



Food and Drug Administration
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July 15, 2015

St. Jude Medical
Maria Obreztkhikova
Sr. Regulatory Affairs Specialist
One St. Jude Medical Drive
St. Paul, MN 55117

Re: K151622

Trade/Device Name: MediGuide Enabled Livewire Steerable Electrophysiology Catheter,
Livewire Steerable Electrophysiology Catheter,
Response Electrophysiology Catheter with Lumen,
Response Electrophysiology Catheter,
SJM Epicardial Catheter System,
Supreme 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: June 15, 2015

Received: June 16, 2015

Dear Maria Obreztkhikova:

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

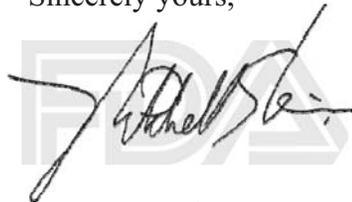
<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go 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,

A handwritten signature in black ink, appearing to read "Bram D. Zuckerman", is written over a large, faint, light-gray watermark of the FDA logo.

for Bram D. Zuckerman, M.D.

Director

Division of Cardiovascular Devices

Office of Device Evaluation

Center for Devices and Radiological Health

Enclosure

MediGuide Enabled Livewire EP Catheter,
 Livewire EP Catheter, Response EP Catheter with Lumen,
 Response EP Catheter, SJM Epicardial Catheter System,
 Supreme EP Catheter
 Special 510(k)

510(k) Summary	
510(k) Number	K151622
Submitter Information:	
Date Prepared:	15 June 2015
Submitter Name & Address:	St. Jude Medical 14901 DeVeau Place Minnetonka, MN 55345 Establishment Registration Number: 3005188751
Contact Person:	Maria Obreztchikova Senior Regulatory Affairs Specialist Phone (651) 756-4424 Fax (651) 756-3298 mobreztchikova@sjm.com
Device Information:	
Trade Name:	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:	MediGuide Enabled Livewire Steerable Electrophysiology Catheter (K101955, K150631)
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

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	<p>compatible with MediGuide™ Technology to enable real-time 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	<p>The MediGuide Enabled Livewire Steerable Electrophysiology Catheter that is the subject of this application remains substantially equivalent to the predicate device. There have been no changes to the device materials, packaging, sterilization or labeling. The proposed catheter includes a new outer insulation manufacturing process that results in a different surface morphology than the predicate catheter. The biocompatibility and design verification (DV) testing demonstrated that the surface morphology modification to the outer layer of the catheter proximal shaft does not adversely affect the device safety and effectiveness.</p>
Summary on Non-Clinical Testing	<p>Biocompatibility testing was performed according to ISO 10993. The catheters with the modified surface morphology of the proximal shaft demonstrated acceptable biocompatibility profile. DV testing was performed according to ISO 10555. The catheters with the modified surface morphology of the proximal shaft met product performance specifications.</p>
Statement of Equivalence	<p>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.</p>
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™ Steerable Electrophysiology Catheter (K913940, K022380, K102721, K150631)
Device Description:	<p>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.</p>
Intended Use: (Indications for Use)	<p>The Livewire™ Steerable Electrophysiology Catheter can be used in the evaluation of a variety of cardiac arrhythmias from endocardial and intravascular sites.</p>

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Comparison to Predicate Devices	The Livewire Steerable Electrophysiology Catheter that is the subject of this application remains substantially equivalent to the predicate device. There have been no changes to the device materials, packaging, sterilization or labeling. The proposed catheter includes a new outer insulation manufacturing process that results in a different surface morphology than the predicate catheter. The biocompatibility and design verification (DV) testing demonstrated that the surface morphology modification to the outer layer of the catheter proximal shaft does not adversely affect the device safety and effectiveness.
Summary on Non-Clinical Testing	Biocompatibility testing was performed according to ISO 10993. The catheters with the modified surface morphology of the proximal shaft demonstrated acceptable biocompatibility profile. DV testing was performed according to ISO 10555. The catheters with the modified surface morphology of the proximal shaft met product performance 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.
Device Information:	
Trade Name:	Response™ Electrophysiology Catheter with Lumen
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:	Response™ Electrophysiology Catheter with Lumen (K914278, K942379, K120544)
Device Description:	The Response™ Electrophysiology Catheter with Lumen is a sterile, single use, electrophysiological diagnostic catheter with a fixed distal curve and multiple electrodes. The electrodes detect cardiac electrical signals that are transmitted to an electrocardiogram recorder for diagnosis or deliver the electrical signal from an external pacemaker to the heart for electrical pacing purposes. The catheter body is a continuous tube with a central lumen for fluid infusion through a 3-way valve.
Intended Use: (Indications for Use)	St Jude Medical (SJM) Electrophysiology Catheters can be used in the evaluation of a variety of cardiac arrhythmias from endocardial and intravascular sites.
Comparison to Predicate Devices	The Response™ Electrophysiology Catheter with Lumen that is the subject of this application remains substantially equivalent to the

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	predicate device. There have been no changes to the device materials, packaging, sterilization or labeling. The proposed catheter includes a new outer insulation manufacturing process that results in a different surface morphology than the predicate catheter. The biocompatibility and design verification (DV) testing demonstrated that the surface morphology modification to the outer layer of the catheter proximal shaft does not adversely affect the device safety and effectiveness.
Summary on Non-Clinical Testing	Biocompatibility testing was performed according to ISO 10993. The catheters with the modified surface morphology of the proximal shaft demonstrated acceptable biocompatibility profile. DV testing was performed according to ISO 10555. The catheters with the modified surface morphology of the proximal shaft met product performance specifications.
Statement of Equivalence	The Response™ Electrophysiology Catheter with Lumen 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:	Response™ 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:	Response™ Electrophysiology Catheter (K894500, K002976)
Device Description:	The Response™ Electrophysiology Catheter is a sterile, single use, electrophysiological diagnostic catheter. The catheter has fixed distal curve available in various styles, no lumen, and varying electrode numbers and spacing. The electrodes detect cardiac electrical signals that are transmitted to an electrocardiogram recorder for diagnosis or deliver the electrical signal from an external pacemaker to the heart for electrical pacing purposes.
Intended Use: (Indications for Use)	St Jude Medical (SJM) Electrophysiology Catheters can be used in the evaluation of a variety of cardiac arrhythmias from endocardial and intravascular sites.
Comparison to Predicate Devices	The Response™ Electrophysiology Catheter that is the subject of this application remains substantially equivalent to the predicate device. There have been no changes to the device materials, packaging, sterilization or labeling. The proposed catheter includes a new outer insulation manufacturing process that results in a different surface morphology than the predicate catheter. The

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	biocompatibility and design verification (DV) testing demonstrated that the surface morphology modification to the catheter outer shaft does not adversely affect the device safety and effectiveness.
Summary on Non-Clinical Testing	Biocompatibility testing was performed according to ISO 10993. The catheters with the modified surface morphology of the proximal shaft demonstrated acceptable biocompatibility profile. DV testing was performed according to ISO 10555. The catheters with the modified surface morphology of the proximal shaft met product performance specifications.
Statement of Equivalence	The Response™ Electrophysiology Catheter with Lumen 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:	SJM™ Epicardial Catheter System
Common Name:	Epicardial Catheter System
Classification Name:	Electrode recording catheter or electrode recording probe
Class:	Class II, 21 CFR 870.1220, Product Code DRF
Predicate Device:	SJM™ Epicardial Catheter System (K081803) Response™ Electrophysiology Catheter (K894500)
Device Description:	<p>The SJM™ Epicardial Catheter System consists of the following SJM components:</p> <ul style="list-style-type: none"> • 17 Gauge Tuohy Needle, 11.4 cm • Response™ Electrophysiology Catheter, 6F • Agilis™ NxT Steerable Introducer, 40 cm (includes steerable sheath, dilator, and guidewire) <p>The Response™ Electrophysiology Catheter, 6F, is designed to provide pacing and recording capabilities during electrophysiology studies involving the epicardial surface of the heart. The distal tip of the catheter contains four platinum electrodes. It is curved to facilitate greater reach when advanced out of the steerable introducer.</p>
Intended Use: (Indications for Use)	The SJM™ Epicardial Catheter System is intended for electrophysiology studies involving the epicardial surface of the heart.
Comparison to Predicate Devices	The Epicardial Catheter System that is the subject of this application remains substantially equivalent to the predicate device. There have been no changes to the device materials, packaging, sterilization or

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	labeling. The proposed catheter includes a new outer insulation manufacturing process that results in a different surface morphology than the predicate catheter. The biocompatibility and design verification (DV) testing demonstrated that the surface morphology modification to the Response catheter outer shaft does not adversely affect the device safety and effectiveness.
Summary on Non-Clinical Testing	Biocompatibility testing was performed according to ISO 10993. The catheters with the modified surface morphology of the proximal shaft demonstrated acceptable biocompatibility profile. DV testing was performed according to ISO 10555. The catheters with the modified surface morphology of the proximal shaft met product performance specifications.
Statement of Equivalence	The SJM™ Epicardial Catheter System 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:	Supreme™ 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:	Supreme™ Electrophysiology Catheter (K894500, K002976)
Device Description:	The Supreme™ Electrophysiology Catheter is a sterile, single use, electrophysiological diagnostic catheter. The catheter has fixed distal curve available in various styles, no lumen, and varying electrode numbers and spacing. The electrodes detect cardiac electrical signals that are transmitted to an electrocardiogram recorder for diagnosis or deliver the electrical signal from an external pacemaker to the heart for electrical pacing purposes.
Intended Use: (Indications for Use)	St Jude Medical (SJM) Electrophysiology Catheters can be used in the evaluation of a variety of cardiac arrhythmias from endocardial and intravascular sites.
Comparison to Predicate Devices	The Supreme™ Electrophysiology Catheter that is the subject of this application remains substantially equivalent to the predicate device. There have been no changes to the device materials, packaging, sterilization or labeling. The proposed catheter includes a new outer insulation manufacturing process that results in a different surface morphology than the predicate catheter. The biocompatibility and design verification (DV) testing demonstrated that the surface morphology modification to the catheter outer shaft does not

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	adversely affect the device safety and effectiveness.
Summary on Non-Clinical Testing	Biocompatibility testing was performed according to ISO 10993. The catheters with the modified surface morphology of the proximal shaft demonstrated acceptable biocompatibility profile. DV testing was performed according to ISO 10555. The catheters with the modified surface morphology of the proximal shaft met product performance specifications.
Statement of Equivalence	The Supreme™ 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.