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

December 02, 2016

Stryker Medical
Brian Orwat
Sr. Staff Regulatory Affairs Specialist
3800 East Centre Avenue
Portage, Michigan 49002

Re: K152266
Trade/Device Name: Altrix Precision Temperature Management System
Regulation Number: 21 CFR 870.5900
Regulation Name: Thermal Regulating System
Regulatory Class: Class II
Product Code: DWJ, FLL
Dated: November 18, 2016
Received: November 21, 2016

Dear Brian Orwat:

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K152266

Device Name
Altrix Precision Temperature Management System

Indications for Use *(Describe)*

The Altrix system is intended for circulating temperature controlled warm or cold water via patient contact thermal transfer devices for the application of regulating human body temperature in situations where a physician or clinician with prescription privileges determines that temperature therapy is necessary or desirable.

Indications for use for the Altrix system include:
a. Maintain pre-set body temperature as determined by the physician
b. Maintain normal body temperature during surgical procedures
c. For use in all clinical settings including coronary care units, operating, recovery and emergency departments, burn units, and medical/surgical units
d. Adult and pediatric patients
e. Monitoring and controlling patient temperature
f. Temperature reduction in patients where clinically indicated, e.g. in hyperthermic patients

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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Medical

Section 5

510(k) Summary

Altrix Precision Temperature Management System

Submitter / 510(k) Holder

Name:	Stryker Medical
Address:	3800 E. Centre Ave Portage, MI 49002
Contact Person:	Brian L. Orwat
Telephone:	269 389 6817

Date Prepared:	August 10, 2015

Device Name

Proprietary Name:	Altrix Precision Temperature Management System
Catalog Number:	8001
Common/Usual Name:	Hyper/Hypothermia System
Classification Name:	Thermal Regulating System (21 CFR 870.5900)
Product Code:	DWJ
Regulation Class:	Class II
Review Panel:	Cardiovascular
Classification Name:	Clinical Electronic Thermometer (21 CFR 880.2910)
Product Code:	FLL
Regulation Class:	Class II
Review Panel:	General Hospital

Predicate Device

Stryker Medical claims substantial equivalence to Stryker Medical (previously Gaymar Industries Inc.) Medi-Therm Hyper/Hypothermia System cleared per K100585.

Device Description

The Altrix Precision Temperature Management System components include the controller, reusable hose set(s), thermal transfer devices, patient temperature probes and reusable adaptor cable(s). The controller regulates water temperatures between 4.0° C (39.2° F) and 40.0° C (104.0° F) and circulates the heated or cooled water via hose set(s) through the thermal transfer device(s). A graphical display provides the user an interface for selecting desired water or patient temperature settings, operating modes, help menus and other key parameters. Visual indicators are displayed to inform the user of system status or when the user must confirm a setting selection. The system's water temperature and flow outputs are monitored to ensure optimal system operation.

The controller can supply water to an individual or multiple thermal transfer devices simultaneously with each of these circuits monitored separately. Three operating modes are available to facilitate patient care: Automatic, Manual and Monitor. The patient temperature probe is used with the controller to provide closed loop feedback for automatic patient temperature management and monitoring. The controller alarms activate visual and audible indications for when safety parameters are exceeded or it detects system function or performance irregularities. The Altrix system also includes the ability to provide a patient temperature output reference signal to be connected to a non-specific third party device/system.

Indications for Use

The Altrix system is intended for circulating temperature controlled warm or cold water via patient contact thermal transfer devices for the application of regulating human body temperature in situations where a physician or clinician with prescription privileges determines that temperature therapy is necessary or desirable.

Indications for use for the Altrix system include:

a. Maintain pre-set body temperature as determined by the physician
b. Maintain normal body temperature during surgical procedures
c. For use in all clinical settings including coronary care units, operating, recovery and emergency departments, burn units, and medical/surgical units
d. Adult and pediatric patients
e. Monitoring and controlling patient temperature
f. Temperature reduction in patients where clinically indicated, e.g. in hyperthermic patients

Technological Characteristics and Substantial Equivalence Summary

Both Altrix and Medi-Therm share the same basic principles of operation. Altrix and Medi-Therm are temperature management systems that circulate temperature controlled water via centrifugal pump through a configurable combination of hoses connected to single or multiple thermal transfer devices which can be applied around, placed over or under a patient. Both systems use a heater to increase water temperature and a refrigeration system to decrease water temperature. Delivery and removal of thermal energy to and from the patient occurs at the contact point of the patient skin and thermal transfer device to raise or lower patient temperature. A patient temperature probe can also be used with each device to provide closed-loop feedback for patient temperature control capability.

Table 5-1 summarizes the main technological characteristics between Altrix and the predicate device.

Category	**Subject Device:** Altrix Precision Temperature Management System	**Predicate Device:** Medi-Therm Hyper/Hypothermia System	**Comparison**
510(k)		K100585	
General			
Indications for Use	The Altrix system is intended for circulating temperature controlled warm or cold water via patient contact thermal transfer devices for the application of regulating human body temperature in situations where a physician or clinician with prescription privileges determines that temperature therapy is necessary or desirable. a. Maintain pre-set body temperature as determined by the physician b. Maintain normal body temperature during surgical procedures c. For use in all clinical settings including coronary care units, operating, recovery and emergency departments, burn units, and medical/surgical units d. Adult and pediatric patients e. Monitoring and controlling patient temperature f. Temperature reduction in patients where clinically indicated, e.g. in hyperthermic patients	The Medi-Therm is intended for use in supplying warm or cold water at controlled temperatures via water circulating blankets or body wraps for the application of regulating patient temperature in situations where a physician determines that temperature therapy is necessary and desirable. a. To maintain pre-set body temperature as determined by the physician b. To maintain normal body temperature during surgical procedures c. For use in all hospital areas including invasive and coronary care units, in operating, recovery and emergency rooms, in burn units and on medical/surgical floors d. This system can be used with adult and pediatric patients e. Monitoring and controlling patient temperature f. Temperature reduction in patients where clinically indicated, e.g. in hyperthermic patients	Same
Anatomical Site	Trunk; upper and lower extremities	Trunk; upper and lower extremities	Same
Sterility	Accessory patient probes only	Non-sterile accessories	Different
Rx Only	Yes	Yes	Same

Voltage - AC/hertz	120/60	120/60	Same
Current (A)	12	11.5	Similar
Heat Source	500W Cartridge heater	500W Cartridge heater	Same
Circulating Fluid	Water	Water	Same
Flow Rate	1.2 L/Min (minimum)	1 L/Min (minimum)	Similar
Reservoir Volume	5.0 L	9.5 L	Different
Outlet Ports	3	2	Different
Control	Microprocessor	Microprocessor	Same
Modes	Automatic, Manual, Monitor	Automatic, Manual, Monitor	Same
Automatic Mode Warming Rates	Min, Med, Max, Custom	Gradual, Moderate, Rapid	Similar
Automatic Mode Cooling Rates	Min, Med, Max	Gradual, Moderate, Rapid	Same
Setting Range - Water Temperature	4.0 - 40.0^{o} C	4 - 42^{o} C	Different
Controller Accuracy - Water Temperature	± 0.3^{o} C	± 0.8^{o} C	Different
Display Accuracy - Water Temperature	±0.2^{o} C	± 0.3^{o} C	Different
Settings Range -Patient Temperature	32.0 - 38.0^{o} C	30 - 41^{o} C	Similar
Controller Accuracy - Patient Temperature	± 0.3^{o} C (25.0 ^{o} - 45.0^{o} C)	± 0.5^{o} C	Different
Patient Temperature Display Accuracy	± 0.3^{o} (25.0 ^{o} - 45° C)	± 0.3^{o} C	Same
Patient Temperature Output Capability	Yes	No	Different
Controller Dimensions	42.5" h x 23" d x 15" w	37”h x18.75”d x14”w	Similar

Weight (without water)	150 lbs	141 lbs	Similar
SAFETY			
Patient Probe Alarm	Yes	Yes	Same
Patient Temperature Deviation Alarm	Yes	No	Different
Normothermia Deviation Alarm	Yes	No	Different
High Water Temp Limits (software)	≥42.5° C	43° C	Similar
Water Temperature Deviation Alarm	Yes; ±0.8° C	No	Different
System Self-Test at Power-up	Yes	Yes	Same
Water Level Alarm	Yes	Yes	Same
Water Flow Alarm	Yes (for each water circuit)	Yes	Same
General requirements for basic safety and essential performance	Yes; ANSI/AAMI ES60601-1:2005 (R)2012 and A1 2012, C1: 2009/(R) 2012 and A2:2010/(R)2012	No; UL 416 (Refrigerated Medical Equipment)	Different
EMC/EMI	IEC60601-1-2	EN60601-1-2	Same
Basic Safety and Essential Performance for Heating Devices	IEC80601-2-35	No	Different
Basic Safety and Essential Performance of Clinical Thermometers	ISO 80601-2-56	No	Different
ACCESSORIES			
Patient Probes	400 series; Sterile; skin, rectal/esophageal, catheter	400 series; Non-sterile; skin, rectal/esophageal	Similar
Hose	Vinyl with Clik-tite connector and insulation sleeve; Vinyl with Colder connector and insulation sleeve	Vinyl with Clik-tite connector	Similar

Reusable Adapter Cable	Yes; with IEC compliant connector	Yes; with 1/4" phono connector	Similar
Patient Contact Device	Mul·T·Blankets; Rapr·Round Body Wraps	Mul·T·Blankets; Rapr·Round Body Wraps	Same

Table 5-1 – Altrix Predicate Comparison

The indications for use, basic design, operational and technical characteristics of the Altrix Precision Temperature Management System is substantially equivalent to the predicate Medi-Therm Hyper/Hypothermia System.

Bench and Standards Testing

Non-Clinical bench testing was successfully completed to verify Altrix's function and performance to specified requirements. Bench testing included warming and cooling performance, mechanical and thermal overload conditions, cleaning, controller abuse, environmental, fluid intrusion, and packaging.

Disinfection of the Altrix internal water system was validated using M. Mucogenicum. Additionally, Altrix was designed and/or tested to be in compliance with the relevant sections of the following standards.

- ISO 14971 Second Edition 2007-03-01 - Medical Devices - Application Of Risk Management To Medical Devices
- AAMI / ANSI ES60601-1:2005/(R)2012 And A1:2012, C1:2009/(R)2012 And A2:2010/(R)2012 - Medical Electrical Equipment - Part 1: General Requirements For Basic Safety And Essential Performance
- AAMI / ANSI / IEC 60601-1-2:2007/(R)2012 - Medical Electrical Equipment - Part 1-2: General Requirements For Basic Safety And Essential Performance - Collateral Standard: Electromagnetic Compatibility - Requirements And Tests
- IEC 60601-1-6 Ed 3.0 - 2010-01- Medical Electrical Equipment -- Part 1-6: General Requirements For Basic Safety And Essential Performance -- Collateral Standard: Usability
- IEC 60601-1-8 Ed 2.1 - 2012-11- Medical Electrical Equipment - Part 1-8: General Requirements For Basic Safety And Essential Performance - Collateral Standard: General Requirements, Tests And Guidance For Alarm Systems In Medical Electrical Equipment
- IEC 60601-1-10 Ed 1.0 - 2007-11 - Medical Electrical Equipment - Part 1-10: General Requirements For Basic Safety And Essential Performance - Collateral Standard: Requirements For The Development Of Physiologic Closed-Loop Controllers
- IEC 80601-2-35 Ed 2.0 - 2009-10 - Medical Electrical Equipment - Part 2-35: Particular Requirements For The Basic Safety And Essential Performance Of Heating Devices Using Blankets, Pads Or Mattresses And Intended For Heating In Medical Use
- IEC 62304 First Ed - 2006-05- Medical Device Software - Software Life Cycle Processes
- AAMI / ANSI / ISO 15223-1:2012 - Medical devices -- Symbols to be used with medical device labels, labeling and information to be supplied -- Part 1: General requirements

- AAMI / ANSI / IEC 62366:2007/(R) 2013 - Medical Devices - Application Of Usability Engineering To Medical Devices.
- ISO 80601-2-56 First Ed 2009-10-01- Medical Electrical Equipment - Part 2-56: Particular Requirements For Basic Safety And Essential Performance Of Clinical Thermometers For Body Temperature Measurement
- AAMI / ANSI / ISO 10993-1:2009/(R) 2013 - Biological Evaluation Of Medical Devices -- Part 1: Evaluation And Testing Within A Risk Management Process
- AAMI / ANSI / ISO 10993-5:2009/(R) 2014 - Biological Evaluation Of Medical Devices -- Part 5: Tests For In Vitro Cytotoxicity
- AAMI / ANSI / ISO 10993-10:2010 - Biological Evaluation Of Medical Devices - Part 10: Tests For Irritation And Skin Sensitization

The results of the non-clinical bench and standards testing provides evidence of Altrix's substantial equivalence when compared to the predicate device.

Clinical testing was determined not to be required to prove Altrix's substantial equivalence when compared to the predicate device.

Conclusion

The Altrix Precision Temperature Management System has been designed, tested and confirmed to comply with recognized safety and performance standards applicable to medical devices.

Based on Altrix's technological characteristics, completed non-clinical bench testing and comparison with the predicate device, we conclude that Altrix performs as well or better and is substantially equivalent to the predicate Medi-Therm device.