510(k) Summary

K101685

Administrative:

JUL - 1 2010

Submitter: Integral-Process
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Date of preparation: May 18, 2010

I Device Name:

Classification Name: Electrode, Electrocardiograph
Common/Usual Name: ECG Electrode
Proprietary Name: IP-SET®

Classification: Class II
Registration #: 870.2360
Product Code: DRX

II Predicate Devices:

Substantial Equivalence	K #	Manufacturer / Current marketer	Device I/D (ECG Electrodes)
Functionality		MSB Ltd. (UK) -1994 / Unomedical USA - 2008	
Diagnostics	K944260		ECG Electrode – (0915M)
Other Monitoring appl.	K944497		Unilect™, Monitab and Biotrace-HR (1014M)
Manufacturing		NIKO Medical Products – 2000 / Unomedical USA - 2008	Sensi-prema neonatal ecg electrodes – (45550)
Ultrasonic welding	K003804		
Electrode Components			
Adhesive / hydrogel	K011564	Neotech Products Inc.	Neolead

III Device Description:

Set of disposable, single-use, pre-gelled ECG electrodes are regrouped on a flat cable sole or by pair (dual electrodes) and located to ease their positioning on the patient. Electrode number and positioning design vary according to the monitoring/diagnostics application.

Pre-gelled (hydro-gel) electrodes are of Ag/AgCl construction with a sensor element area between 10 and 20 mm in diameter, and an adhesive part between 20 and 90 mm in diameter or oblong / rectangular shape.

Lead wires are regrouped in a flat cable and are made of copper (radio-opaque) or carbon fiber (radio-translucent).

Sets are supplied non-sterile. Each set / harness is packaged in one OPP/PE laminated pouch (sealed foil); 10 to 50 pouches are supplied per box; Shipping cartons contain 12 boxes.

V Intended Use

ECG pre-wired harnessed sets of electrodes for short and long term use; for adults, pediatrics and neonates.

Follows a reference chart for most commonly suggested used (but not limited to) among which the Physician will determine which one is better suited for the desired application:

IP-Set® P/N	Application	X Rays	Basic (B) / Combined (C)	**Combination**
50502-US	Diagnostic	No	C	50500-US + 50503-US
50505-US	Diagnostic	No	C	50501-US + 50504-US
50506-US	Diagnostic	No	C	50500-US + 50510-US
50507-US	Diagnostic	No	B	
50510-US (*)	Used only in conjunction with P/N 50500-US for P/N 50506-US	No	B	
50600-US	Coronary/X Rays	Yes	B	
50601-US	Coronary/X Rays	Yes	B	
50603-US	Coronary/X Rays	Yes	B	
50604-US	Coronary/X Rays	Yes	B	
50602-US	Coronary/X Rays	Yes	C	50600-US + 50603-US
50605-US	Coronary/X Rays	Yes	C	50601-US + 50604-US
50500-US	Monitoring	No	B	
50501-US	Monitoring	No	B	
50503-US	Monitoring	No	B	
50504-US	Monitoring	No	B	
50400-US	Pediatrics	Yes	B	
50401-US	Neonat	Yes	B	

Nota: Ref # 50510-US is used for manufacturing only, and is always marketed in conjunction with ref # 50500-US under ref # 50506-US.

VI Comparison of Technological Characteristics

The Disposable, Single-Use, Pre-Wired and Pre-Gelled Integral-Process Sets of ECG Monitoring Electrodes IP-SET® are identical in function, and have the same intended use as the legally marketed disposable ECG monitoring range of electrodes Unilect™ for diagnostics (K944260) or other monitoring applications (K944497), manufactured today by Unomedical Ltd. (U.K.) and imported, marketed and distributed by Unomedical (USA) Inc. Unomedical is the new company name for MSB ltd (UK) which was granted both 510(k) marketing authorizations in reference.

The Disposable, Single-Use, Pre-Wired and Pre-Gelled Integral-Process Sets of ECG Monitoring Electrodes IP-SET® have the identical welding process of lead wire to electrode as performed for the legally marketed predicate Sensi-Prema ECG monitoring electrode granted to Maesrk/Niko medical under # K003804. The ultrasonic welding is in fact a proprietary process of Integral Process, technologically transferred to then Maersk Medical (UK), which became Unomedical

Ltd. (see history). Therefore the pre wiring electrical and mechanical safety of the connection is covered.

Electrical safety and biocompatibility of skin-contact components have been cleared by predicate Neolead ECG electrode manufactured and legally marketed by Neotech Products Inc. under # K011564.

Other effectiveness and safety compliance to required standards and requirements are demonstrated in the market authorization file.

Accordingly Integral-Process concluded that the Disposable, Single-Use, Pre-Wired and Pre-Gelled Integral-Process Sets of ECG Electrodes IP-SET® are safe and effective for their intended use and perform at least as well as other disposable ECG electrodes.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Integral Process SAS, Z.A. des Boutries
c/o Mr. Tamas Borsai
TUV Rheinland of North America
Responsible Third Party Official
12 Commerce Road
Newtown, CT 06470

JUL - 1 2010

Re: K101685
IP-SET®M3/IP-SET®M5/IP-SET®12, Models 50500-US/50501-US/50502-US;
IP-SET®6V/IP-SET®5V/IP-SET®M12, Models 50503-US/50504-US/50505-US;
IP-SET®12S/IP-SET®C, Models 50506-US/50507-US;
IP-SET®M3RT/IP-SET®M5RT/ P-SET®M12RT/IP-SET®6VRT, Models 50600 US/50601-US/50602-US/50603-US; and
IP-SET®5VRT/ IP-SET®M12RT/IP-SET®P3/IP-SET®N3, Models 50604-US/50605 US/50400-US/50401-US
Regulatory Number: 21 CFR 870.2360
Regulation Name: Electrocardiograph electrode
Regulatory Class: II (two)
Product Code: 74 DRX
Dated: May 3, 2010
Received: May 4, 2010

Dear Mr. Borsai:

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

K101685

Indications for Use

510(k) Number (if known):

Device Name: IP-SET®, ECG Pre-Wired Sets of Electrodes

Indications For Use:

ECG pre-wired harnessed sets of electrodes for short and long term use; for adults, pediatrics and neonates.

By design and manufacturing process, the IP-SET® ECG electrodes are of multidisciplinary use, and the unit choice is performed by the Physician, in function of the desired application.

As per the reference chart:

IP-Set® P/N	Suggested Application (left to the Physician's discretion)	X Rays	Basic (B) / Combined (C)	Combination
50502-US	Diagnostic	No	C	50500-US + 50503-US
50505-US	Diagnostic	No	C	50501-US + 50504-US
50506-US	Diagnostic	No	C	50500-US + 50510-US
50507-US	Diagnostic	No	B	
50510-US (*)	Used only in conjunction with P/N 50500-US for P/N 50506-US	No	B	
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50601-US	Coronary/X Rays	Yes	B	
50603-US	Coronary/X Rays	Yes	B	
50604-US	Coronary/X Rays	Yes	B	
50602-US	Coronary/X Rays	Yes	C	50600-US + 50603-US
50605-US	Coronary/X Rays	Yes	C	50601-US + 50604-US
50500-US	Monitoring	No	B	
50501-US	Monitoring	No	B	
50503-US	Monitoring	No	B	
50504-US	Monitoring	No	B	
50400-US	Pediatrics	Yes	B	
50401-US	Neonatal	Yes	B	

Nota: Ref # 50510-US is used for manufacturing only, and is always marketed in conjunction with ref # 50500-US under ref # 50506-US

Prescription Use ___√___ **AND/OR** **Over-The-Counter Use** _____
(Part 21 CFR 801 Subpart D) **(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)

(Division Sign-Off)
Division of Cardiovascular Devices

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