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OCT 10 2008

Unmedical Medical Supplies Inc
No. 37, Yanshan Road, Shekou, Shenzhen, China 518067
Tel: 86 755 26828795 Fax: 86 755 26697984
www. Unimed.cn Email: info@unimed.cn

510(K) Summary

Submitter Information:

Unimed Medical supplies Inc
No.37, yanshan Road, Shekou, Shenzhen, China 518067

Contact:

Liming Xue
President
Tel: 86 755 26828795
Fax: 86 755 26697984
Email: limingx@unimed.cn

Date Prepared: June 18, 2008

Trade Name: Patient monitoring Cables for ECG, EKG,Spo2 and Blood Pressure Monitors
Common Name: Patient Cables and Lead wires
Product Classification: Class II: Cardiovascular 74 DSA, per 21 CFR section 870.2900

Predicate Device:

Advantage Medical Cables: K992524

Description:

Unimed's most common cable lead wire configuration ECG cables with specific various length are the replacements for similar cables manufactured by Original Equipment Manufacturers(OEM) and other third party after market manufacturers for their respective monitors.

These cables consist of connectors on each cable end and a shielded bulk cable. The cables are used to transfer the signals from the electrodes to the patient monitor.

The Unimed cables use the same type of constructions and have the same technological characteristics as the predicate devices. They use a medical grade PVC cable jacket with medical grade PVC overmolded connectors with integral relief.

Intended Use:

The Unimed patient cables and lead wires are intended to be used with ECG, EKG, Spo2 and BP monitoring devices. The patient cables and lead wires are used to connect electrodes, catheters, and/or sensors placed at appropriate sites on the patient to a monitoring device for general monitoring and/or diagnostic evaluation by heath care professional.

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Manufacturing Facility:

Unimed Medical Supplies inc is the China based manufacturer and distributor of medical cables and accessories. 2500 square meter facility is equipped with all tools and equipments required to produce high quality cables and lead wires.

Unimed is a CE certificated of Class II products and ISO13485-2003 full quality management registered company.

Comparison to Predicate Device:

	Unimed Medical	**Advantage medical**
Intended use	To conduct impulse signals from the sensor to the patient monitor	Same
Patent Usage	Reusable	Same
Anatomical Sites	Attached to sensors places at standard specified locations on the chest wall	Same
Design/Appearance	Cables with various connectors(monitor, trunk/lead wire, electrode grabber & snapper)	Same
Cable length	Various specified standard lengths	Same
Wire color	Snappers and grabbers color coded e.g, red, white, green, black, brown	Same
Wire material	Tin copper/PVC jacket	Same
Sterility	Used non-sterile	Same
Connector Retention Force	ANSI/AAMI EC53A-1998(R)2001 EC53A-1998(Amendment)	Same
Electrical Performance and Safety	ANSI/AAMI EC53A-1998(R)2001	Same

Performance data and Conclusions:

1. Unimed design is equivalent to predicate device design.
2. Bench Testing demonstrates that Unimed devices perform as intended
3. The company has declares conformity to consensus standard ANSI/AAMI EC53-1995(R)2001 and its attachment EC53A-1998(R) 2001 relating to Electrical/Safety/Mechanical
4. These devices do not raise new issues of safety and effectiveness, nor do they alter the fundamental technology of the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 10 2008

Unimed Medical Supplies Inc.
c/o Intertek Testing Services NA, Inc.
Mr. Jay Y. Kogoma
Responsible Third Party Official
2307 E. Aurora Road, Unit B7
Twinsburg, OH 44087

Re: K082959
Trade/Device Name: Patient Cable and Lead Wire for ECG, EKG, Spo2 and Blood Pressure Monitors
Regulation Number: 21 CFR 870.2900
Regulation Name: Patient Transducer and electrode cable (including connector)
Regulatory Class: Class II (two)
Product Code: DSA
Dated: October 1, 2008
Received: October 3, 2008

Dear Mr. Kogoma:

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

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Section 2

Applicant Name: Unimed Medical Supplies Inc

510(k) Number:

Device Name: Patient Cable and Lead wire for ECG, EKG, Spo2 and Blood Pressure Monitors.

Model numbers:
DX-2595,DX-90S,MQ-2586,MQ3-90P,MQ5-90P,AA-2585,AA5-90P,2540S,
D5-90S,E10-HP-B,E10-MQ12-B,U708-01,U708-21,U708-40,BC-6P-UT

Indications for Use

The Unimed patient cables and lead wires are intended to be used with ECG, EKG, Spo2 and BP monitoring devices. The patient cables and lead wires are used to connect electrodes, catheters, and/or sensors placed at appropriate sites on the patient to a monitoring device for general monitoring and/or diagnostic evaluation by heath care professional.

Prescription Use __X_____ **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)

for B Zuckerman
10/10/07

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K082959