K092744 1/2

510(k) Summary

Submitter's Information:	R&D Medical Products, Inc. 20492 Crescent Bay Drive, Building 106 Lake Forest, CA 92630
	DEC 10 2009
Contact Person:	James Perrault Phone: (949) 472-9346 x202 Fax: (949) 472-9347
Date Prepared:	September 3, 2009, revised November 19, 2009
Proprietary Name:	Neonatal ECG Electrodes
Common Name:	Electrocardiograph (ECG) Electrodes
Classification Name:	Electrodes, Electrocardiograph
Regulation:	Electrocardiographic electrode, 21 C.F.R. § 870.2360
Regulatory Class:	Class II
Product Code:	DRX
Predicate Devices:	K050443 – Ameritus Accu-Lead of Kentec Medical, Inc. K011564 – Neolead of Neotech Products, Inc.
Description of Device:	The Neonatal ECG Electrodes are three prewired ECG electrodes supplied on the same release card in a single package. The electrodes are a multi-layer construction containing a first layer surface (made of tricot/polyester fabric, polyethylene foam, or polypropylene substrate), a second layer (metallic with Ag/AgCl coating) prewired for connection to patient leadwires, and a third layer (made of biocompatible conductive hydrogel coupling media). The electrodes are placed on the neonate patient's chests.
Intended Use:	Neonatal ECG Electrodes are intended for use in pediatric or neonatal electrocardiographic procedures where resting ECG monitoring is deemed necessary and is ordered by a physician. Such procedures include, in particular, patient ECG surveillance and ECG diagnosis recording. The Neonatal ECG Electrodes are

	applied to the surface of the body, single use only, and disposable. Neonatal ECG electrodes should be changed every 24 hours.
Technological Comparison:	The Neonatal ECG Electrodes have technological characteristics that are substantially equivalent to those of the predicate devices as determined by testing, common materials, and common manufacturer. The following testing was conducted: AC impedance; DC offset voltage; defibrillation overload recovery; combined offset instability and internal noise; and bias current tolerance. The Neonatal ECG Electrodes and the predicate devices all meet the specifications as established in ANSI/AAMI EC12:2000/(R) 2005 and ANSI/AAMI EC53:1995/(R) 2008.
Basis for Equivalence:	R&D Medical Products, Inc. contract manufactures the predicate devices and now seeks to make the same product under private label for distribution.
-Performance testing:	Biocompatibility testing was performed, and the device passed the required skin sensitivity testing criteria. According to the performance data, the Neonatal ECG Electrodes met specifications as established in ANSI/AAMI EC12:2000 (R) 2005 for skin contact. The tests included cytotoxicity, sensitization and primary skin irritation tests. The predicate devices use the same materials and meet the same biocompatibility specifications. Bench testing demonstrated that the characteristics of the Neonatal ECG Electrodes are substantially equivalent to those of the predicate devices.
-Labeling:	The labeling of the Neonatal ECG Electrodes is substantially equivalent to that of the predicate devices.
Conclusions from Testing:	In all material respects, the Neonatal ECG Electrodes are substantially equivalent to the predicate devices. Testing was performed according to FDA recognized standards. Test results support the conclusion that the electrical output is substantially equivalent to the predicate devices, and there are no differences in construction and materials between the devices to pose new questions of safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

DEC 10 2009

R&D Medical Products, Inc.
c/o Mr. James Perrault
20492 Crescent Bay Drive
Building 106
Lake Forest, CA 92630

Re: K092744
Trade Name: Neonatal ECG Electrode, M203KEN
Regulation Number: 21 CFR § 870.2360
Regulation Name: Electrocardiograph Electrode
Regulatory Class: Class II (two)
Product Code: 74 DRX
Dated: November 23, 2009
Received: November 24, 2009

Dear Mr. Perrault:

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.

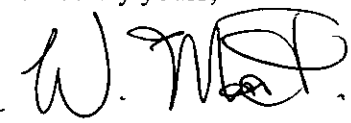
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

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

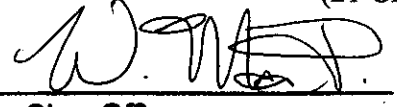
510(k) Number: K092744

Device Name: Neonatal ECG Electrodes

Indications for Use:

These electrodes are to be used in the neonatal or pediatric unit of hospitals for the resting ECG monitoring of newborn and premature birth infants. They are applied to the surface of the body, single use only, and disposable. These electrodes should be changed every 24 hours.

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



(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K092744