K062760/S1
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DEC 1 1 2006

510(k) Summary

510(k) Summary of Safety and Effectiveness
(as required by 21 CFR § 807.92)

510(k) Submitter	Orbital Research Inc. 4415 Euclid Ave, Suite 500 Cleveland, Ohio 44103
Contact Person	Aaron Rood Senior Research Scientist & Regulatory Affairs Associate Phone: (216) 649-0399 Fax: (216) 649-0347
Date Prepared	9/14/06
Device Name	*Proprietary Name:* ORI F6T Dry ECG Monitoring Electrode *Common Name:* electrocardiograph (ECG) electrode *Classification Name:* "electrode, electrocardiograph," a class II device per 21 CFR § 870.2360 (product code DRX).
Device Description	The ORI F6T Dry ECG Monitoring Electrode is a non-sterile, single-use, disposable electrode system consisting of a solid, Ag/AgCl-coated conductive polymer element with a mechanical skin interface surface designed to ensure adequate skin interface without the use of a component electrolytic gel. The conductive polymer element is held in place using a novel adhesive tape patch.
Intended Use	The ORI F6T Dry ECG Electrode is intended for use in all ECG monitoring applications where standard ECG monitoring electrodes are used. The F6T Electrode can be used in short term and long term (up to 2 days) ECG monitoring.
Predicate Devices	The F6T Electrode is substantially equivalent to the following legally marketed ECG electrodes: -3M Red Dot™ 2570 Monitoring Electrode (K970796) 3M Health Care -AccuHeart™ Electrode Belt (K043361) Advanced Bioelectric Corporation
Substantial Equivalence	The F6T Electrode is substantially equivalent in terms of safety and effectiveness to a combination of the predicate devices cited above and is designed to ensure stable ECG monitoring performance over the life of the device.

Non-clinical Testing

The biological safety of the F6T Electrodes has been assessed through the tests specified in accordance with ISO 10993-1, *Biological Evaluation of Medical Devices.*

The electrical performance of the F6T Electrode was assessed and determined to meet the applicable requirements of ANSI/AAMI EC 12:2000, *Disposable ECG Electrodes.*

Clinical Testing

The safety and effectiveness of the F6T Electrode was assessed in clinical testing conducted in accordance with the requirements of the ANSI/AAMI EC 12:2000, *Disposable ECG Electrodes* and FDA's ECG Electrode 510(k) guidance document. The performance of the device was substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 11 2006

Orbital Research Inc.
Aaron Rood
Regulatory Affairs Associate
4415 Euclid Ave.
Suite 500
Cleveland, OH 44103

Re: K062760
Trade/Device Name: Ori F6T Dry ECG Monitoring Electrode
Regulation Number: 21 CFR 870.2360
Regulation Name: Electrocardiograph Electrode
Regulatory Class: II
Product Code: DRX
Dated: November 10, 2006
Received: November 1, 2006

Dear Mr. Rood:

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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

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

Enclosure

Indications for Use Statement

510(k) Number: K062760

Device Name: ORI F6T Dry ECG Electrode

Indications for Use: The ORI F6T Dry ECG Monitoring Electrodes are intended for use in adults (persons 18 years and older) in all ECG monitoring applications where standard ECG monitoring electrodes are used. The F6T Electrodes can be used in short term and long term (up to 2 days) ECG monitoring.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Figure 3 [redacted] **Version 1.1 created 10 November 2006**

12/8/06

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K062760