August 10, 2018

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

Re: K180834
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: July 6, 2018
Received: July 9, 2018

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Fernando Aguel -S

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K180834

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

Section 5

510(k) Summary

Altrix Precision Temperature Management System

Submitter / 510(k) Holder

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

Date Prepared:	March 30, 2018

Device Information

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

Purpose of Traditional 510(k)

The purpose of this Traditional 510(k) is due to modifications of the Altrix software, minor components and labeling related to the modifications.

Predicate Device

Altrix Precision Temperature Management System - 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

Device Description

Altrix 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 - 40.0^{o} C 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.

Technological Characteristics Predicate Comparison Summary

The indications for use, basic functionality and technological characteristics of the subject and predicate devices are the same as cleared per K152266. Modifications to Altrix include:

- Patient temperature control algorithm
- Patient temperature deviation alarm configuration
- Water flow alarm configuration
- Minor component changes
- Various Operations Manual updates related to the modifications

Performance/Standards Testing

Software modifications were completed using a software development life cycle process in accordance with FDA recognized standard 13-32, ANSI AAMI IEC, 62304:2006, Medical device software - Software life cycle processes, and related guidances. Non-clinical bench testing was successfully completed to verify the software modifications meet specified requirements. Software modifications were also validated to user needs with acceptable results. Other modifications were also successfully verified to meet specified requirements. The results of the non-clinical bench testing concluded that the subject device is substantially equivalent to the predicate device.

Substantial Equivalence Summary

The Altrix predicate shares the same basic principles of operation, intended/indications for use, basic design, operational and technical characteristics. Altrix is concluded to be substantially equivalent to the predicate device.

Conclusion

Based on Altrix's technological characteristics, completed non-clinical bench testing and comparison with the predicate, it is concluded that the modified Altrix is substantially equivalent to the predicate device.