DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

November 4, 2014

Unimed Medical Supplies, Inc.
Ms. Tan Xinmei
QA & RA Manager
No.37, Yanshan Road, Shekou
Shenzhen, 518067 China

Re: K142489
Trade/Device Name: Unimed Disposable ECG Lead Wires
Regulation Number: 21 CFR 870.2900
Regulation Name: Patient Transducer and Electrode Cable (Including Connector)
Regulatory Class: Class II
Product Code: DSA
Dated: August 10, 2014
Received: September 4, 2014

Dear Ms. Tan Xinmei,

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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 contact the Division of Industry and Consumer Education 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. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 Industry and Consumer Education 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

510(k) Number (if known): __K142489_____

Device Name: __ Unimed Disposable ECG Lead Wires ____

Indications for Use

The Unimed Disposable ECG Lead Wires are indicated for use in the monitoring of cardiac signals for both diagnostic and monitoring purposes. Use is limited by the indications for use of the connected monitoring or diagnostic equipment.

Model:

HT3-90DS	DG5-90DS	SMB3-90DP	HPA5-90DP	2385DS	MR5-90DS	AP5-90DS
MQ3-90DS	NKB6-90DS	D3-90DS	AAB5-90DS	DT5-90DS	2586DP	MQB6-90DS
AAB3-90DP	AP6-90DS	DG3-90DP	AT5-90DP	MR5-90DP	DT3-90DS	DG6-90DS
AT3-90DS	2396DS	2386DP	HT5-90DS	SM5-90DS	2585DP	NKB3-90DS
D5-90DP	AP3-90DP	2596DS	2312DP	2512DP	HP3-90DS	MQ5-90DS

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use __X__ OR **Over-The-Counter Use** _____
(Per 21 CFR 801.109)

510(K) Summary

Prepared Date: 2014-8-15

1. Submitter Information

Name	Unimed Medical Supplies Inc
Address	No. 37, Yanshan Road, Shekou, Shenzhen, China 518067
Tel	+86-755 26695165
Fax	+86-755 26697984
Establishment Registration No.	3007307487

2. Contact Person

Contact person	Tan xinmei
Title	QA&RA manager
Address	No. 37, Yanshan Road, Shekou, Shenzhen, China 518067
Tel	+86-755 26695165
Fax	+86-755 26697984
E-mail	tanxinmei@unimed.cn

3. Manufacturer Information

Name	Unimed Medical Supplies Inc
Address	No. 37, Yanshan Road, Shekou, Shenzhen, China 518067
Establishment Registration No.	3007307487

4. Proposed Device Information

Trade Name	Unimed Disposable ECG lead wires
Common name	ECG lead wires
Classification name	Patient transducer and electrode cable (including connector)
Regulatory class	Class 2
Production regulation	21 CFR § 870.2900
Product code	DSA
Panel	Cardiovascular

5. Predicate Device Information

510(K)No.	K110287
Submitter's Name	Philips Medical Systems
Trade Name	Philips ECG Leadwire Set
Common name	ECG Leadwire Set
Classification name	Patient transducer and electrode cable (including connector)
Regulatory class	Class 2
Production regulation	21 CFR § 870.2900
Product code	DSA
Panel	Cardiovascular

6. Device description

The unimed disposable ECG lead wire is a single patient electrode cable system used to transmit signals from patient surface electrodes to various electrocardiograph recorders/monitors for both diagnostic and monitoring purposes. This type of device is common to both industry and to most medical establishments. The system is designed to provide a family of lead wires that will link the patient and the compatible patient trunk cable system.

7. Intended use

The subject device are intended for use only by trained healthcare professionals for measurement of a patient's ECG for both diagnostic and monitoring purposes. Use is limited by the indications for use of the connected monitoring or diagnostic equipment. These leadwires are intended for short-term use only (an average patient stay of 5 days).

8. Comparison to predicate device

Comparison item	Subject Device Unimed	Predicate Device K110287	Note
Intended use	The subject device are intended for use only by trained healthcare professionals for measurement of a patient's ECG for both diagnostic and monitoring purposes. Use is	Philips Single-Patient-Use Disposable ECG Leadsets are intended for use only by trained healthcare professionals for measurement of a patient's ECG for both diagnostic and	Same

	limited by the indications for use of the connected monitoring or diagnostic equipment. These leadwires are intended for short-term use only (an average patient stay of 5 days).	monitoring purposes. Use is limited by the indications for use of the connected monitoring or diagnostic equipment. These Philips leadsets are intended for short-term use only (an average patient stay of *5* days).	
Indications for Use	The subject device are indicated for use in the monitoring of cardiac signals for both diagnostic and monitoring purposes. Use is limited by the indications for use of the connected monitoring or diagnostic equipment.	Philips ECG leadsets are indicated for use in the monitoring of cardiac signals for both diagnostic and monitoring purposes. Use is limited by the indications for use of the connected monitoring or diagnostic equipment.	Same
Anatomical Sites	Attached to electrodes placed at standard specified locations on chest wall and extremities	Attached to electrodes placed at standard specified locations on chest wall and extremities	Same
Design /Appearance	Cables with "grabber/snap" configuration of ECG electrode connector (distal connector) and common "header" connection (proximal connector)	Cables with "grabber" configuration of ECG electrode connector (distal connector) and common "header" connection (proximal connector)	Same
Sterility	Supplied non-sterile;canot be sterilized or otherwise reprocessed	Supplied non-sterile;canot be sterilized or otherwise reprocessed	Same
Usage	Single patient use	Single patient use	Same
Material	PA66,PVC,ABS	PA66,PVC,ABS	Same
Cable Length	0.9m/3.4m	1.0m/0.85m	Similar
Cable Construction	Flexible shielded multi conductor electrical cable	Flexible shielded multi conductor electrical cable	Same
Wire Color	White	White	Same
Leadwire Construction	Shielded copper leadwire with polymer jacket	Ribbonized leads with individual coax shields	Same
Lead number	3,5&6	3,5	Similar

Proximal connector Design	Compatible to MultiLink yoke design	Compatible to MultiLink yoke design	Same
Distal connector Design	"Grabber"or"Snap"electrode connectors are labeled LL(red),RA(white),RL(green) ,LA(black)&,V(brown)	"Grabber" electrode connectors are color coded (red, white, green, coded (red, white, green, black, brown) Connector designations (LL,RL etc.) molded into plastic	Similar
Conformance standard	IEC60601-1(Safety) EC53(Performance) ISO10993-5,-10(Biocompatibility)	IEC60601-1(Safety) EC53(Performance) ISO10993-5,-10(Biocompatibility)	Same

From the comparison form above, both devices have the same intended use ,indications for use, Anatomical Sites, Design /Appearance, Sterility, Usage, Material,Cable Construction, Wire Color& Conformance standard,have the similar cable length, Lead number& Distal connector Design item.

But in cable length, Lead number& Distal connector Design item,both devices have some difference, please see the following analysis.

Note1 Cable Length

The subject devices is longter than philips unit,but unimed units meet the requirements of EC53 and IEC60601-1, so this difference does not bring any safety and effectiveness problem.

Note2 Lead number

The subject devices have 6 lead type which fit the clinical use. Meanwhile the subject units meet the requirements of EC53 and IEC60601-1, so this difference also does not bring any safety and effectiveness problem.

Note3 Distal connector Design

In this item,the suject device have grabber type and snap type ,which is more suitable for clinical use.Futhermore, the subject devices meets meet the requirements of EC53 and IEC60601-1, so this difference also does not bring any safety and effectiveness problem.

9. Performance data

The subject device meets the following the recognized standards:

- ANSI/ANMM EC53-1995 (R)2001, R(2008) ECG Cables and Leadwires (except4.3.1)
- ANSI/AAMI EC13 Cardiac monitors, heart rate meters and alarms (only product markings, chapter 4.1.1.5),2002
- FR 898: Guidance Document on the Performance Standard for Electrode Lead Wires and Patient Cables, May 11, 1998

- IEC 60601-1 Medical Electrical Equipment-Part 1: General Requirements for Safety, 1988+A1:1991+A2:1995
- ISO 10993-5, Biological evaluation of medical devices-Part 5: Tests for In Vitro cytotoxicity, 2009
- ISO 10993-10, Biological evaluation of medical devices-Part 10: Tests for irritation and delayed-type hypersensitivity, 2010

10. Substantial Equivalence Statement

Based on the comparison ,analysis, and the submitted performance data, unimed believes that the unimed disposable ECG Lead Wire is as safe and effective and is substantially equivalent to the predicate devices.