



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

April 1, 2015

St. Jude Medical
Harlan Jones
Sr. Regulatory Affairs Specialist
14901 De Veau Place
Minnetonka, Minnesota 55345-2126

Re: K150631

Trade/Device Name: St. Jude Medical MediGuide Enabled Livewire Steerable
Electrophysiology Catheter
Livewire Steerable Electrophysiology Catheter

Regulation Number: 21 CFR 870.1220

Regulation Name: Electrode Recording Catheter or Electrode Recording Probe

Regulatory Class: Class II

Product Code: DRF

Dated: March 10, 2015

Received: March 11, 2015

Dear Harlan Jones:

We have reviewed your Section 510(k) premarket notification of intent to market the devices referenced above and have determined the devices are 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 devices, 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 devices are 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,


Shawn W. Forrest -S

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K150631

Device Name: St. Jude Medical MediGuide Enabled Livewire Steerable Electrophysiology Catheter

Indications for Use:

- The SJM™ Livewire™ Diagnostic Catheter, MediGuide Enabled™ can be used with evaluation of a variety of cardiac arrhythmias from endocardial and intravascular sites.
- The Livewire™ Diagnostic Catheter, MediGuide Enabled™ is compatible with MediGuide™ Technology to enable real-time tip positioning and navigation.
- The MediGuide™ Technology is indicated for use as an adjunct to fluoroscopy.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

INDICATIONS FOR USE

510(k) Number (if known): K150631

Device Name: Livewire™ Steerable Electrophysiology Catheter

Indications for Use:

St. Jude Medical (SJM™) Livewire™ Steerable Electrophysiology Catheter can be used in the evaluation of a variety of cardiac arrhythmias from endocardial and intravascular sites.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

St. Jude Medical – 510(k) Summary

510(k) Summary	
510(k) Number	K150631
Submitter Information:	
Date Prepared:	06 March 2015
Submitter Name & Address:	St. Jude Medical - Atrial Fibrillation Division 14901 DeVeau Place Minnetonka, MN 55345 Establishment Registration Number: 3005188751
Contact Person:	Harlan Jones Senior Regulatory Affairs Specialist Phone (651) 756-3429 Fax (651) 756-3298 HJones02@sjm.com
Device Information:	
Trade Name:	St. Jude Medical MediGuide Enabled Livewire Steerable Electrophysiology Catheter
Common Name:	Diagnostic Electrophysiology Catheter
Classification Name:	Electrode recording catheter or electrode recording probe
Class:	Class II, 21 CFR 870.1220, Product Code DRF
Predicate Device:	St. Jude Medical MediGuide Enabled Livewire Steerable Electrophysiology Catheter (K101955)
Device Description:	<p>The MediGuide Enabled Livewire Steerable Electrophysiology Catheter is designed to allow electrophysiological mapping at various endocardial and intravascular sites including the inferior vena cava, superior vena cava, pulmonary veins and coronary sinus.</p> <p>The use of the MediGuide Enabled Livewire diagnostic mapping catheter in conjunction with the MediGuide gMPS system allows real-time tip positioning and navigation during routine diagnostic evaluation.</p> <p>When connected to the ECG, the MediGuide Enabled Livewire Catheter will transmit routine electrical signals while the passive sensor at the tip of the catheter is tracked by gMPS and is superimposed on any 2D X-ray image in real time (“Live”) fluoroscopy mode (the actual 3D position of the catheter tip is projected on the real time 2D image).</p>
Intended Use: (Indications for Use)	<ul style="list-style-type: none"> • The SJM™ Livewire™ Diagnostic Catheter, MediGuide Enabled™ can be used in the evaluation of a variety of cardiac arrhythmias from endocardial and intravascular sites. • The Livewire™ Diagnostic Catheter, MediGuide Enabled™ is compatible with MediGuide™ Technology to enable real-time

	<p>tip positioning and navigation.</p> <ul style="list-style-type: none"> The MediGuide™ Technology is indicated for use as an adjunct to fluoroscopy.
Comparison to Predicate Devices	The MediGuide Enabled Livewire Steerable Electrophysiology Catheter that is the subject of this application remains substantially equivalent to the predicate device. The changes made to the buckle force requirement do not alter the fundamental design, packaging, biocompatibility, sterilization or labeling.
Summary on Non-Clinical Testing	Historical bench test data for buckle force was evaluated to set the proposed buckle force specifications.
Statement of Equivalence	The MediGuide Enabled Livewire Steerable Electrophysiology Catheter that is the subject of this application has the same indications for use and technological characteristics as the predicate device. Based on this and the data provided in this pre-market notification, the subject device remains substantially equivalent to the predicate device.
Device Information:	
Trade Name:	Livewire™ Steerable Electrophysiology Catheter
Common Name:	Diagnostic Electrophysiology Catheter
Classification Name:	Electrode recording catheter or electrode recording probe
Class:	Class II, 21 CFR 870.1220, Product Code DRF
Predicate Device:	Livewire™ Electrophysiology Catheter (K102721, K022380, K913940)
Device Description:	The SJM Livewire™ Steerable Electrophysiology Catheter is a flexible electrode catheter constructed of a polyurethane insulation/shaft and incorporates platinum electrodes. The active tip may be manipulated by a remote means located at the proximal end of the catheter.
Intended Use: (Indications for Use)	The SJM Livewire™ Steerable Electrophysiology Catheter can be used in the evaluation of a variety of cardiac arrhythmias from endocardial and intravascular sites.
Comparison to Predicate Devices	The Livewire Steerable Electrophysiology Catheter that is the subject of this application remains substantially equivalent to the predicate device. The changes made to the buckle force requirement do not alter the fundamental design, packaging, biocompatibility, sterilization or labeling.
Summary on Non-Clinical Testing	Historical bench test data for buckle force was evaluated to set the proposed buckle force specifications.
Statement of Equivalence	The Livewire Steerable Electrophysiology Catheter that is the subject of this application has the same indications for use and technological characteristics as the predicate device. Based on this and the data provided in this pre-market notification, the subject device remains substantially equivalent to the predicate device.