K121427

MAY 29 2012

Unimed Medical Supplies Inc
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Section 5 510(K) Summary

Date: 2012-01-15

Submitter Information:

Unimed Medical supplies Inc.

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Proposed Device:

Trade Name: Unimed Temperature Probe (Unimed Skin Temperature Probe, Unimed General Purpose Temperature Probe)

Common Name: Temperature Probe

Product Classification: FLL; 880.2910; Class II

Classification Panel: General Hospital

Model	Name
T2252-AS	Unimed Skin Temperature Probe
THP-AS	Unimed Skin Temperature Probe
TMQ-AS	Unimed Skin Temperature Probe
TSW-AS	Unimed Skin Temperature Probe
TSM-15AS	Unimed Skin Temperature Probe
TSL-AS	Unimed Skin Temperature Probe
TMR-AS	Unimed Skin Temperature Probe
T2252-AG	Unimed General Purpose Temperature Probe
THP-AG	Unimed General Purpose Temperature Probe
TMQ-AG	Unimed General Purpose Temperature Probe
TSW-AG	Unimed General Purpose Temperature Probe

TSM-15AG	Unimed General Purpose Temperature Probe
TSL-AG	Unimed General Purpose Temperature Probe
TMR-AG	Unimed General Purpose Temperature Probe

Predicate Device:

YSI 400 Series Autoclavable Temperature Probe (K962070)

GE Reusable Temperature Probes (K050837)

Indications for use

Unimed Temperature Probes are intended to be used for monitoring temperature. The temperature probes are reusable and designed for use with monitors of Philips, Marquette, Mindray, Spacelabs, Siemens, Artema/S&W and other monitors compatible with YSI 400 series temperature probes.

These devices are indicated for used by qualified medical personnel only.

Device description

Unimed Skin Temperature Probe (T2252-AS, THP-AS, TMQ-AS, TSW-AS, TSM-15AS, TSL-AS, TMR-AS), and Unimed General Purpose Temperature Probe (T2252-AG, THP-AG, TMQ-AG, TSW-AG, TSM-15AG, TSL-AG, TMR-AG) are used during patient temperature measurement. These probes consist of a connector on the monitor end and a thermistor on the patient end. These probes are to be used with YSI 400 series compatible temperature measurement systems only.

Temperature probes measure temperature by a resistor that is sensitive to temperature changes.

The probe is connected to the monitor either directly by using the connector or by an extension cable. These probes have a skin or core contact with a patient.

Summary of technological characteristics of device compared to the predicate device

The Unimed temperature probes are substantially equivalent in safety and effectiveness to the predicate YSI temperature probes (K962070) and GE temperature probes (K050837).

They have the same thermistor, accuracy in 25-45℃ range and they all apply to

monitors compatible with YSI temperature probes and GE temperature probes. They are different in labeling, cable material, plug material, cable length.

From the biocompatibility test, safety test and other bench tests, these differences will not bring any safety and effectiveness problem.

In summary, Unimed temperature probes, described in this submission are substantially equivalent to the predicate YSI temperature probes (K962070) and GE temperature probes (K050837).

Performance data

Bench and laboratory testing to demonstrate safety and effectiveness per:

IEC 60601-1 Medical Electrical Equipment - Part 1: General Requirements for Safety, 1988; Amendment 1:1991; Amendment 2:1995

EN 12470-4:2000+A1:2009 Clinical thermometers - Part 4: Performance of electrical thermometers for continuous measurement

ISO 10993-5:2009 Biological evaluation of medical devices - Part 5: Tests for In Vitro cytotoxicity

ISO 10993-10:2002+A1:2006 Biological evaluation of medical devices - Part 10: Tests for irritation and delayed-type hypersensitivity

Conclusion:

Unimed Temperature Probes have the same intended use, the same technology as the predicate devices. They are claimed to be Substantially Equivalent to the predicate devices.

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. Jeffrey D. Rongero
Responsible Third Party Official
Underwriters Laboratories, Inc.
12 Laboratory Drive
Research Triangle, North Carolina 27709

MAY 29 2012

Re: K121427
Trade/Device Name: Unimed Temperature Probe
Regulation Number: 21 CFR 880.2910
Regulation Name: Clinical Electronic Thermometer
Regulatory Class: II
Product Code: FLL
Dated: May 14, 2012
Received: May 14, 2012

Dear Mr. Rongero:

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 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,

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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Section 4 Indications for Use

510(k) Number: K121427

Device Name: Unimed Temperature Probe
Skin Types: T2252-AS, THP-AS, TMQ-AS, TSW-AS, TSM-15AS, TSL-AS, TMR-AS;
General Purpose Types: T2252-AG, THP-AG, TMQ-AG, TSW-AG, TSM-15AG, TSL-AG, TMR-AG

Indications for Use

Unimed Temperature Probes are intended to be used for monitoring temperature. The temperature probes are reusable and designed for use with monitors of Philips, Marquette, Mindray, Spacelabs, Siemens, Artema/S&W and other monitors compatible with YSI 400 series temperature probes.
These devices are indicated for used by qualified medical personnel only.

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)

5/29/12
(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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