Guidance for Industry and FDA Staff

Class II Special Controls Guidance Document: Arrhythmia Detector and Alarm

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C·D·R·H
Center for Devices and Radiological Health

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Food and Drug Administration
Center for Devices and Radiological Health

Cardiac Electrophysiology and Monitoring Branch
Division of Cardiovascular and Respiratory Devices
Office of Device Evaluation

Preface

Public Comment

Written comments and suggestions may be submitted at any time for Agency consideration to Dockets Management Branch, Division of Management Systems and Policy, Office of Human Resources and Management Services, Food and Drug Administration, 5630 Fishers Lane, Room 1061, (HFA-305), Rockville, MD, 20852. Alternatively, electronic comments may be submitted to http://www.fda.gov/dockets/ecomments. When submitting comments, please refer to Docket No. 02D-0421. Comments may not be acted upon by the Agency until the document is next revised or updated.

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Guidance for Industry and FDA Staff

Class II Special Controls Guidance Document: Arrhythmia Detector and Alarm

This guidance represents the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the FDA staff responsible for implementing this guidance. If you cannot identify the appropriate FDA staff, call the appropriate number listed on the title page of this guidance.

1. Introduction

This guidance document was developed as a special controls guidance to support the reclassification of the arrhythmia detector and alarm into class II (special controls). The device is intended to monitor an electrocardiogram (ECG)[1] and to produce a visible or audible signal or alarm when an atrial or ventricular arrhythmia exists. This guidance is issued in conjunction with a Federal Register notice announcing the reclassification of this device type.

Following the effective date of a final rule reclassifying the device, any firm submitting a 510(k) premarket notification for an arrhythmia detector and alarm 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's guidance documents, including this guidance, do not establish legally enforceable responsibilities.

[1] An ECG is a record of the electrical activity of the heart recorded at the surface of the body. Each phase of cardiac electrical activity produces a specific wave or complex in which the basic ECG waves are labeled alphabetically beginning with the P wave (atrial depolarization). The P-QRS-T sequence represents the repetitive cycle of the electrical activity of the heart. The QRS complex represents ventricular depolarization and the cycle ends with the return of stimulated ventricular muscle to its resting state (ST segment and T wave sequence). The ST segment is usually isoelectric (i.e., flat on the baseline) but may be slightly elevated or normally depressed. Abnormal deviations of the ST segment may be indicative of some pathologic conditions, such as myocardial infarction.

Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidances means that something is suggested or recommended, but not required.

The Least Burdensome Approach

The issues identified in this guidance document represent those that we believe need to be addressed before your device can be marketed. In developing the guidance, we carefully considered the relevant statutory criteria for Agency decision-making. We also considered the burden that may be incurred in your attempt to comply with the guidance and address the issues we have identified. We believe that we have considered the least burdensome approach to resolving the issues presented in the guidance document. If, however, you believe that there is a less burdensome way to address the issues, you should follow the procedures outlined in the "A Suggested Approach to Resolving Least Burdensome Issues" document. It is available on our Center web page at: http://www.fda.gov/cdrh/modact/leastburdensome.html.

2. Background

FDA believes that special controls, when combined with the general controls, will be sufficient to provide reasonable assurance of the safety and effectiveness of arrhythmia detector and alarm devices. Thus, a manufacturer who intends to market a device of this generic type should (1) conform to the general controls of the Federal Food, Drug, and Cosmetic Act (the Act), including the premarket notification requirements described in 21 CFR 807, Subpart E, (2) address the specific risks to health associated with arrhythmia detector and alarm devices identified in this guidance, and (3) obtain a substantial equivalence determination from FDA prior to marketing the device, unless exempt from the premarket notification requirements of the Act (refer to 21 CFR 807.85).

This special controls guidance document identifies the classification regulation and product codes for the arrhythmia detector and alarm devices (Refer to Section 4 – **Scope)**. In addition, other sections of this special controls guidance document list the risks to health identified by FDA and describe measures that, if followed by manufacturers and combined with the general controls, will generally address the risks associated with these arrhythmia detector and alarm devices and lead to a timely premarket notification (510(k)) review and clearance. This document supplements other FDA documents regarding the specific content requirements of a premarket notification submission. You should also refer to 21 CFR 807.87 and other FDA documents on this topic, such as the **510(k) Manual - Premarket Notification: 510(k) - Regulatory Requirements for Medical Devices**, http://www.fda.gov/cdrh/manual/510kprt1.html.

Under "**The New 510(k) Paradigm - Alternate Approaches to Demonstrating Substantial Equivalence in Premarket Notifications; Final Guidance,"**[2] a manufacturer may submit a

[2] http://www.fda.gov/cdrh/ode/parad510.html

Traditional 510(k) or an Abbreviated 510(k). FDA believes an Abbreviated 510(k) provides the least burdensome means of demonstrating substantial equivalence for a new device, particularly once a class II special controls guidance document has been issued. Additionally, manufacturers considering modifications to their own cleared devices may lessen the regulatory burden by submitting a Special 510(k).

3. The Content and Format of an Abbreviated 510(k) Submission

An Abbreviated 510(k) submission must include the required elements identified in 21 CFR 807.87, including the proposed labeling for the device sufficient to describe the device, its intended use, and the directions for its use. In an Abbreviated 510(k), FDA may consider the contents of a summary report to be appropriate supporting data within the meaning of 21 CFR 807.87(f) or (g); therefore, we recommend that you include a summary report. The report should describe how this special controls guidance document was used during the device development and testing and the methods or tests used. The report should also include a summary of the test data or description of the acceptance criteria applied to address the risks identified in this document, as well as any additional risks specific to your device. This section suggests information to fulfill some of the requirements of 21 CFR 807.87, as well as some other items that we recommend you include in an Abbreviated 510(k).

Coversheet

The coversheet should prominently identify the submission as an Abbreviated 510(k) and cite the title of this special controls guidance document.

Proposed labeling

Proposed labeling should be sufficient to describe the device, its intended use, and the directions for its use. (Refer to Section 11 for specific information that should be included in the labeling for devices of the types covered by this guidance document.)

Summary report

We recommend that the summary report contain a:

- Description of the device and its intended use. We recommend that the description include a complete discussion of the performance specifications and, when appropriate, detailed, labeled drawings of the device. (Refer to Section 5 for specific information that we recommend you include in the device description for devices of the types covered by this guidance document.) You should also submit an "indications for use" enclosure.[3]

[3] Refer to http://www.fda.gov/cdrh/ode/indicate.html for the recommended format.

- Description of the device design.

- Identification of the risk analysis method(s) used to assess the risk profile, in general, as well as the specific device's design and the results of this analysis. (Refer to Section 6 for the risks to health generally associated with the use of this device.)

- Discussion of the device characteristics that address the risks identified in this class II special controls guidance document, as well as any additional risks identified in your risk analysis.

- Brief description of the test method(s) you have used or intend to use to address each performance aspect identified in Sections 7-10 of this class II special controls guidance document. If you follow a suggested test method, you may cite the method rather than describing it. If you modify a suggested test method, you may cite the method but should provide sufficient information to explain the nature of and reason for the modification. For each test, you may either (1) briefly present the data resulting from the test in clear and concise form, such as a table, **or** (2) describe the acceptance criteria that you will apply to your test results.[4] (See also 21 CFR 820.30, Subpart C - Design Controls under the Quality System Regulation.)

- If any part of the device design or testing relies on a recognized standard, (1) a statement that testing will be conducted and meet specified acceptance criteria before the product is marketed, or (2) a declaration of conformity to the standard.[5] Please note that you must certify that the device is in conformity with the standard. (Section 514(c)(1)(B) of the Act); this means that testing must be completed before you submit a declaration of conformity. For more information, refer to the FDA guidance, **Use of Standards in Substantial Equivalence Determinations; Final Guidance for Industry and FDA**, http://www.fda.gov/cdrh/ode/guidance/1131.html.

If it is not clear how you have addressed the risks identified by FDA or additional risks identified through your risk analysis, we may request additional information about aspects of the device's

[4] If FDA makes a substantial equivalence determination based on acceptance criteria, the subject device should be tested and shown to meet these acceptance criteria before being introduced into interstate commerce. If the finished device does not meet the acceptance criteria and, thus, differs from the device described in the cleared 510(k), FDA recommends that submitters apply the same criteria used to assess modifications to legally marketed devices (21 CFR 807.81(a)(3)) to determine whether marketing of the finished device requires clearance of a new 510(k).

[5] See Required Elements for a Declaration of Conformity to a Recognized Standard (Screening Checklist for All Premarket Notification [510(K)] Submissions), http://www.fda.gov/cdrh/ode/reqrecstand.html.

performance characteristics. We may also request additional information if we need it to assess the adequacy of your acceptance criteria. (Under 21 CFR 807.87(l), we may request any additional information that is necessary to reach a determination regarding substantial equivalence.)

As an alternative to submitting an Abbreviated 510(k), you can submit a Traditional 510(k) that provides all of the information and data required under 21 CFR 807.87 and described in this guidance. A Traditional 510(k) should include all of your methods, data, acceptance criteria, and conclusions as described in Appendix I Suggested Format for Test Reports. Manufacturers considering modifications to their own cleared devices should consider submitting Special 510(k)s.

The general discussion above applies to any device subject to a special controls guidance document. The following is a specific discussion of how you should apply this special controls guidance document to a premarket notification submission for arrhythmia detector and alarm devices.

4. Scope

The scope of this document is limited to the following device, classified under 21 CFR 870.1025, identified as:

The arrhythmia detector and alarm device monitors an electrocardiogram and is designed to produce a visible or audible signal or alarm when atrial or ventricular arrhythmia, such as premature contraction or ventricular fibrillation, occurs.

Panel

Circulatory System Devices Panel (74)

Product Codes

DSI Arrhythmia Detector and Alarm

MLD Monitor, ST Segment with Alarm

MHX Patient Physiological Monitor (with arrhythmia detection or alarms)

This generic type of device includes arrhythmia monitors and alarm with or without ST segment with alarms.

The product code MHX describes patient physiological monitors that include an arrhythmia detection and alarm component. These devices contain other, non-arrhythmia-related components, such as temperature monitors, non-invasive blood pressure monitors, carbon dioxide monitors, and pulse oximeters. The arrhythmia detection and alarm component of these devices should address the specific risks to health associated with the arrhythmia detector and alarm that are identified in this guidance. You also need to demonstrate substantial equivalence of the additional components of patient physiological monitors in your 510(k) by including appropriate information (device description, bench

testing, labeling, etc.) for any non-arrhythmia-related components included in your device. That information will depend on the component.

This generic type of device does **not** include:

ECG with a computerized algorithm that interprets ECG data and provides a diagnostic interpretive statement. These are class II devices under 21 CFR 870.2340, Electrocardiograph.

Devices with arrhythmia analysis algorithms intended to provide therapy, such as automated external defibrillators (AEDs). AEDs use an interpretive algorithm to identify shockable and non-shockable cardiac rhythms and are capable of delivering electrical energy in the fully automated or semi-automated mode (where additional operator steps are required). AEDs will remain class III devices (Product Code, MKJ) (21 CFR 870.5310).

5. Device Description

We recommend that you identify your device by regulation and product code and include the following information:

Device components[6] and theory of operation. You should identify all components, system software, and accessories within the scope of the 510(k), and any collateral devices that can be connected or used with the monitor (e.g., personal computers (PCs), database management software, printers).

Photograph or drawing of the device. You should also provide a photograph or drawing of the device. You should also provide a functional block diagram (including all accessories).

Functional performance characteristics. You should describe the functional performance characteristics of the device, including computing capability, the display or storage of information, trending capability, data sampling communication (samples per second, bit resolution, interface), telemetry specifications (e.g., FCC frequency bands, transmission system, antenna), number of beds/patients, printer requirements, and system alarms.

[6] Electrode lead wires and patient cables intended for use with arrhythmia detector devices must be in compliance with the test requirements and test methods of subclause 56.3(c) of IEC 60601-1 (1998), *"Medical Electrical Equipment - Part 1: General Requirements for Safety,"* Amendment No. 1 (1991), and Amendment No. 2 (1995) as set forth in the mandatory performance standard 21 CFR Part 898. See **Performance Standard for Electrode Lead Wires and Patient Cables**, http://www.fda.gov/cdrh/comp/leadwire.html and the FDA guidance entitled, **Electrocardiograph (ECG) Electrode**, http://www.fda.gov/cdrh/ode/25.pdf.

Arrhythmia processor and analysis software. You should describe the arrhythmia processor and analysis software (i.e., the arrhythmia detection algorithm, including noise detection and filtering techniques and computerized ST measurement capability).

ST segment capability. For the ST segment capability, you should provide a brief technical description of the aspects of the algorithm listed below, as well as examples of all displays and reports that may be generated by the device.

- isoelectric point determination
- J-point determination
- ST segment measurement
- noise reduction
- ventricular and noisy beat rejection
- response to changes in heart rate

Alarm conditions. You should describe the conditions that will produce an alarm. The description should include whether they are physiologic or technical (device or system) alarm conditions.

User interface. You should describe the user interface, including whether the device can be programmed and the extent of the device's programmability.

Technical specifications. You should summarize the technical specifications (i.e., product specifications, such as the examples below, with ranges and/or accuracy, and any other functional, physical, and environmental specifications of the device), including

- measurement tolerances
- operating limitations
- power source specifications
- modes or settings.

Patient contacting materials. You should identify the components of the device that are patient contacting. For each component, you should identify the generic material of construction, the supplier, and the unique material identifier.

Comparison to the predicate device. You should identify the legally marketed predicate device by model name, number, and manufacturer, and provide the 510(k) number, if available. You should also provide a table that compares your device with the predicate. You should explain why any differences between them do not adversely affect safety and effectiveness. The table should

include all of the preceding device description information, except for the photograph or drawing, with an emphasis on the following information:

- the patient population and intended environment of use
- basic technology or characteristics of the device, such as analog or digital technology, electrode configuration, frequency response, input impedance, dynamic range, common mode rejection ratio (CMRR), QRS detection sensitivity, pacemaker pulse rejection, system noise, etc.
- level of system communication, transmission characteristics, computer interfaces, and other technological features (e.g., hard-wired, radio frequency telemetry, transtelephonic and/or fax capability.)
- heart rate indicators and alarms system (alarm levels and management) for both standalone devices and devices connected or linked to a central station.

6. Risks to Health

In the table below, FDA has identified the risks to health generally associated with the use of the arrhythmia detector and alarm devices addressed in this document. The measures recommended to mitigate these identified risks are given in this guidance document, as shown in the table below. You should also conduct a risk analysis, before submitting your 510(k), to identify any other risks specific to your device.[7] The premarket notification should describe the risk analysis method. If you elect to use an alternative approach to address a particular risk identified in this document, or have identified risks additional to those in this document, you should provide sufficient detail to support the approach you have used to address that risk.

Identified risk	Recommended mitigation measures
misdiagnosis and misclassification of arrhythmias	section 7, 8, 9, 10, 11
incorrect pacemaker pulse detection	section 7, 8, 9, 10
delayed response to life threatening arrhythmias	section 7, 8, 9, 10, 11
loss of alarm at central station or bedside	section 7, 10
excessive patient leakage current	section 8

[7] Remote, real-time arrhythmia detectors, networked systems, and ambulatory wireless systems are examples of device features that may present other risks. We encourage you to contact the review division to discuss the risk analysis and additional testing for these features.

Arrhythmia detectors include parts that are applied to patients and should be considered to have prolonged contact with intact skin. We recommend that you evaluate the biocompatibility of the materials in these parts as described in the International Standard Organization (ISO) standard **ISO-10993, "Biological Evaluation of Medical Devices Part 1: Evaluation and Testing."** We also recommend that you document the results in your design history file as a part of the Quality Systems Requirements (21 CFR 820.30).[8] You should select tests appropriate for the duration and level of contact with your device. If *identical* materials are used in a predicate device with the same type and duration of patient contact, you may identify the predicate device in lieu of performing biocompatibility testing.

7. Software Validation Activities

Please refer to the **Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices** (*Software Guidance*), http://www.fda.gov/cdrh/ode/software.pdf, for a discussion of the software documentation that you should provide. As discussed in the *Software Guidance*, the "level of concern" is related to the possible consequences of software failure, and may be minor, moderate, or major. FDA generally considers the software for arrhythmia detectors to have a "major level of concern." If you believe that the software in your arrhythmia detector should be considered a minor or moderate level of concern, you should provide a clear scientific justification that discusses the possible consequences of a software failure.

We encourage you to take advantage of any recognized software standards and provide statements or declarations of conformity as described in FDA guidance, **Use of Standards in Substantial Equivalence Determinations,** already cited. Please visit the following website to search for the standards that have been recognized when a medical device contains software, http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm. We have created a supplemental information sheet for each software standard that we have recognized. The supplemental information sheet includes a table indicating the documentation that you should include in a submission when a declaration of conformity is provided.

If the device includes off-the-shelf software, you should provide the additional information as recommended in the **Guidance for Industry, FDA Reviewers and Compliance on Off-the-Shelf Software Use in Medical Devices**, http://www.fda.gov/cdrh/ode/1252.html.

[8] If your device is labeled sterile, we recommend that you follow the guidance for devices intended for contact with intact skin in **Updated 510(k) Sterility Review Guidance K90-1; Final Guidance for Industry and FDA**, http://www.fda.gov/cdrh/ode/guidance/361.html.

8. Electrical Safety and Environmental Handling Testing

We recommend that you evaluate the electrical safety of your device and its ability to function after exposure to environmental handling hazards. We recommend that you evaluate your device according to **one or more** of the following standards:

- International Electrotechnical Commission (IEC) 60601-1 Medical Electrical Equipment - Part 1: General Requirements for Safety
- Association for the Advancement of Medical Instrumentation (AAMI) EC 11, Diagnostic Electrocardiographic Devices
- Underwriters Laboratory (UL) 2601-1 Amendment 1 Medical Electrical Equipment: General Requirements for Safety
- American National Standards Institute (ANSI)/AAMI ES-1 Safe current limits for electromedical apparatus
- IEC 60529 Degrees of protection provided by enclosures (IP Code) Consolidated Edition
- IEC 60721-4-x TR (Technical Reports).

The features and design of your device will determine which of the above standards you should use and whether other standards are appropriate in addition to or in place of these. The Cardiac Electrophysiology and Monitoring Branch is available to discuss which standards are appropriate for your device's features and design.

Arrhythmia Detectors used in Transport Environments

If your device is intended to be used in a transport environment such as an ambulance, you should test your device according to the standards listed below for shock and vibration.

- IEC 60068-2-27 (1987): Basic environmental testing procedure: Part 2: Tests - Test Ea and guidance: Shock. Test to severity level of 30g (300 m/s/s) peak acceleration.

-or-

IEC 60068-2-32 (1975): Basic environmental testing procedure: Part 2: Tests - test Ed: Free fall. Test to a free fall height of 500 mm.

Note: Other conditions of shock testing should still be met, as outlined in the appropriate standard.

- IEC 60068-2-64 (1993-05) and Corr 1 (1993-10): Environmental testing: Part 2: Test methods - Test Fh: Vibration, broad-band Random (digital control) and guidance: Method 2.

9. Electromagnetic Compatibility

Electromagnetic compatibility (EMC) encompasses both emissions (interference with other electronic devices) and immunity (interference with device performance created by emissions from other electronic devices). We recommend that you evaluate the EMC of your device as discussed below.

Emissions

EMC testing should demonstrate that the device will not adversely interfere with the performance of other electronic devices (*emissions*). Testing should include radio frequency (RF) electromagnetic, low frequency magnetic, and conducted emissions.

Immunity

EMC testing should also demonstrate that the device will perform as expected in the presence of other electrical and electronic devices or other sources of electromagnetic disturbance (EMD) in the intended environment of use (*immunity*). The device should operate in an acceptable manner (few EMC standards require operation within specification) during and after exposure to various forms of electromagnetic disturbance. Testing should include:

- electrostatic discharge (ESD)
- radiated RF electromagnetic fields
- electrical fast transients and bursts
- surges
- conducted RF electromagnetic energy
- voltage dips, short interruptions, and voltage variations on power supply input lines
- low-frequency magnetic fields
- quasi-static electric fields.

We recommend that you test your device according to IEC 60601-1- 2 Medical Electrical Equipment -- Part 1: General Requirements for Safety; Electromagnetic Compatibility -- Requirements and Tests (Second Edition, 2001) to demonstrate the EMC characteristics of your device.

Ambulatory Monitoring Systems

If your device is intended for use as an ambulatory monitoring system, you should test your device according to AAMI EC 38-1998 Ambulatory Electrocardiographs. Part 4.2.10 Electromagnetic Compatibility.

Arrhythmia Detectors used in Transport Environments

FDA believes an arrhythmia detector intended for use in an ambulance should demonstrate immunity to a field strength of 20 V/m or greater (rather than the 3 V/m specified in IEC 60601-1-2). Therefore, we recommend that you test immunity to a field strength of at least 20 V/m, amplitude modulated 80%, according to the method described in IEC 60601-1- 2.

As an alternative to following IEC 60601-1- 2 and, where applicable, EC 38, we recommend that you identify:

- the possible sources of EMI (Electromagnetic Interference) that could affect the device
- each intended use environment (e.g., hospital general ward, hospital intensive care or critical care unit, clinic, vehicle/traffic areas, emergency vehicle)
- the selected test method, an explanation for its use, and test reports that conform to Appendix I, "Suggested Format for Test Reports." Testing should be applicable to the environments you have identified and address emissions and immunity.

10. Performance Testing

The accuracy of the automated arrhythmia detection and ST segment measurement algorithms is generally demonstrated by ECG waveform database testing described below. FDA believes that if a device has only been tested for its accuracy in detecting specific arrhythmias or ST level changes, it should be labeled only for that purpose.

ECG and/or Cardiac Monitor Capabilities

We recommend that you evaluate the ability of your device to perform basic cardiac monitoring and ECG functions according to the following:

- ANSI/AAMI EC-13:2002, Cardiac monitors, heart rate meters, and alarms
- AAMI EC 11-1991, Diagnostic Electrocardiographic Devices.

If your device is intended for use as an ambulatory monitor, you should also test your device according to AAMI EC 38-1998**,** Ambulatory Electrocardiographs.

Algorithm Evaluation of the Automated Arrhythmia Detection Accuracy

You should follow the recommendations in ANSI/AAMI-EC 57:1998, Testing and Reporting Performance Results of Cardiac Rhythm and ST Segment Measurement Algorithms, for testing the beat-detection algorithm. If you use an alternative test method, you should describe the method, objective(s) of the testing, and any limitations of the test method. You should report accuracy as specificity and sensitivity. Automated test methods need to be reproducible to be evaluated.

Most arrhythmia detectors detect abnormal beats by feature extraction/clustering, template matching, or both methods in combination. Any testing needed in addition to that described in AAMI EC 57 for your arrhythmia detector will vary depending on its intended use, operational features, and the kind of data generated.

For all arrhythmia detectors, you should include the following basic information about system accuracy in your summary report.

- An identification of the algorithm for arrhythmia detection. You should discuss the over-all detection scheme employed by the arrhythmia detector.

- A list of the criteria used in the assessment of each arrhythmia. These criteria should be based on empirical data that are used by electrocardiographers in making ECG determinations.

- A complete description of any testing procedures and databases of tapes, if they are not in EC 57.

We recommend that you evaluate the algorithm with at least two databases of tapes. The database used to develop the device's algorithm should not be used to test and verify the performance of the device. Annotation of the cardiac rhythms should be performed by at least three qualified cardiologists. The waveforms utilized should generally be from actual patient ECG recordings. Simulated tapes should only be used when existing databases do not include a sufficient number of examples of a particular arrhythmia. If you use simulated tapes for a particular arrhythmia because it is too rare to obtain sufficient numbers of actual patient ECGs, you should submit a brief statistical validation of its rarity. This statistical validation may be based on peer-reviewed literature.

If the database of tapes used to validate the system is not in EC 57, you should provide validation information supporting the use of that database. This information should describe the development of the database in detail.

ST Segment Measurement

For devices with the ability to automatically measure and display or trend changes in the ST segment, you should follow EC 38, 4.2.14 Automated Analysis and 4.2.15 Minimum Requirements for Clinical Report. You should explain if you modified or did not use the test methods specified in EC 38, or if any section of EC 38 4.2.14 or 4.2.15 is not applicable to your device.

EC 57 also describes testing and reporting performance results of the ST segment measurement algorithms.

Alarm System

The arrhythmia system should accurately alarm for critical, life-threatening arrhythmias as specified in ANSI/AAMI EC-13:2002, Cardiac monitors, heart rate meters, and alarms.

Other Standards

If you choose to follow a standard other than one described above, we recommend that you list each requirement of the other standard. If the other standard is not recognized, you should compare its requirements with the requirements described in standards cited above and identify where they differ. The list of FDA recognized consensus standards is available on the web at http://www.fda.gov/cdrh/modact/recstand.html

Clinical Studies

In accordance with the least burdensome provisions of the Act, the agency will rely upon well-designed bench and/or animal testing rather than requiring clinical studies for new devices, unless there is a specific justification for asking for clinical information to support a determination of substantial equivalence. While, in general, clinical studies will not be needed for most arrhythmia detector and alarm devices, FDA may recommend that you collect clinical data for arrhythmia detector and alarm devices with:

- designs dissimilar from designs previously cleared under a 510(k), such as those incorporating significant new features or algorithm techniques
- new technology, i.e., technology different from that used in legally marketed arrhythmia detectors
- indications for use dissimilar from arrhythmia detector and alarm devices of arrhythmia detectors of the same type.

FDA will always consider alternatives to clinical testing when the proposed alternatives are supported by an adequate scientific rationale. The Cardiac Electrophysiology and Monitoring Branch is available to answer any questions you may have about clinical testing.

11. Labeling

The premarket notification should include labeling in sufficient detail to satisfy the requirements of 21 CFR 807.87(e). The following suggestions are aimed at assisting you in preparing labeling that satisfies the requirements of 21 CFR 807.87(e).[9]

[9] Although final labeling is not required for 510(k) clearance, final labeling must comply with the requirements of 21 CFR Part 801 before a medical device is introduced into interstate commerce. In addition, final labeling for prescription medical devices must comply with 21 CFR 801.109. Labeling recommendations in this guidance are consistent with the requirements of part 801.

Directions for use

As a prescription device, under 21 CFR 801.109, the device is exempt from having adequate directions for lay use. Nevertheless, under 21 CFR 807.87(e), we expect to see clear and concise instructions that delineate the technological features of the specific device and how the device is to be used on patients. Instructions should encourage local/institutional training programs designed to familiarize users with the features of the device and how to use it in a safe and effective manner.

ST algorithm

In addition, the ST-Segment monitor labeling should include the following statement, or an equivalent statement: "The ST algorithm has been tested for accuracy of the ST segment data. The significance of the ST segment changes need to be determined by a clinician."

Appendix I. Suggested Format for Test Reports

If you choose to submit a traditional 510(k), or if you use test methods not given in the standards cited in this guidance, you should submit test reports. These test reports should include the following elements or an explanation for their omission:

1. **Test protocol**, which minimally includes:
   a. the purpose of the test
   b. a clear description (with schematics) of the test set-up and any device modifications
   c. the identification and precision of the equipment used
   d. step-by-step descriptions of the data collection methods and device modes used
   e. the justification for the testing parameters (e.g., testing temperature, length of test, the selection of device modes) and the pass/fail criteria. The testing parameters and pass/fail criteria should be conservative and based on the extreme clinical use of the device, according to the intended use or applicable standard. Depending on the test, it may be appropriate to base the testing parameters on the normal use of the device. However, if an extreme exists, it should be explored.

2. **Data and results**, which minimally include:
   a. clearly labeled data with the appropriate units
   b. data that are easily associated with the methods described in the protocol
   c. for any graph, a table listing each data point shown on the graph
   d. for any calculated values, the calculated values should be obvious and calculated according to formulae presented in the protocol.

3. **Analysis**, which minimally includes:
   a. an evaluation of the test data according to the pass/fail criteria and purpose defined in the test protocol
   b. identification of the inadequacies and accuracy of the test
   c. an evaluation of the need for additional testing, and a clear conclusion that is within the scope of the particular test.