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BIO PROTECH INC.

510(k) Summary

Data : June 30, 2005

Manufacturing Facility : BIO PROTECH, INC.
1720-26, Taejang 2-Dong, Wonju
Medical Instrument Ind. Park
Wonju-Si, Gangwon-Do, REPUBLIC OF KOREA
Tel: 82-33-735-7720 Fax: 82-33-735-7736

Contract Person : Eunseo Heo
Researcher of Regulatory Affairs
Tel: 82-33-735-7720 Fax: 82-33-735-7736

Device Trade Name : PRO-NEO NEONATAL ECG ELECTRODE

Device Common Name : Neonatal ECG Monitoring Electrode

Classification Name : Electrocardiograph Electrode

Regulatory Reference : 74 DRX

Predicate Device :

K000206, PALS NEONATAL PEDIATRIC ECG ELECTRODE, AXELGAARD MFG. CO., LTD.

Description:

The PRONEO Neonatal ECG Electrodes *(and also to be sold under various private label trade names; i.e. Multiple Labels)* are 22mm in square and consist of a conductive adhesive hydrogel, a Ag/AgCl plated sensor element a non-woven substrate and vinyl label, and a 100cm flexible tinned copper or carbon lead wire terminating in a 1.5mm, 2.0mm standard DIN connector. Electrodes are packaged in pouches of 3, 100 pouches per carton and are supplied non-strerile.

Intended Use:

The PRONEO Neonatal ECG Electrodes are designed for use whenever cardiac monitoring for neonatal or pediatric patients is deemed or desirable by trained medical or emergency personnel. This electrode is for use on neonatal and pediatric patients.

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Performance Summary:

The device and the predicate were subjected to AAMI electrical tests as described in ANSI/AAMI voluntary standard, EC12:2000, Disposable ECG Electrodes. Test results for both the device and the predicate met the specifications as established in ANSI/AAMI EC12:2000.

Biocompatibility Testing:

The device was subjected to biocompatibility testing as recommended FDA memorandum entitled Use of International Standard ISO 10993, Biological Evaluation of Medical Devices Part 1: Evaluation and Testing. The device was found to be non-irritating, non-cytotoxic and non-sensitizing.

Shelf Life:

Accelerated aging testing was performed to substantiate an expiration of 24 months.

Conclusion:

This device is substantially equivalent to the devices approved as K000206

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 14 2005

Bio Protech, Inc.
c/o Mr. E. J. Smith
Smith Associates
1676 Village Green
Suite A
Crofton, MD 21114

Re: K053011
Trade Name: Neonatal Electrocardiograph (ECG) Electrode
Regulation Number: 21 CFR 870.2360
Regulation Name: Electrocardiograph Electrode
Regulatory Class: Class II (two)
Product Code: DRX
Dated: June 29, 2005
Received: October 26, 2005

Dear Mr. Smith:

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/industry/support/index.html.

Sincerely yours,

B Zuckerman 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

510(k) Number (if known): K053011

Device Name: NEONATAL ELECTROCARDIOGRAPH (ECG) ELECTRODE

Indications for Use:

The PRONEO Neonatal ECG Electrodes are designed for use whenever cardiac monitoring for neonatal or pediatric patients is deemed or desirable by trained medical or emergency personnel. This electrode is for use on neonatal and pediatric patients. The PRONEO Neonatal ECG Electrodes are non-sterile and are to be used on intact (uninjured) skin.

Caution: Federal law restricts this device to sale by or on the order of physician.

Prescription Use __X_____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K053011