K080179
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St. Jude Medical
510(k) Premarket Notification

Reflexion HD™ High-Density Mapping Catheter

510(k) Summary

as required by 21 CFR 807.92(c)

JAN – 7 2009

510(k) Number: TBD

Date Prepared: January 23, 2008

Submitter Information:

Submitter's Name/ Address:	St. Jude Medical 14901 DeVeau Place Minnetonka, MN 55345-2126
Contact Person:	Andrea Hudack Regulatory Affairs Specialist Tel: 952-351-1627 Fax: 952-930-9481 ahudack@sjm.com
Alternate Contact Person:	Glenn Jacques Manager, Regulatory Affairs Tel: 952-351-1356 Fax: 952-930-9481 gjacques@sjm.com

Device Information:

Trade Name:	Reflexion HD™ High-Density Mapping Catheter
Common Name:	Electrode recording catheter
Classification Name:	Electrode recording catheter or electrode recording probe
Class:	Class II, 21 CFR 870.1220, Product Code DRF

Predicate Device:

1. Reflexion Spiral™ Variable Radius Catheter (K062251)
2. Reflexion Spiral™ Variable Radius Catheter (K072012)

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510(k) Summary

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Device Description:

The St. Jude Medical (SJM) Reflexion HD™ High Density Mapping Catheter is a flexible, bi-directional, fixed radius loop catheter constructed of a polymer shaft that incorporates platinum electrodes.

The Reflexion HD™ High Density Mapping Catheter has a fixed loop and a proximal handle (the ComfortGrip™ handle) that contains: A shaft actuator mechanism for deflecting the distal portion of the shaft; and An electrical connector.

Indications for Use:

The Reflexion HD™ High-Density Mapping Catheter can be used for recording intracardiac signals and for cardiac stimulation during electrophysiology studies. The Reflexion HD™ High-Density Mapping Catheter is to be used to map the atrial regions of the heart.

Comparison to Predicate Devices:

The Reflexion HD™ High-Density Mapping Catheter has the same intended use and fundamental scientific technology as the predicate device. All technological characteristics of the of the Reflexion HD™ High-Density Mapping Catheter is substantially equivalent to the predicate devices including packaging, biocompatibility, sterilization, and labeling. Where dimensional and material differences exist between the proposed device and the predicate devices, performance testing demonstrated that these differences do not adversely affect the safety and effectiveness of the proposed device.

Summary of Non-Clinical Testing:

Bench testing of the Reflexion HD™ High Density Mapping Catheter was performed to support substantial equivalence. Results of the testing demonstrates that the Reflexion HD™ High-Density Mapping Catheter design meets product specifications and intended uses.

Statement of Equivalence:

The St. Jude Medical Reflexion HD™ High-Density Mapping Catheter has the same indications for use and technological characteristics as the predicate devices. Based on this and the design and engineering data provided in the pre-market notification, SJM's Reflexion HD™ High-Density Mapping Catheter has been shown to be substantially equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN - 7 2009

St. Jude Medical
c/o Mr. Joshua Clarin
Regulatory Affairs Specialist II
14901 DeVeau Place
Minnetonka, MN 55345

Re: K080179
Trade/Device Name: Reflexion™ HD High Density Mapping Catheter
Regulation Number: 21 CFR 870.1220
Regulation Name: Electrode Recording Catheter or Electrode Recording Probe
Regulatory Class: Class II (two)
Product Code: DRF
Dated: November 12, 2008
Received: November 13, 2008

Dear Mr. Clarin:

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 such 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); 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. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometrics' (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

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

Enclosure

St. Jude Medical
510(k) Premarket Notification

Reflexion HD™ High-Density Mapping Catheter

Indications for Use

510(K) Number (if known): K080179

Device Name: **Reflexion HD™ High-Density Mapping Catheter**

Indications for Use:

The Reflexion HD™ High-Density Mapping Catheter can be used for recording intracardiac signals and for cardiac stimulation during electrophysiology studies. The Reflexion HD™ High-Density Mapping Catheter is to be used to map the atrial regions of the heart.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) 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)

Donna R. Lochner

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K080179