MAR 2 2 2005

510(k) Summary

AccuHeart™ ELECTRODE BELT

K K043361

Submitter: Advanced Bioelectric Corporation
21 Park Street, 2nd. Floor, Suite B
Gatineau, Quebec, J9H 4J6
CANADA
Telephone: 819-682-0505
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Contact person: Alastair R. B. Samson
President and CEO

Date of preparation: 2004/12/01

Device Name: Proprietary Name: *AccuHeart*™ Electrode Belt
Common Name: Electrocardiograph Electrode
Classification Name: Electrocardiograph Electrode

Regulatory Classification:
Class: 2
Medical Specialty Panel: Cardiovascular
Product Code: 74 DRX

Devices to Which Substantial Equivalence is Claimed:
Device Name: Medi-Trace 200 and Medi-Trace 200-30 ECG Electrodes
510(k) Number: K960968
Device Name: ECG Electrodes Apron
510(k) Number: K982470

Device Description:
The *AccuHeart*™ Electrode Belt is a reusable electrode system consisting of an electrode assembly, an elastic chest belt, and an optional shoulder strap. The *AccuHeart*™ electrodes are positioned against the skin with light pressure, using the elastic chest belt. The *AccuHeart*™ Electrode Belt is designed to be used without electrolytic gels and without adhesives on unprepared skin, i.e., without the requirements for shaving, abrading or other skin preparations.

Intended Use:
The *AccuHeart*™ Electrode Belt is a reusable electrode system intended for use in general electrocardiograph procedures where ECG monitoring is deemed necessary and is ordered by a physician. The *AccuHeart*™ Electrode Belt is compatible for use with most ECG instruments on the market.

Substantial Equivalence:
The *AccuHeart*™ Electrode Belt is substantially equivalent to the Medi-Trace 200 and Medi-Trace 200-30 ECG Electrodes (K960968) and to the ECG Electrodes Apron (K982470).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 2 2 2005

Advanced Bioelectric Corporation
c/o Mr. Alaistair R. B. Samson
President & CEO
21 Park Street, 2nd Floor, Suite B
Gatineau, Quebec, J9H 4J6
CANADA

Re: K043361
Trade Name: *AccuHeart*™ Electrode Belt
Regulation Number: 21 CFR 870.2360
Regulation Name: Electrocardiograph Electrode
Regulatory Class: II (two)
Product Code: DRX
Dated: March 08, 2005
Received: March 09, 2005

Dear Mr. Samson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

Applicant: ADVANCED BIOELECTRIC CORPORATION

510(k) Number (if known): K043361

Device Name: ***AccuHeart™* Electrode Belt**

Indications For Use:

The *AccuHeart™* Electrode Belt is a reusable electrode system intended for use in general electrocardiograph procedures where ECG monitoring is deemed necessary and is ordered by a physician. The *AccuHeart™* Electrode Belt is compatible for use with most ECG instruments on the market.

Prescription Use X OR Over-the-counter _____
Per 21 CFR 801.109

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular, Respiratory, and Neurological Devices
510(k) Number K043361