

Draft Guidance for Industry and FDA Staff

Class II Special Controls Guidance Document: Electrocardiograph Electrodes

DRAFT GUIDANCE

**This guidance document is being distributed for comment purposes only.
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**U.S. Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health**

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

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Preface

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This draft guidance, when finalized, will represent the Food and Drug Administration's (FDA's) current thinking on this topic.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This draft guidance document was developed as a special controls guidance for this class II device and to support the exemption from premarket notification (510(k)) requirements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)). A 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. A electrocardiograph electrode is not intended to deliver therapy to the patient.

This draft guidance is being issued in conjunction with a Federal Register notice announcing the proposal to designate a special controls guidance and to exempt this device type. This guidance is issued for comment purposes only. If a final rule is not issued designating this guidance as a special control, the guidance will not be issued

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

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

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1 Manufacturers who choose to provide other equivalent assurances of safety and effectiveness
2 will need to submit a 510(k) and receive marketing clearance for their device. Manufacturers
3 who follow the recommendations to address the issues identified in this guidance, before
4 introducing their device into commercial distribution in the United States, will be able to market
5 their device without being subject to the premarket notification requirements of section 510(k) of
6 the act. As a class II device, the device must comply with general and special controls (section
7 513(a)(1)(B) of the act).

8
9 Section 510(m) of the act provides that FDA may exempt a class II device from the premarket
10 notification requirements under section 510(k) of the act if FDA determines that a 510(k) is not
11 necessary to provide reasonable assurance of the safety and effectiveness of the device. FDA has
12 determined that a 510(k) is not necessary to provide reasonable assurance of the safety and
13 effectiveness of this generic type of device if the manufacturer follows the recommendations in
14 this special controls guidance to address the issues identified in this guidance. Thus, persons
15 who intend to market a device of this type do not need to submit a 510(k) to FDA and receive
16 agency clearance prior to marketing the device if they follow the recommendations in this special
17 controls guidance document. If a manufacturer does not follow the recommendations in this
18 guidance document but instead chooses to use alternative means to address the issues covered in
19 this guidance, then it will not be exempt from the requirements under section 510(k) and will
20 need to submit a 510(k) and receive clearance for its device prior to marketing.

21
22 FDA's guidance documents, including this guidance, do not establish legally enforceable
23 responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should
24 be viewed only as recommendations, unless specific regulatory or statutory requirements are
25 cited. The use of the word *should* in Agency guidances means that something is suggested or
26 recommended, but not required.

The Least Burdensome Approach

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28
29 This draft guidance document reflects our careful review of what we believe are the relevant
30 issues related to ECG electrodes and what we believe would be the least burdensome way of
31 addressing these issues. If you have comments on whether there is a less burdensome
32 approach, however, please submit your comments as indicated on the cover of this document.

2. Scope

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37 The scope of this document is limited to ECG electrodes. The ECG electrode is regulated under
38 21 CFR 870.2360 (see below), class II, product codes DRX, electrocardiograph electrode, which
39 includes disposable electrodes and MLN, multi-function electrocardiograph electrode.

21 CFR 870.2360

40
41
42 An electrocardiograph electrode is the electrical conductor which is applied to the surface of
43 the body to transmit the electrical signal at the body surface to a processor that produces an

design history file, in accordance with [21 CFR 820.30](#).

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1 electrocardiogram or vectorcardiogram.

2
3 We consider both pre-gelled and bare (non-pre-gelled) electrodes to be included in this
4 classification.

5
6
7 **3. Risks to Health**

8
9 In the table below, FDA has identified the following risks to health associated with the use of the
10 cutaneous electrode. We recommend the following measures to mitigate the risks identified in
11 this guidance document.

12

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

13
14 **4. Device Description**

15
16 Under 21 CFR 820.181(a), the device master record must include or reference, for each type of
17 device:

- 18
- specifications, including appropriate drawings,
 - composition,
 - formulation, and
 - component specifications.
- 19
20
21
22

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

- 25
- 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
 - 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
 - a listing of all features and specifications of the device (a tabular format is desirable).
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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.

A. Electrodes

We recommend that you specify the:

- materials
- construction, and
- type and size of the electrodes.

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

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

Our recommendations 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 10993-1:2003, "*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. To establish material safety of ECG electrodes with a limited contact duration (e.g., less than 24 hours), limited to only intact skin, we recommend testing:

- dermal irritation,
- sensitization, and
- 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

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1 cytotoxic. In these circumstances, evaluation using other tests specified in the standard
2 may be appropriate.

2. Electrical Performance

5 To establish the electrical performance of ECG electrodes, you should consult
6 ANSI/AAMI EC12:2000, *Disposable ECG Electrodes* or other equivalent methods of
7 assuring the electrical performance for:

- 8 • AC impedance,
- 9 • DC offset voltage,
- 10 • combined offset instability and internal noise,
- 11 • defibrillation overload recovery, and
- 12 • bias current tolerance.

13
14 If your submission is for a bare electrode, we recommend you conduct the above testing
15 with the electrode gel(s) you recommended in your labeling.

3. Adhesive Performance

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

4. Shelf Life

26 We recommend testing that establishes, for labeling purposes, the device's shelf life and
27 storage conditions.

28
29 For disposable ECG electrodes, we also recommend that you follow ANSI/AAMI
30 EC12:2000, "*Disposable ECG electrodes*" or an equivalent method of assuring
31 appropriate shelf life.

5. Reuse

34 If the electrodes are not limited to single-patient use, we recommend the labeling include
35 instructions for handling, transport, cleaning, and biological decontamination. For
36 reusable ECG electrodes, you should follow ANSI/AAMI ST35:2003, *Safe handling and*
37 *biological decontamination of reusable medical devices in health care facilities and in*
38 *nonclinical* settings or other equivalent methods. We recommend you evaluate the
39 potential for skin reactions and disease transmission. We also recommend you
40 demonstrate that the cleaning and biological decontamination of the electrodes provides
41 sufficient protection and does not impact their functional performance.

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

If the electrode is intended for use in radiographic or x-ray imaging, magnetic resonance 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.

B. Electrode Conductive Medium (Gel)

Electroconductive media used with cutaneous electrodes are regulated as class II devices under 21 CFR 882.1275.

C. Electrode Lead Wires and Patient Cables

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 (1998), “*Medical Electrical Equipment - Part 1: General Requirements for Safety,*” Amendment No. 1 (1991), and Amendment No. 2 (1995). More information about this performance standard can be found on FDA’s website at: <http://www.fda.gov/cdrh/comp/leadwire.html>. Your documentation should contain information sufficient to demonstrate conformance to this performance standard.

For disposable electrodes that are designed with pre-attached leadwires, we recommend you follow ANSI/AAMI EC53:1995, *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

Package Insert

Your package insert should include:

- quantity, dimensions, sensor type, gel system, adhesive system, materials, and options (pre-wired, connector type, etc.);
- model number, date of manufacture;

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.

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- 1 • storage instructions, shelf life, and lot number;
- 2 • instructions for skin preparation;
- 3 • instructions for electrode preparation, if applicable;
- 4 • cleaning and maintenance instructions, if the electrodes are reusable;
- 5 • duration of application;
- 6 • electrical and any other technical specifications; and
- 7 • environmental specifications, e.g., MRI compatible, X-ray translucent.

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

11
12 The labeling recommendations below are not intended to capture all possible limitations or
13 instructions for ECG electrodes. Additional contraindications, warnings, precautions, adverse
14 reactions, and other instructions may be appropriate for your device, depending on its design,
15 features, and performance characteristics.

Indications for Use

16
17 The indications for use should identify the patient population, e.g., adult, pediatric, or
18 neonate. The intended use should also identify the environment of use, e.g., acute care
19 facility, hospital, chronic care facility, clinic, physician's office, ambulance, or daily use
20 environment (for Holter monitoring).

Cautions

21
22 The package insert should advise users of the following:

- 23 • ECG electrodes should only be used by or in consultation with a health care
24 provider familiar with their proper placement and use;
- 25 • ECG electrodes may damage the skin if removed carelessly;
- 26 • ECG electrodes should be applied only to intact, clean skin (e.g., not over open
27 wounds, lesions, infected, or inflamed areas); and
- 28 • To properly dispose of the electrodes if they are pre-gelled electrodes and other
29 electrodes that cannot be fully cleaned between uses.

Precautions

30
31 The package insert should advise users of the following:

- 32 • During surgical procedures, electrodes should be placed as far as possible from any
33 electro-surgical area to minimize unwanted RF current flow
- 34 • To replace self-adhesive electrodes if they no longer stick firmly to the skin.

Adverse Reactions

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36 The package insert should list known adverse reactions, including the possibility that users

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1 may experience skin irritation at contact points with the electrodes.
2

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