Guidance for Industry and Food and Drug Administration Staff

Class II Special Controls Guidance Document: Electrocardiograph Electrodes

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For questions regarding this document contact Sharon Lappalainen at (301) 796-6322 or by email at sharon.lappalainen@fda.hhs.gov.



U.S. Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health

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

Preface

Public Comment

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Class II Special Controls Guidance Document: Electrocardiograph Electrode

1. Introduction

This guidance document was developed as a special controls guidance for this class II device and to support the exemption from premarket notification (510(k)) requirements of the Federal Food, Drug, and Cosmetic Act (the act) of electrocardiograph (ECG) electrodes (see sections 510(m) and 513(a)(1)(B) of the act; 21 USC 360(m) and 360c(a)(1)(B)). An electrocardiograph electrode is an electrode applied directly to the patient's skin to acquire and transmit the electrical signal at the body surface to a processor that produces an electrocardiogram (ECG) or vectorcardiogram. An electrocardiograph electrode is not intended to deliver therapy to the patient. This guidance does not apply to electrodes or dispersive pads used for defibrillation, pacing, or cardioversion.

This guidance is being issued in conjunction with a Federal Register notice announcing the final rule to designate a special controls guidance and to exempt this device type.

This guidance document describes a means by which ECG electrodes may comply with the requirement of class II special controls (513(a)(1)(B) of the act). Designation of this guidance document as a special control will mean that manufacturers of ECG electrodes will need to address the issues identified in this special controls guidance document. However, a manufacturer need only show that its device meets the recommendations of the guidance document or in some other way provides equivalent assurances of safety and effectiveness.[1] Manufacturers who choose to provide other equivalent assurances of safety and effectiveness will need to submit a 510(k) and receive marketing clearance for their device. Manufacturers who follow the recommendations to address the issues identified in this guidance, before introducing their device into commercial distribution in the United States, will be able to market their device without being subject to the premarket notification requirements of section 510(k) of the act. As a class II device, the device must comply with general and special controls (section 513(a)(1)(B) of the act).

Section 510(m) of the act provides that FDA may exempt a class II device from the premarket notification requirements under section 510(k) of the act if FDA determines that a 510(k) is not necessary to provide reasonable assurance of the safety and effectiveness of the device. FDA has determined that a 510(k) is not necessary to provide reasonable assurance of the safety and effectiveness of this generic type of device if the manufacturer follows the recommendations in this special controls guidance to address the issues identified in this

[1] We recommend that manufacturers document how they address the recommendations of this guidance in their design history file. Manufacturers must maintain design controls, including a design history file, in accordance with 21 CFR 820.30.

guidance. Thus, persons who intend to market a device of this type do not need to submit a 510(k) to FDA and receive agency clearance prior to marketing the device if they follow the recommendations in this special controls guidance document. If a manufacturer does not follow the recommendations in this guidance document but instead chooses to use alternative means to address the issues covered in this guidance, then it will not be exempt from the requirements under section 510(k) and will need to submit a 510(k) and receive clearance for its device prior to marketing.

2. Scope

The scope of this document is limited to ECG electrodes, which are regulated under 21 CFR 870.2360 (see below), class II, with product code DRX "Electrocardiograph electrode."

21 CFR 870.2360

An electrocardiograph electrode is the electrical conductor which is applied to the surface of the body to transmit the electrical signal at the body surface to a processor that produces an electrocardiogram or vectorcardiogram.

The scope includes electrodes used for bioimpedance measurements. Bioimpedance electrodes are generally used to deliver a small amount (about 2 mA (rms)) of alternating current with a high frequency (about 60 kHz) to the human thorax to measure changes in thoracic impedance as a result of the patient's respiratory or cardiac activities.

The scope includes bare ECG electrodes or ECG electrodes that incorporate, as part of their design, a conductive gel, an adhesive system, or a leadwire. ECG electrodes may be supplied for use as reusable, disposable, sterile, or non-sterile products.

The scope excludes electrodes or dispersive pads used to deliver therapy such as defibrillation or cardioversion. Electrodes or dispersive pads used to deliver defibrillation or for cardioversion are regulated under 21 CFR 870.5310.

The scope excludes electrodes used for external pacing or other treatment effect. Electrodes used for external pacing are regulated under 21 CFR 870.5550.

3. Risks to Health

In the table below, FDA has identified the following risks to health associated with the use of the ECG electrode. We recommend the following measures to mitigate the risks identified in this guidance document.

Identified risk	Recommended mitigation measures
Adverse tissue reactions to the skin-contacting electrode materials	Section 5. Performance Characteristics Section 6. Labeling
Misdiagnosis	Section 5. Performance Characteristics Section 6. Labeling
Electrical shock	Section 5. Performance Characteristics 21 CFR 898 Performance standard for electrode lead wires and patient cables

4. Device Description

In accordance with 21 CFR 820.181(a), you must maintain a device master record (DMR) for each type of device that shall include, or refer to the location, of, the following information:

- device specifications, including appropriate drawings,
- composition,
- formulation, and
- component specifications.

In addition, we recommend that you maintain a complete description of the device and all accessories in the DMR. This description should include:

- an identification of the device by the regulation number and product code described in Section 2 above,
- a written description of the device and all device accessories, if any,
- an identification of the dimensions and composition of the device or accessory,
- a description of how the device interconnects with other components,
- engineering drawings or photographs of the device, and
- a listing of all features and specifications of the device (a tabular format is desirable).

5. Performance Characteristics

FDA believes that special controls, when combined with the general controls, will be sufficient to provide reasonable assurance of the safety and effectiveness of ECG electrodes. We recommend that you evaluate your device as described below and, where appropriate, document the results in your design history file as a part of the Quality Systems Requirements, 21 CFR 820.20. The section below address these main types of devices encompassed in the scope of this regulation: electrodes, electrode conductive medium (gel), and electrode lead wire and patient cable.

A. <u>Electrodes</u>

We recommend that you specify the following:

- materials,
- construction,
- type (e.g., bare, incorporating a conductive gel, an adhesive system, a lead wire, etc.)
- size and dimensions, and
- how supplied (e.g., reusable, disposable, sterile, non-sterile, etc.); and
- if have a specific property (e.g., radio-lucent, magnetic resonance imaging (MRI) conditional).

We also recommend that, to ensure the device performs as intended, you evaluate and document the following electrode characteristics:

- biocompatibility,
- electrical performance,
- adhesive performance, and
- shelf life.

Our recommendations regarding these characteristics are described in detail below.

1) Biocompatibility

The skin-contacting materials, such as the electroconductive gel, adhesives, and electrodes, should be biocompatible for their intended use. To determine the device category and tests, you should consult ANSI/AAMI/ISO 10993-1, *"Biological evaluation of medical devices -- Part 1: Evaluation and testing"* or equivalent method. This FDA-recognized standard recommends evaluation and testing of medical devices based upon the duration and type of contact. So you may establish material safety of ECG electrodes with limited contact duration (e.g., less than 24 hours), limited to only intact skin, we recommend that you conduct these tests:

- Dermal irritation and delayed type sensitivity (See ISO 10993-10 Biological evaluation of medical devices – Part 10: Tests for irritation and delayed type sensitivity),
- Cytotoxicity (See ISO 10993-5 Biological evaluation of medical devices – Part 5: Tests for cytotoxicity).

We recommend you test the electrodes under the intended conditions of use, e.g., duration of application. The electrodes should not cause toxic or electrolytic effects that could produce an irritating, sensitizing or cytotoxic effect upon the skin or allow irritating sensitizing, or cytotoxic materials to enter the skin by iontophoresis. However, due to the electrolytic composition of some electroconductive gels that contain high levels of saline, a positive cytotoxicity result may not be a correct indication that the hydrogel is truly cytotoxic. In these circumstances, evaluation using other tests specified in the standard may be appropriate.

2) Electrical Performance

To establish the electrical performance of ECG electrodes, you should consult ANSI/AAMI EC12 "*Disposable ECG Electrodes"* or other equivalent methods of assuring the electrical performance for:

- AC impedance,
- DC offset voltage,
- combined offset instability and internal noise,
- defibrillation overload recovery, and
- bias current tolerance.

If your submission is for a bare electrode, we recommend you conduct the above testing on your electrode using the electrode gel(s) recommended in the labeling.

3) Adhesive Performance

The design of the electrode should ensure it will adhere to the patient's skin for the duration of use compatible with the intended use of the device. We recommend you test adhesive performance to show it meets the specifications of the design and meets user needs. If the electrode is intended to be used on a diaphoretic patient or during strenuous exercise, we recommend you test the device specifically to demonstrate adequate adhesive performance for the labeled duration of use, under these conditions of use.

4) Shelf Life

We recommend that you conduct shelf life testing of disposable ECG electrodes to support the expiration date in the labeling of your device. For both disposable and reusable devices, we recommend you establish the storage conditions in the labeling of your device.

Stability studies should monitor the critical parameters of your final finished disposable ECG electrode to assure adequate device performance during its entire shelf-life. We recommend your disposable ECG electrodes, follow the performance characteristics established in ANSI/AAMI EC12, *"Disposable ECG electrodes"*.

We recommend that you perform stability testing on representative aged samples at time zero and at several intervals during the real time study. For example, during a 12-month real time stability study, we recommend that you place samples of the finished, packaged device on stability trials at storage temperatures recommended in your labeling. We recommend that you test the device at 1, 3, 6, 9, and 12-month intervals to assess stability at each of these points.

Any accelerated shelf life testing should be supported and validated by real-time shelf life testing. The validity of the accelerated stability testing relies on the assumption

that the mechanisms of product inactivation and decomposition remain the same at elevated temperatures that simulate testing at lower temperatures for longer times according to the assumptions of thermodynamics. However, because there is no validated accelerated testing method and because of the nature of adhesives and conductive gels, the usefulness of predicting an expiration date from accelerated stability studies may be unclear. Thus, the validity of an accelerated stability study is generally confirmed by a real-time stability study performed at the labeled product storage temperature(s). Therefore, if you perform accelerated shelf-life testing, you should also include information that demonstrates the role of accelerated stability testing in predicting the expiration date.

5) **Reuse**

If the electrodes are not limited to single-patient use, we recommend the labeling include instructions for handling, transport, cleaning, and biological decontamination. For reusable ECG electrodes, you should follow **Labeling Reusable Medical Devices for Reprocessing in Health Care Facilities: Food & Drug Administration Reviewer Guidance,** April 1996 located here: http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM080268.pdf and AAMI/ANSI/ISO ST79. We recommend you evaluate the potential for skin reactions and disease transmission. We also recommend you demonstrate that the cleaning and biological decontamination of the electrodes provides sufficient protection and does not impact their functional performance.

6) **Electrodes Intended for Use in Specified Procedures**

If the electrode is intended for use in radiographic or x-ray imaging, MRI, or any other procedures, we recommend you test the electrode for the potential for radio frequency (RF) heating, radio-translucency, and safety of use in MRI environments.

7) **Sterility**

In general, most disposable ECG electrodes are provided and used non-sterile because they are intended for use on non-critical areas of the body, e.g., clean, intact skin. However, for some applications and in certain circumstances, manufacturers may produce sterile, disposable ECG electrodes. If the disposable ECG electrodes are provided sterile, FDA recommends that you provide sterilization information in accordance with the **Updated 510(k) Sterility Review Guidance K90-1** located here: https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm109897.pdf

B. Electrode Conductive Medium (Gel)

Electroconductive media are the conductive creams or gels used with ECG electrodes. When these products are available separately and not physically incorporated into the ECG electrode design, they are regulated under 21 CFR 882.1275.

C. Electrode Lead Wires and Patient Cables

For electrodes that incorporate a lead wire, we recommend you document the length(s), construction, materials, and connections between the ECG recording device and the electrodes. The electrode lead wires and patient cables intended for use with a medical device are subject to the performance standard set forth in 21 CFR Part 898. Therefore, the electrode lead wires and patient cables must be in compliance with the test requirements and test methods of subclause 56.3(c) of IEC 601-1, *"Medical Electrical Equipment - Part 1: General Requirements for Safety,"* Amendment No. 1 (1991), and Amendment No. 2 (1995). Your documentation should contain information sufficient to demonstrate conformance to this performance standard.

For ECG electrodes that are designed with pre-attached leadwires, we recommend you follow ANSI/AAMI EC53, *"ECG cables and leadwires"* or other equivalent measures, for performance testing and assurance that the pre-attached leadwires and connector cannot contact ground, a main outlet, or induce a possible hazardous potential.

6. Labeling

The following suggestions are intended to help you prepare labeling that satisfies the requirements of 21 CFR Part 801.[2] For additional information on developing labeling, please consult FDA Guidance: Labeling - Regulatory Requirements for Medical Devices (FDA 89-4203) located on our webpage at the following address: http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM095308.pdf.

Package Insert

Your package insert should include:

- quantity, dimensions, type, gel system, adhesive system, materials, and options;
- model number, date of manufacture;
- storage instructions, shelf life (for disposable electrodes), and lot number;
- instructions for skin preparation;
- instructions for electrode preparation, if applicable;
- cleaning and maintenance instructions, if the electrodes are reusable;
- duration of application;
- electrical and any other technical specifications; and
- environmental specifications, e.g., MRI compliant, X-ray translucent.

[2] 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 and final labeling for an over the counter (OTC) device must comply with 801 Subpart C. Labeling recommendations in this guidance are consistent with the requirements of Part 801.

The package insert should also include the indications, contraindications, warnings, precautions, and adverse reactions, as appropriate to your device. We recommend that you place this information prominently in the package insert.

The labeling recommendations below are not intended to capture all possible limitations or instructions for ECG electrodes. Additional contraindications, warnings, precautions, adverse reactions, and other instructions may be appropriate for your device, depending on its design, features, and performance characteristics.

Indications for Use

The indications for use should identify the patient population, e.g., adult, pediatric, or neonate. The intended use should also identify the duration and application of use, e.g., at rest, ambulatory, stress testing, Holter monitoring, etc.

Cautions

The package insert should advise users of the following:

- CAUTION: Federal law restricts this device to sale by or on the order of a physician.
- ECG electrodes should only be used by or in consultation with a health care provider familiar with their proper placement and use;
- ECG electrodes may damage the skin if removed carelessly;
- ECG electrodes should be applied only to intact, clean skin (e.g., not over open wounds, lesions, infected, or inflamed areas); and
- ECG electrodes should be properly disposed of if they are disposable by design or they are reusable but cannot be fully cleaned between uses.

Precautions

The package insert should advise users of the following:

- During surgical procedures, electrodes should be placed as far as possible from any electro-surgical area to minimize unwanted RF current flow.
- Self-adhesive electrodes should be replaced if they no longer stick firmly to the skin.

Adverse Reactions

The package insert should list known adverse reactions, including the possibility that users may experience skin irritation at contact points with the electrodes. For example, some electrodes or electrode packaging may contain natural rubber latex. In this case, the label should follow 21 CFR 801.437 "*User labeling for devices that contain natural rubber latex*". Please note that labeling your device "latex-free" indicates your product or product packaging does not contain latex, is manufactured in a latex-free environment, and that the raw materials used to make your product have not been exposed to latex proteins.

7. Limitations of Exemption from Premarket Notification

FDA's decision to exempt a class II device from the requirement of 510(k) is based on the existing and reasonably foreseeable characteristics of devices within that generic type that currently are, or have been, in commercial distribution. Section 21 CFR 870.9 specifies the limitations to exemption. If any of these limitations apply, your device is not exempt, and you must submit a premarket notification.

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