This guidance was written prior to the February 27, 1997 implementation of FDA's Good Guidance Practices, GGP's. It does not create or confer rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute, regulations, or both. This guidance will be updated in the next revision to include the standard elements of GGP's.

DCRND

Electrocardiograph (ECG) Electrode

Version 1.0

This Document is intended to provide guidance in the preparation of a regulatory submission. It does not bind the FDA or the regulated industry in any manner.

Office of Device Evaluation
Division of Cardiovascular, Respiratory and Neurological Devices
Anesthesiology and Defibrillator Devices Group

Document issued on:

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While this guidance document represents a final document, comments and suggestions may be submitted at any time for Agency consideration by writing to Charles Ho, Ph.D., Center for Devices and Radiological Health, 9200 Corporate Boulevard, HFZ-450, Rockville, MD 20850. For questions regarding the use or interpretation of this guidance, contact Charles Ho, Ph.D. at (301) 443-8609.

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration
Center for Devices and Radiological Health

Guidance for the Submission of 510(k) Premarket Notifications for Electrocardiograph (ECG) Electrodes

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

Guidance Document

Device: Electrocardiograph (ECG) Electrode

I. Device Description

Common name:	Electrocardiograph (ECG) electrode
Class:	II
Classification panel:	74
Product code:	DRX
Regulation number:	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.

Electrode arrays are excluded from third party reviews due to the difficulty of fitting the arrays to the various sizes and body contours of patients.

II. Indications for Use

ECG electrodes are used to record the following ECGs from a patient:

resting ECG, exercise ECG and/or ambulatory (Holter) monitoring.

The intended patient population can be adult, pediatric and neonatal, while the environment of use can be hospital (or clinic), ambulance, or daily use environment (for Holter monitoring).

III. Preclinical Data

a. Bench testing is performed generally in accordance with the Association for the Advancement of Medical Instrumentation (AAMI) EC12-1991 standard. Special features can be verified using additional standards. For example, radiolucence may be verified with Method B of the American Society for Testing and Materials (ASTM) F 640 "Standard Test Methods for Radiopacity of Plastics for Medical Use". Accuracy should be maintained in the units of measurement; for example, the symbol for millivolt is "mV", not "MV".

   If an electrode is made of several layers of materials held together by adhesives only (these are sometimes called tab electrodes), provide a report on the minimum force that can be used to de-laminate the electrode, and compare it with the corresponding force of the predicate.

b. Test the shelf life of the electrode both in the environment of use (real-time aging) and in an environment using elevated temperatures (accelerated aging). For accelerated aging, provide both the baseline temperature and the oven temperature. Provide the result of the

accelerated aging test in the 510(k) submission and keep the real-time aging result in company records for inspection by the Food and Drug Administration (FDA).

c. Biocompatibility testing is performed in accordance with the FDA modified ISO-10993 standard, Biological Evaluation of Medical Devices, ISO-10993 Part 1: Evaluation and Testing. Both the hydrogel and the adhesive, if used, should be tested.

IV. Clinical Data

a. Provide at least three ECG tracings using the subject electrodes. Each tracing should contain at least 10 seconds of data.

b. Provide a wear test report for Holter monitoring electrodes that can be used for more than 24 hours.

V. Software/Hardware Information

A description of the hardware should be provided. In particular, provide concentrations of the ingredients of the hydrogel and adhesive in the electrode, if applicable. Please note that the FDA has proposed banning all unprotected electrode leadwires, including any electrode with an integral leadwire whose connector at the end distal to the patient can be inserted into an AC power source. (Federal Register 60 FR 32408, dated June 21, 1995)

VI. Examples of Predicate Devices

a. K960968: Graphic Controls Corporation

b. K953649: Kendall-LTP

VII. Sterilization Information

If the electrode can be used on more than one patient, describe the method of sterilization and provide the test report to verify its effectiveness (sterility assurance level).

VIII. Labeling Information

Labeling is done in accordance with the EC12-1991 standard. Textual instructions of use should be used; graphic instructions are optional. State the maximum duration of use. Avoid the claim of hypoallergenicity since different patients have greatly different levels of tolerance to allergenic agents.

Include the lot number and an expiration date. The expiration date should be

consistent with the shelf life test conditions described above. A storage temperature at the user's site that is higher than the baseline temperature used for accelerated aging will necessarily shorten the shelf life validated through accelerated aging.

In general, electrodes should be placed on the patient by a physician or ECG technician. If electrodes are to be placed by the patients themselves, provide proof that all intended patients can be instructed to place the electrodes on themselves within a specified location tolerance, and for each time the electrodes are applied.

Check List

Device: Electrocardiograph (ECG) Electrode

Information for the following items should be provided in the 510(k) submission:

1. Intended Use and Indications for Use statements
2. Bench testing
3. Shelf life
4. Biocompatibility
5. Clinical data
6. Hardware information
7. Sterilization, if applicable
8. Labeling.