K040256

10.0 510(k) Summary; pedi•padz™ Radiolucent Pediatric Multi-Function Electrodes

Company:	BIO-DETEK 525 Narragansett Park Drive Pawtucket, RI 02861-4323
Contact:	Robert Morse QA/QC Manager
Date Prepared:	February 3, 2004
Name of Device:	pedi•padz™ Radiolucent Pediatric Multi-Function Electrode
Predicate Device:	ZOLL Pediatric Multi-Function Electrode K915159A & ZOLL stat•padz™ Radiolucent Adult Multi-Function Electrode K960676

Device Description and Intended Use:

The pedi•padz™ Radiolucent Pediatric Multi-Function Electrodes will connect to ZOLL Pacemakers/Defibrillators, as defined by ZOLL Medical Corporation, for pediatric patients, 0-8 years of age at <55lbs/<25kg weight. The electrodes can be used in the radiology department, catheterization laboratory, and electrophysiology laboratory of the Hospital because the image of the electrode on radiographs or fluoroscopic video does not block out anatomical detail. Once the electrodes are connected to the defibrillator they may be used for:

- ECG monitoring
- External defibrillation
- Noninvasive pacing
- Cardio-version

The pedi•padz™ Radiolucent Pediatric Multi-Function Electrodes consist of a pair of liquid gel electrodes with permanently attached lead wires that join together at a proprietary ZOLL connector. The connector interfaces with the ZOLL Pacemaker/Defibrillator multifunction cable.

Technological Characteristics

The pedi•padz™ Radiolucent Pediatric Multi-Function Electrode is designed to comply with the applicable portions of the following standards:

- IEC 60601-2-4 Medical Electrical Equipment
- ANSI/AAMI DF-2: 1996, Cardiac Defibrillator Devices
- ANSI/AAMI/ISO DF39-1993
- 21 CFR Par 898 Performance Standards for Electrode Lead Wires and Patient

Basis for Substantial Equivalence:

Operation and technological characteristics form the basis for the determination of substantial equivalence of the pedi•padz™ Radiolucent Pediatric Multi-Function Electrode with legally marketed predicate devices. Information supplied in this premarket notification includes descriptive information about the intended use, operation and technological characteristics.

This information is provided pursuant to the requirements of the Safe Medical Devices Act of 1990 (SMDA).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR - 9 2004

Bio-Detek, Inc.
c/o Mr. Robert Morse
QA/QC Manager
525 Narragansett Park Drive
Pawtucket, RI 02861-4323

Re: K040256
Trade Name: pedi•padz™ Radiolucent Multi-Function Pediatric Electrodes
Regulation Number: 21 CFR 870.2360
Regulation Name: Electrocardiograph Electrode
Regulatory Class: II (two)
Product Code: MLN
Dated: February 03, 2004
Received: February 04, 2004

Dear Mr.Morse:

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 (301) 594-4648. 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

510(k) Number K040256:

Device Name: pedi•padz™ Radiolucent Pediatric Multi-Function Electrodes

Intended Use: The pedi•padz™ Radiolucent MFE's are intended to be used on pediatric patients, 0-8 years of age at <55 lbs/25kg weight, for defibrillation, non-invasive pacing, cardioversion, and ecg monitoring in conjunction with ZOLL Pacemaker/Defibrillator equipment.

These disposable electrodes will be used with the following devices:

- ZOLL PD™ 1200 Pacemaker/Defibrillator
- ZOLL PD™ 1400 Pacemaker/Defibrillator
- ZOLL PD™ 2000 Pacemaker/Defibrillator
- ZOLL D900 Defibrillator
- ZOLL D1400 Defibrillator
- ZOLL D2000 Defibrillator
- ZOLL 1600 Pacemaker/Defibrillator
- ZOLL 1700 Pacemaker/Defibrillator
- ZOLL NTP 1000 Noninvasive Temporary Pacemaker
- ZOLL M Series Equipment
- Future ZOLL Devices, as defined by ZOLL Operators Manuals

Prescription Use _√_ AND/OR Over-the-Counter Use ___
(Part 21 CFR 801 Subpart D)

(Please do not write below this line – Continue on another page if needed)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Vochmer
(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K040256