May 13, 2020

Stryker Sustainability Solutions
Mia McCorkel
Senior Regulatory Affairs Specialist
18101 W Drake Drive
Tempe, Arizona 85283

Re: K200205
Trade/Device Name: Reprocessed Advisor FL Circular Mapping Catheter, Sensor Enabled
Regulation Number: 21 CFR 870.1220
Regulation Name: Electrode Recording Catheter or Electrode Recording Probe
Regulatory Class: Class II
Product Code: NLH
Dated: April 14, 2020
Received: April 15, 2020

Dear Mia McCorkel:

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/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Mark Fellman
Assistant Director
Division of Cardiac Electrophysiology, Diagnostics
and Monitoring Devices
Office of Cardiovascular Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Model numbers intended for reprocessing:

Model Number	Description	Curve	Number of Loop Electrodes	Electrode Spacing	Loop Diameter
D-AVSE-DF10-F15	Bi-Directional Circular Mapping Catheter	DF	10	3-3-3	15
D-AVSE-DF10-F20	Bi-Directional Circular Mapping Catheter	DF	10	5-5-5	20

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)*

K200205

Device Name
Reprocessed Advisor FL Circular Mapping Catheter, Sensor Enabled

Indications for Use *(Describe)*
The Reprocessed Advisor FL Circular Mapping Catheter, Sensor Enabled is a sensor-enabled steerable electrophysiology catheter used for recording intracardiac signals and cardiac stimulation during diagnostic electrophysiology studies. The catheter can be used to map the atrial regions of the heart.

The catheter is used with the EnSite Precision System to combine and display magnetic processed patient positioning and navigation mapping information.

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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SECTION 5: 510(k) SUMMARY

Submitter:

Stryker Sustainability Solutions
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Contact:

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Date of Preparation: January 27, 2020

Name of Device:

Trade/Proprietary Name:	Reprocessed Advisor FL™ Circular Mapping Catheter, Sensor Enabled™
Common Name:	Diagnostic Electrophysiology Catheter, Electrode Recording Catheter or Electrode Recording Probe
Classification Information:	Cardiovascular (21 CFR § 870.1220, NLH, Class II)
Model Numbers:	D-AVSE-DF10-F15, D-AVSE-DF10-F20

Predicate Device:

Model Numbers	510(k) Number	510(k) Title	Original Manufacturer
D-AVSE-DF10-F15 D-AVSE-DF10-F20	K160335	Advisor FL Circular Mapping Catheter, Sensor Enabled	St. Jude Medical

Device Description:

The Reprocessed Advisor™ FL Circular Mapping Catheters, Sensor Enabled™ are steerable, flexible, insulated electrophysiology catheters constructed of thermoplastic elastomer material and noble metal electrodes. The shaft curvature is manipulated by the control mechanism located on the handle at the catheter's proximal end. To adjust the curve on the bi-directional catheter, use the actuator to deflect the catheter in either direction. The distal loop is oriented counter-clockwise as viewed from the handle.

This device is compatible with the EnSite Precision™ System which is a three dimensional (3-D) cardiac mapping system that combines impedance and magnetic field technology.

The model numbers included in the scope of this submission are as follows:

Model Numbers	Description	Curve	Loop Diameter
D-AVSE-DF10-F15	Reprocessed Advisor FL Circular Mapping Catheter, Sensor Enabled	DF	15mm
D-AVSE-DF10-F20	Reprocessed Advisor FL Circular Mapping Catheter, Sensor Enabled	DF	20mm

Intended Use:

The Reprocessed Advisor™ FL Circular Mapping Catheter, Sensor Enabled™ is a sensor-enabled steerable electrophysiology catheter used for recording intracardiac signals and cardiac stimulation during diagnostic electrophysiology studies. The catheter can be used to map the atrial regions of the heart.

The catheter is used with the EnSite Precision™ System to combine and display magnetic processed patient positioning and navigation mapping information.

Summary of Technological Characteristics:

The design, materials, and intended use of Reprocessed Advisor™ FL Circular Mapping Catheter, Sensor Enabled™ are equivalent to the predicate device. The mechanism of action of the reprocessed device is identical to the predicate device in that the same standard mechanical design, materials, and sizes are utilized. There are no changes to the claims, intended use, clinical applications, patient population, performance specifications, or method of operation. In addition, Stryker Sustainability Solutions' reprocessing of the device includes removal of adherent visible soil and decontamination. Each individual device is tested for appropriate function of its components prior to packaging and labeling operations.

Performance Data:

Bench and laboratory testing was conducted to demonstrate performance (safety and effectiveness) of the Reprocessed Advisor™ FL Circular Mapping Catheter, Sensor Enabled™. This included the following tests:

- Biocompatibility
- Validation of Reprocessing
- Sterilization Validation
- Functional Performance Testing
    - EEPROM verification
    - Location sensor testing
    - Visual inspection
    - Dimensional testing
    - Electrode continuity and isolation testing
    - Curve and in-plane deflection testing
    - Rigidity testing
    - Freedom from leakage

  - Tensile testing
  - Locking mechanism testing
- Electrical Safety Testing

The performance testing demonstrates that reprocessed devices are as safe and effective as the predicate and operate as originally intended.

The Reprocessed Advisor™ FL Circular Mapping Catheter, Sensor Enabled™ is reprocessed no more than one (1) time. Each reprocessed device is tracked with a serial number label which is affixed to the catheter shaft. Once the device reaches the maximum number or reprocessing cycles, it is rejected and taken out of service. Reprocessing is conducted only by Stryker Sustainability Solutions. Stryker Sustainability Solutions restricts its reprocessing to exclude devises previously reprocessed by other reprocessors.

Conclusion:

The results of bench and laboratory testing demonstrate that the Reprocessed Advisor™ FL Circular Mapping Catheters, Sensor Enabled™ are at least as safe and effective and perform as well as the identified legally marketed predicate device as described herein.