deliver the shock (semi-automated or shock advisory AED) to treat ventricular fibrillation or pulseless ventricular tachycardia.

(2) *Classification.* Class III (premarket approval).

(3) *Date PMA or notice of PDP is required.* No effective date has been established of the requirement for premarket approval.

Dated: 10/23/02

October 23, 2002.

Linda S. Kahan

Linda S. Kahan,
Deputy Director,
Center for Devices and Radiological Health.

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Dawn P. Hawkins