K112544

NOV 22 2011

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

Section 3 510(K) Summary

Summary prepared Date: April 2, 2011

Submitter Information:

Unimed Medical supplies Inc.

No.37, Yanshan Road, Shekou, Shenzhen, China 518067

Contact Person:

Xinmei Tan, QA manager

No.37, Yanshan Road, Shekou, Shenzhen, China 518067

Tel: (86) 755 26695165

Fax: (86) 755 26697984

Email: info@unimed.cn, tanxinmei1979@163.com

Device Name

Trade Name: Unimed Blood Pressure Cuff

Common Name: Non-invasive Blood pressure cuff

Product Code/Classification: DXQ/21 CFR870.1120

Review Panel: Cardiovascular

Predicate Device

Sensa-Cuff (K022482)

GE Medical Systems Information Technologies

Intended Use

The Unimed Blood Pressure Cuff is an accessory used in conjunction with non-invasive

blood pressure measurement systems. The cuff is non-sterile and may be reused. It is available in pediatric and adult sizes. The cuff is not designed, sold, or intended for use except as indicated.

Device Description

The device comprises tubing attached to an inelastic sleeve with an integrated inflatable bladder that is wrapped around the patient's limb and secured by hook and loop closure. The device tubing is connected to a non-invasive blood pressure measurement system.

Comparison to the Predicate Device

Features	**Unimed Medical**	**GE Medical**
Intended use	Indirect measurement of blood pressure	Indirect measurement of blood pressure
Patient Populations	Adults/Pediatrics	Adults/Pediatrics
Material	Cuff: PU Synthetic Leather Bladder: Transparent Polyurethane (TPU Film) Tubing: PVC Hook: Molded Nylon Loop: Nylon	Cuff: Woven nylon Film (bladder): Ethylene vinyl acetate copolymer (EVA) Tubing: PVC Ribbon: Textured polyester Hook: Molded Nylon Loop: Nylon
Tube Configuration	One or two tube	One or two tube
Size (Range in cm)	Conform to AHA bladder sizes recommendations Neonatal (6-11cm) Infant (10-19cm)	Conform to AHA bladder sizes recommendations Infant (8-13cm) Child (12-19cm)

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	Pediatric (18-26cm) Small Adult (20-28cm) Adult (25-35cm) Adult Long (25-35cm) Large Adult (33-47cm) Large Adult Long (33-47cm) Adult Thigh (46-66cm)	Small Adult (17-25) Adult (23-33cm) Large Adult (31-40cm) Thigh (38-50cm)
Repeated inflation	10,000 inflations 3,000 hook and loop closures	10,000 inflations 3,000 hook and loop closures
Pressure limits	0-300mmHg	0-300mmHg
Sterility	Non-sterile	Non-sterile
Biocompatibility	Comply with ISO 10993 biocompatibility evaluation	Comply with ISO 10993 biocompatibility evaluation

The Unimed Blood Pressure Cuff has the same Intended Use, basic construction, and technology specification as the predicated device. Both devices are wrapped the patient's arm or leg and secured by a hook and loop fastener commonly called Velcro. Both devices are available in the same size and range and are intended for the same patient populations.

(1) Material: Although the patient materials for subject device and predicate device are not all the same, but they are all conformed to ISO 10993.

(2) Size: We extend the length of the cuffs in order to accommodate special groups, such as neonates and overweight subjects. Based on the performance testing in this submission, the slight difference on the range of these blood pressure cuffs does not raise any safety or effectiveness issue.

Performance Summary

The Unimed Blood Pressure Cuff has been tested according to the following standards:

- ANSI/AAMI SP10, Manual, electronic or automated sphygmomanometers, 2002+A1:2003+A2:2006+(R)2008
- ISO 10993-1, Biological evaluation of medical devices -- Part 1: Evaluation and testing, 2003
- 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, 2002+A1:2006

Conclusion

The subject device Unimed Blood Pressure Cuff has all features of the predicate device. The few differences do not affect the safety and effectiveness of the subject devices.

Thus, the subject device is substantially equivalent to the predicate device.

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

Unimed Medical Supplies, Inc.
c/o Mr. Clare He
Underwriters Laboratories Inc.
Electronic Building, Parage Electronic Industrial Park
No. 8 Nanyun Er Road, Gangzhou 510663
CHINA

NOV 22 2011

Re: K112544
Trade/Device Name: Unimed Blood Pressure Cuffs: U1883S, U1883D, U1882S, U1882D, U1881S, U1881D, U1885S, U1885D, U1880S, U1880D, U1886S, U1886D, U1869S, U1869D, U1889S, U1889D, U1884S, and U1884D (18 models)
Regulatory Number: 21 CFR 870.1120
Regulation Name: Blood Pressure Cuff
Regulatory Class: Class II (Two)
Product Code: DXQ
Dated: November 4, 2011
Received: November 8, 2011

Dear Mr. He:

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,

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 4 Indications for Use Statement

510(k) Number: K112544

Device Name: Unimed Blood Pressure Cuff

Indications for Use

The Unimed Blood Pressure Cuff is an accessory used in conjunction with noninvasive blood pressure measurement systems. The cuff is non-sterile and may be reused. It is available in pediatric and adult sizes. The cuff is not designed, sold, or intended for use except as indicated.

Prescription Use __X__ AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Sub part 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

510(k) Number K112544