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

July 18, 2017

Stryker Medical
Brian Orwat
Principal Regulatory Affairs Specialist
3800 East Centre Avenue
Portage, Michigan 49002

Re: K171149
Trade/Device Name: Altrix Temperature Management Wraps
Regulation Number: 21 CFR 870.5900
Regulation Name: Thermal Regulating System
Regulatory Class: Class II
Product Code: DWJ
Dated: April 17, 2017
Received: April 19, 2017

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,

for Kenneth J. Cavanaugh -S

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)*
K171149

Device Name
Altrix Temperature Management Wraps

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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stryker

Section 5

510(k) Summary

Altrix Temperature Management Wraps

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:	April 12, 2017

Device Information

Proprietary Name:	Altrix Temperature Management Wraps
Catalog Number:	8003
Common/Usual Name:	Thermal Regulating System
Classification Name:	Thermal Regulating System (21 CFR 870.5900)
Product Code:	DWJ
Regulation Class:	Class II
Review Panel:	Cardiovascular

Purpose of Traditional 510(k)

The purpose of this 510(k) is to add the accessory patient contacting Altrix Temperature Management Wraps (“Wraps”) for use with the Altrix Precision Temperature Management System.

Predicate Device

Rapr·Round accessory of the Altrix Precision Temperature Management System - K152266 Stryker Medical

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

Device Description

The Altrix Temperature Management Wraps are the patient contact accessory for the Altrix Precision Temperature Management System. The Wraps are applied around the patient's thigh and torso. The Wraps are made from multiple layers of materials sealed together. A hose is used to connect the Wraps to the Altrix controller device.

Technological Characteristics Predicate Comparison Summary

Temperature controlled water is circulated through the Wraps and Rapr·Round which are applied around the patient for the purpose of thermal regulation through conduction. The Wraps include layers of thin polymer film, nonwoven and insulation materials sealed together to create channels for water flow. Insulated tubing protrudes from the Wraps which connect to hoses which terminate at the Altrix controller.

Table 5-1 summarizes the main technological characteristics between the Wraps and predicate Rapr·Round.

Table 5-1 – Predicate Comparison

Category	**Subject Device:** Altrix Temperature Management Wraps	**Predicate Device:** Altrix Precision Temperature Management System - Rapr·Round	**Comparison**
510(k)		K152266	
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		Same
Anatomical Site	Torso, Thigh		Same
Sterility	Non-sterile		Same
Material	Polymer film, nonwoven, insulation material	Polymer film, nonwoven	Different
Basic Safety and Essential Performance	ANSI/AAMI ES60601-1:2005 (R)2012 and A1 2012, C1: 2009/(R) 2012 and A2:2010/(R)2012		Same
Basic Safety and Essential Performance for Heating Devices	IEC80601-2-35: 2009		Same
Biocompatibility	ISO 10993-1; ISO 10993-5; ISO 10993-10		Same

Performance/Standards Testing

Non-Clinical bench testing was successfully completed to verify Altrix Wraps function and performance to specified requirements. Bench testing included temperature warming and cooling performance, mechanical overload conditions, environmental, and packaging.

Additionally, Altrix Wraps were 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

- 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
- 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 / 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 concluded Altrix Wraps are substantially equivalent to the predicate device.

Clinical testing was determined not to be required to prove substantial equivalence to the predicate device.

Substantial Equivalence Summary

The Altrix Wraps and Rapr·Round share the same basic principles of operation, intended/indications for use, basic design, operational and technical characteristics. The Altrix Wraps are substantially equivalent to the predicate Rapr·Round.

Conclusion

The Altrix Wraps have been designed, tested and confirmed to comply with recognized safety and performance standards applicable to this type of medical device.

Based on Altrix Wraps' technological characteristics, completed non-clinical bench testing and comparison with the predicate device, we conclude that Altrix Wraps are substantially equivalent to the predicate Rapr·Round device.