DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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JAN 1 0 2017

Ms. Cynthia Engelhardt
Regulatory Affairs Specialist
Smiths Medical ASD, Incorporated
160 Weymouth Street
Rockland, Massachusetts 02370

Re: K072080
Trade/Device Name: Normoflo® Irrigation Warming Set
Regulation Number: 21 CFR 880.5725
Regulation Name: Infusion Pump
Regulatory Class: Class II
Product Code: LGZ
Dated: May 2, 2008
Received: May 5, 2008

Dear Ms. Engelhardt:

This letter corrects our substantially equivalent letter of June 2, 2008.

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 Parts 801 and 809); 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 Parts 801 and 809]), 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" (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 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,

Erin I. Keith -S

Erin I. Keith, M.S.
Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

SECTION 4, Indications for Use Statement

Indications for Use

510(k) Number (if known): K972080

Device Name: **Normoflo® Irrigation Warming Set**

Indications for Use:

The Level 1® NORMOFLO® Irrigation Warming Set (Disposable Set) is a disposable irrigating fluid administration set, designed for use by trained medical professionals, for warming irrigating fluids. The Disposable Set is intended for use with the Level 1® H-1100 series NORMOFLO® Irrigation Fluid Warmers only.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (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)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K972080

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SECTION 5, 510(k) Summary

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Contact: Cynthia Engelhardt
Regulatory Affairs Specialist

Summary Prepared: July 27th, 2007

Product Name:

Trade Name: NORMOFLO® Irrigation Fluid Warmer Model H-1100;
NORMOFLO® Irrigation Fluid Warmer Model H-1129;
NORMOFLO® Irrigation Warming Set

Common Name: Irrigation Fluid Warmer and Irrigation Warming Set

Classification Name: Warmer, Thermal, Infusion Fluid (Unclassified, Product Code LGZ)

Predicate Device(s):

K936223 Smiths Medical ASD, Inc. (formerly Level 1 Inc.), Pressure Irrigating System.
K873435 Smiths Medical ASD, Inc. (formerly Level 1 Inc.), Level 1 IR-600 Normothermic Irrigating Set
K060939 Arizant Healthcare Inc. Ranger Irrigation Fluid Warming System

Device Description:

The Level 1® NORMOFLO® Irrigation Fluid Warmer has been designed for safe, rapid, in-line warming of irrigating fluids as they are administered to patients. This method employs single-use, disposable, irrigating sets that include a Heat Exchanger and may include a Gas Vent. The gas vent releases micro-bubbles of gas from fluids as they are warmed.
The Irrigation Fluid Warmer employs a safe re-circulating solution heating system, inherently free of any "hot spots". The primary temperature control circuit sets the recirculating solution to a temperature of approximately 41.7°C for efficient heat exchange and maximum fluid warming.
The H-1129 provides pressurized fluid delivery through the use of an on-board compressor and two 3-Liter (3L) pressure chambers. The pressure chambers pressurize the fluid bags for fast fluid delivery. A control panel on each pressure chamber displays the pressure in the chamber. A pressure regulator knob lets you select the desired pressure; a dial gauge displays the selected pressure.

There are 6 Irrigation Fluid Warming sets available for use on the Irrigation Fluid Warming units. Y-set adapters are available to adapt from 2 spike sets to 4.

Indications for Use:

NORMOFLO® Irrigation Fluid Warmer

The Level 1® NORMOFLO® Irrigation Fluid Warmer (Fluid Warmer) is designed for use by trained medical personnel for in-line warming of irrigating fluids.

NORMOFLO® Irrigation Warming Set

The Level 1® NORMOFLO® Irrigation Warming Set (Disposable Set) is a disposable irrigating fluid administration set, designed for use by trained medical professionals, for warming irrigating fluids. The Disposable Set is intended for use with the Level 1® H-1100 series NORMOFLO® Irrigation Fluid Warmers only.

Technological Characteristics:

The technological characteristics of the NORMOFLO® Irrigation Fluid Warmer and Irrigation Warming Set are substantially equivalent to the predicate devices; Smiths Medical ASD, Inc. (formerly Level 1 Inc.), Pressure Irrigating System (K936223), Smiths Medical ASD, Inc. (formerly Level 1 Inc.), Level 1 IR-600 Normothermic Irrigating Set (K873435) and Arizant Healthcare Inc. Ranger Irrigation Fluid Warming System (K060939) in terms of:

- Irrigation fluid warmer to warm the fluid to normothermic temperatures
- Variable pressure of the output fluid to patient

All statements and representations set forth herein regarding or related to "substantially equivalent" or "substantial equivalence" are in the limited context of the definition and purpose of substantial equivalence in the Federal Food, Drug, and Cosmetic Act, as amended, and applicable regulations of the Food and Drug Administration, and are not made in the context of, for any purpose related to, or as an admission against interest under, any other laws or regulations, including patent laws (whether in the context of patent infringement or otherwise).

Non-Clinical Data:

Non-clinical performance testing has been performed to ensure the device is safe and effective and meets the clinical requirement of irrigation systems.

Clinical Data:

Clinical investigation of warming irrigation fluids for irrigation procedures was done in the form of clinician surveys to ensure the product meets the clinical guidance of the intended uses.

Conclusion:

The proposed device is safe and effective and is substantially equivalent to the predicate device.

Very truly yours,

SMITHS MEDICAL ASD, INC.

Cynthia Engelhardt
Regulatory Affairs Specialist