K 120544 1/2

MAR 19 2012

510(k) Summary	
510(k) Number	
Date Prepared:	February 21, 2012
Submitter Information:	
Submitter Name/Address:	St. Jude Medical - Atrial Fibrillation Division 14901 DeVeau Place Minnetonka, MN 55345 Establishment Registration Number: 3005188751
Contact Person:	Marlene Peterson Principal Regulatory Affairs Specialist Phone (651) 756-3268 Fax (952) 930-9481 MPeterson07@sjm.com
Device Information:	
Trade Name:	Response™ Electrophysiology Catheter with Lumen
Common Name:	Electrode Recording Catheter
Classification Name:	Electrode Recording Catheter
Classification:	Class II, 21 CFR 870.1220, Product Code DRF.
Predicate Device(s):	Response™ Electrophysiology Catheter with Lumen (K914278).
Device Description:	The Response™ Electrophysiology Catheter with Lumen is a sterile, single use, electrophysiological diagnostic catheter with multiple electrodes and a fixed distal curve for intracardiac electrogram sensing (IECG). The 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 evaluation of a variety of cardiac arrhythmias from endocardial and intravascular sites.
Comparison to Predicate Devices	The modified Response™ Electrophysiology Catheter with Lumen has the same intended use and fundamental scientific technology as the predicate device. The technological characteristics of the modified Response™ Electrophysiology Catheter with Lumen are substantially equivalent to the predicate devices including packaging, biocompatibility, sterilization, and labeling. Through

	biocompatibility testing it was demonstrated that the resin modification does not adversely affect the safety and effectiveness.
Summary on Non-Clinical Testing	Bench testing was performed to verify the device modifications. Results of testing demonstrate that the modified design meets specifications as biocompatibility was confirmed in accordance with ISO 10993-1.
Statement of Equivalence	The modified St. Jude Medical Response™ Electrophysiology Catheter with Lumen 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, St. Jude Medical's modified Response™ Electrophysiology Catheter with Lumen has been shown to be substantially equivalent to the predicate.

Note; K914278 was originally submitted under the Daig Corporation which was subsequently obtained by St. Jude Medical. The predicate to K914278 was K894500 for Electrophysiology Catheters

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

MAR 19 2012

St. Jude Medical
c/o Ms. Marlene Peterson
Sr. Regulatory Affairs Specialist
14901 DeVeau Place
Minnetonka, MN 55345

Re: K120544
Trade/Device Name: St Jude Medical Response Electrophysiology Catheter with Lumen
Regulation Number: 21 CFR 870.1220
Regulation Name: Electrode recording catheter or electrode recording probe.
Regulatory Class: Class II (two)
Product Code: DRF
Dated: February 21, 2012
Received: February 23, 2012

Dear Ms. Peterson:

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.

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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

INDICATIONS FOR USE

510(K) Number (if known): K120544

Device Name: Response™ Electrophysiology Catheter with Lumen

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.

Prescription Use X	AND/OR	Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D)		(21 CFR 801 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

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(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K120544