JAN 1 9 2012

510(K) Summary K120010

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR§807.92.

Submission Date: 20 March 2011

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Trade Name: Cable / lead-wire (ECG, EKG, SpO2 and Invasive Blood Pressure), models as below table:

Device Name / Type	Device Model
ECG cable and lead-wires	EA003S5A, EA010C5A, EA007C5A, EA050C5A, EA023C5A, EA035C3A,EA066S3A, EA009S5A, EC021-5AI,EC040S5A, EE007-5AI, EE051C5A, ED023-3AI, ED040C3A, ED040C5A,ED023-5AI, EP055-6AI, EP035S3A, EL009-5AI, EL040S5A, EC072M5I, EC072M5A, EC072S5I, EC072S5A
EKG cable and lead-wires	VA008BBA, VA018BCA, VA005BBA, VA001BNA, VA021BBA, VA025BAA, VE008-BAI, VE008BNA,
Invasive Blood Pressure cables	X0014A, X0014B, X0015A, X0015B, X0018D, X0018F,
SpO2 adapter cables	S0052BC-L, S0036BC-L, S0014OH-L, S0099BC-L, S0002NE-L,S0020CO-L, S0125CO-L, S0010NE-L, S0026OX-L, S0117OX-L,S0005NI-L, S0015OX-L, S0003OX-L, S0072BC-L, S0004NE-L

Common Name: Cable / lead-wire

Classification Name: Patient Transducer and electrode cable (including connector)

Classification Regulation:	21 CFR 870.2900
Product Code:	DSA

Substantially Equivalent Devices:

Shenzhen Med-link Product Group	*Predicate 510(k) Number*	*Predicate Manufacturer*
Cable / Lead-wire	K082959	Unimed Medical Supplies Inc.
Cable / Lead-wire	K992524	Advantage Medical Cables, Inc

Device Description: Med-link Cable / Lead-wire with specific various lengths 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 Med-link cables use the same type of constructions and have the same technological characteristics as the predicate devices. They use a medical grade PVC and TPU cable jacket with medical grade PVC and ABS over molded connectors with integral relief.

Intended Use: Shenzhen Med-link Cable / lead-wire are intended to be used with ECG, EKG, SpO2 and Invasive Blood Pressure monitoring devices. The Cable / lead-wire 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.

Technology Comparison: Med-Link Cable / Lead-wire employ the same technological characteristics as the predicate device to determine the signals between the patient and monitoring Device.

This method is characteristic of all Cable / Lead-wire that is the subject of this submission as well as the predicate device.

Performance Testing:

Biocompatibility Testing Patient contact with materials used in Med-Link Cable / lead-wire were tested in accordance with *ISO 10993-5:1999 Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity and ISO 10993-10:2002/Amd1:2006 Biological evaluation of medical devices - Part 10: Tests for irritation and delayed-type hypersensitivity - Amendment 1.*

Test results indicated that the patient contact material were

	non-toxic, non-sensitizing and non-irritating.
Electrical Safety	Med-Link Cable / Lead-wire tested in accordance with applicable clause of *IEC 60601-1:1998; Am1; A2:1995, Medical electrical equipment-Part 1: General requirements for safety, ANSI/AAMI EC53:1995/(R) 2001 ECG cables and leadwires and FDA 21CFR Part 898 Final rule.*
Lead-wire to trunk cable interconnection	Med-Link Cable / Lead-wire were tested in accordance with *ANIS/AAMI EC53:1995 5/(R) 2001 ECG cables and lead wires* to ensure that the cable assemblies where the patient lead wires are separable from the trunk cable with a single unshielded conductor lead wire, the interconnection between the patient lead-wires and the trunk cable whether meet the requirements of DIN 42-802. Test results indicated that the cable / lead-wires comply with the applicable clause of the Standard.
Performance Testing - Clinical	Clinical performance testing is not required and was not performed to demonstrate safety and effectiveness of the Shenzhen Med-link cable / lead-wire.
Shelf Life Testing	Not Applicable: The Shenzhen Med-link cable / lead-wire are intended to be reusable.
Performance Testing - Bench	Bench testing was conducted on the Shenzhen Med-link cable / lead-wire according with established protocols and test results confirm that the final product met the requirements for the safety and performance standards and its intended use.
Performance Testing -Animal	Animal performance testing is not required and was not performed to demonstrate safety and effectiveness of the Shenzhen Med-link cable / lead-wire.

Comparison to Predicate Device:

The results of Comparison to Predicate Device as following:

Table 1—Comparison of cable / lead-wires has the same or similar technological characteristics as the predicate device.

Table 2—Comparison of Med-link cable / lead-wire has different technological characteristics from the predicate device.

Table 1—Comparison of cable / lead-wires has the same or similar technological characteristics as the predicate device.

Comparison Item	Shenzhen Med-link	Advantage medical	Unimed Medical
Indications	Shenzhen Med-link Cable / lead-wire are intended to be used with ECG, EKG, SpO2 and Invasive Blood Pressure monitoring devices. The Cable / lead-wire 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.	These patient cables and leadwires are intended to be used with ECG, EKG, SpO2 and Blood Pressure monitoring devices.	The Unimed patient cables and lead wires are intended to be used with ECG, EKG, SpO_2 and BP monitoring devices. The patient cables and lead wire 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.
Patent Usage	Reusable	Reusable	Reusable
Anatomical Sites	The ECG and EKG cable attached to sensors places at standard specified locations on the chest wall.	The ECG and EKG cable attached to sensors places at standard specified locations on the chest wall.	The ECG and EKG cable attached to sensors places at standard specified locations on the chest wall.
Design / Appearance	ECG and EKG Cables with various connectors (monitor, trunk / lead wire, electrode grabber & snapper)	ECG and EKG Cables with various connectors (monitor, trunk / lead wire, electrode grabber & snapper)	ECG and EKG Cables with various connectors (monitor, trunk / lead wire, electrode grabber & snapper)
	Invasive Blood Pressure cables with various connectors (Yoke type: Utah 4pin, Instrument connector: Spacelabs 6 Pin etc.)	Invasive Blood Pressure cables with various connectors (Yoke type: Utah 4pin, Instrument connector: Spacelabs 6 Pin etc.)	Invasive Blood Pressure cables with various connectors (Yoke type: Utah 4pin, Instrument connector: Spacelabs 6 Pin etc.)
	SpO2 adapter cables with various connectors for connect for the OEM Instrument connector of SpO2 monitor and SpO2 probe. (DB9F, Din 8Pin and Philips	SpO2 adapter cables with various connectors for connect for the OEM Instrument connector of SpO2 monitor and SpO2 probe. (DB9F, Din 8Pin and Philips round 8Pin etc.)	SpO2 adapter cables with various connectors for connect for the OEM Instrument connector of SpO2 monitor and SpO2 probe. (DB9F, Din 8Pin and Philips round 8Pin etc.)

	round 8Pin etc.)		
Cable length	Various specified standard lengths	Various specified standard lengths	Various specified standard lengths
Wire material	Shielded & Unshielded Copper with PVC or TPU Jacket	Shielded & Unshielded Copper with PVC Jacket	Shielded & Unshielded Copper with PVC Jacket
Sterility	Non sterile	Non sterile	Non sterile
Connector Retention Force	ANSI / AAMI EC53: 1995 /(R) 2001	ANIS/AAMI EC53-1995	ANIS / AAMI EC53A-1998(R)2001 EC53A-1998 (Amendment)
Electrical Performance and Safety	ANSI / AAMI EC53: 1995 /(R) 2001 and IEC 60601-1:1998; Am1; A2:1995	ANSI / AAMI EC53-1995 and IEC 60601-1:1998;Am1; A2:1995	ANSI / AAMI EC53A-1998(R) 2001 and IEC 60601-1: 1998; Am1; A2:1995

Table 2—Comparison of Med-link cable / lead-wire has different technological characteristics from the predicate device.

Item	**Med-link models**	**Predicate device Model**		**Contrast results**		
		AMC	**Unimed Medical**	**Med-link**	**AMC**	**Unimed Medical**
Cable length	EA003S5A	CB-72500R/90	2540S	L:3.6m	L:3.0m	L:3.4m
	EC021-5AI	CB-82516R	/	L:2.7m	L:3.0m	/
	EC040S5A	LW-26000MX/5A	D5-90S	L:1.0m	L:0.74m	L:0.9m
	EC072M5A	W-26000MX/5A	D5-90S	L:0.72m	L:0.74m	L:0.9m
	VA008BBA	/	E10-MQ12-B	L:3.06m	/	L:3.7m
	VE008-BAI	CB-5110006	/	L:2.2m	L:3.0m	/
	X0015B	CB-91068	BC-6P-UT	L:3.6m	L:3.0m	L: 4.0m
	S0052BC-L	CB-A400-1004A	/	L:2.4m	L:3.0m	/
	S0015OX-L	CB-A400-1006VM	U708-40	L:2.4m	L:2.4m	L:2.2m

Conclusion:

- Shenzhen Med-link design is equivalent to predicate devices cleared to market under 510(k) K082959 and K992524.
- Electrical safety and bench Testing confirms that Subject device performs as intended.
- The proposed device does not raise new issues of safety and effectiveness.
- The proposed device is deemed safe and effective for its intended use.
- The bench testing can be fully proved that the different wire length of subject device detailed as table 2 which have not produce new issue to affect the safety and effectiveness.

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

JAN 19 2012

Shenzhen Med-Link Electronics Tech., Co., Ltd.
c/o Ms. Paula Wilkerson
Responsible Third Party Official
Intertek Testing Services NA
2307 E. Aurora Rd., Unit B7
Twinsburg, OH 44087

Re: K120010
Trade/Device Name: Cable/Lead-Wire (ECG, EKG, SpO2 and Invasive Blood Pressure)
Regulatory Number: 21 CFR 870.2900
Regulation Name: Patient transducer and electrode cable (including connector)
Regulatory Class: II (two)
Product Code: DSA
Dated: December 20, 2011
Received: January 3, 2012

Dear Ms. Wilkerson:

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 (if known): K 120010

Device Name: Cable / lead-wire (ECG, EKG, SpO2 and Invasive Blood Pressure), models as below table:

Device Name / Type	Device Model
ECG cable and lead-wires	EA003S5A, EA010C5A, EA007C5A, EA050C5A, EA023C5A, EA035C3A,EA066S3A, EA009S5A, EC021-5AI,EC040S5A, EE007-5AI, EE051C5A, ED023-3AI, ED040C3A, ED040C5A,ED023-5AI, EP055-6AI, EP035S3A, EL009-5AI, EL040S5A, EC072M5I, EC072M5A, EC072S5I, EC072S5A
EKG cable and lead-wires	VA008BBA, VA018BCA, VA005BBA, VA001BNA, VA021BBA, VA025BAA, VE008-BAI, VE008BNA,
Invasive Blood Pressure cables	X0014A, X0014B, X0015A, X0015B, X0018D, X0018F,
SpO2 adapter cables	S0052BC-L, S0036BC-L, S0014OH-L, S0099BC-L, S0002NE-L,S0020CO-L, S0125CO-L, S0010NE-L, S0026OX-L, S0117OX-L,S0005NI-L, S0015OX-L, S0003OX-L, S0072BC-L, S0004NE-L

Indications of Use: Shenzhen Med-link Cable / lead-wire are intended to be used with ECG, EKG, SpO2 and Invasive Blood Pressure monitoring devices. The Cable / lead-wire 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 √ AND/OR Over-The-Counter Use_____

(Part 21 CFR 801 Subparts D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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(Division Sign-Off)
Division of Cardiovascular Devices

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