DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

December 13, 2016

St. Jude Medical
Tamara Stanczak
Principal Regulatory Affairs Specialist
5050 Nathan Lane
Plymouth, Minnesota 55442

Re: K160335
Trade/Device Name: Advisor FL Circular Mapping Catheter, Sensor Enabled
Advisor FL 15mm 12 Pole 333 Uni D
Advisor FL 20mm 12 Pole 555 Uni D
Advisor FL 15mm 12 Pole 333 Bi D
Advisor FL 20mm 12 Pole 555 Bi D
Regulation Number: 21 CFR 870.1220
Regulation Name: Electrode Recording Catheter Or Electrode Recording Probe
Regulatory Class: Class II
Product Code: DRF
Dated: September 26, 2016
Received: September 27, 2016

Dear Tamara Stanczak:

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.

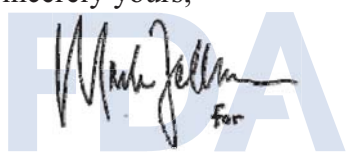
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply

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,



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)*
K160335

Device Name
Advisor™ FL, Circular Mapping Catheter, Sensor Enabled™

Indications for Use *(Describe)*
The 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.

The catheter is used with the MediGuide™ Technology system to enable real-time positioning and navigation. The MediGuide™ Technology system is indicated for use as an adjunct to fluoroscopy.

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.

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ST. JUDE MEDICAL

510(k) Summary	
510(k) Number	**K160335**
Submitter Information:	
Date Prepared:	December 13, 2016
Submitter Name & Address:	St. Jude Medical 5050 Nathan Lane Plymouth, MN 55442
Contact Person:	Tamara L Stanczak Principal Regulatory Affairs Specialist Phone (651) 756-6656 Fax (651) 756-3301 Tstanczak@sjm.com
Device Information:	
Trade Name:	Advisor™ FL, Circular Mapping Catheter, Sensor Enabled™
Common Name:	Diagnostic Electrophysiology Catheter
Class:	II, 870.1220, Product Code DRF
Models	Advisor FL 15mm 12 Pole 333 Uni D Advisor FL 20mm 12 Pole 555 Uni D Advisor FL 15mm 12 Pole 333 Bi D Advisor FL 20mm 12 Pole 555 Bi D
Classification Name:	Electrode recording catheter or electrode recording probe
Primary Predicate Device:	Inquiry AFocus II (K042775)
Secondary Predicate Device:	MediGuide Enabled Livewire Steerable Electrophysiology Catheter (K101955)
Device Description:	Advisor FL Circular Mapping Catheter, Sensor Enabled (Advisor FL, SE) is a circular mapping catheter for performing electrophysiology mapping procedures and providing pacing signals to the heart during electrophysiology procedures. The catheter handle and shaft design allows for improved maneuverability. A magnetic sensor in the distal shaft pocket provides compatibility with visualization and navigation systems. The catheter is compatible with SJM's EnSite™ Precision™ Cardiac Mapping system or MediGuide™ System (MG).
Intended Use: (Indications for Use)	The 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. The catheter is used with the MediGuide™ Technology system to enable real-time positioning and navigation. The MediGuide™ Technology system is indicated for use as an adjunct to fluoroscopy.

510(k) Summary	
510(k) Number	**K160335**
Comparison to Predicate Devices	The Advisor FL, SE has the same intended use and fundamental scientific technology as the predicate devices. The technological characteristics of the Advisor FL,SE are substantially equivalent to the predicate device including packaging, biocompatibility, sterilization, and labeling. Bench and animal testing demonstrated that the subject device is substantially equivalent to the predicate device.
Summary on Non-Clinical Testing	Bench and animal testing was performed to verify the device met the pre-determined acceptance criteria. The following tests were performed: • Patient Leakage • Dielectric Strength • Defibrillation Protection • Anchorage Flex • Handle Push • Radiopacity • Biocompatibility • Surface • Corrosion Resistance • Tensile • Loop Characteristics • Shaft Properties • Functional • Functional Simulated Use • Electrical Properties • Visualization and Navigation • Sterilization/ Microbiology • Packaging • Shelf Life • GLP Animal Safety
Statement of Equivalence	The Advisor FL, SE has the same indications for use and technological characteristics as the predicate devices. Based on this and the data provided in this pre-market notification, the subject device and predicate device has been shown to be substantially equivalent.