

**510(k) Summary**

As required by 21 CFR 807.92(c)

AUG 22 2007

**510(k) Number:****Date Prepared:** July 20, 2007**Submitter Information:**

Submitter's Name/  
Address: St. Jude Medical  
14901 DeVeau Place  
Minnetonka, MN 55345-2126

Contact Person: Laura Moen-Ftacek  
Regulatory Affairs Specialist  
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**Device Information:**

Trade Name: Reflexion Spiral™ Variable Radius 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)

**Device Description:**

The St. Jude Medical Reflexion Spiral™ Bi-directional Variable Radius Mapping Catheter (Reflexion Spiral™ Decapolar EP Catheter) is a flexible, bi-directional, variable radius loop electrophysiology catheter constructed of a polymer shaft that incorporates platinum electrodes.

The Reflexion Spiral™ Decapolar EP Catheter has a loop and a proximal handle (the ComfortGrip™ handle) that contains: 1) A shaft actuator mechanism for varying the distal portion of the shaft; 2) A loop actuator mechanism for varying the loop diameter from approximately 20mm to approximately 15mm; and 3) An electrical connector.

**Indications for Use:**

The Reflexion Spiral catheter can be used for recording intracardiac signals and for cardiac stimulation during electrophysiology studies. The Reflexion Spiral catheter is to be used to map the atrial regions of the heart.

**Comparison to Predicate Devices:**

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

**Summary of Non-Clinical Testing:**

Bench testing of the Reflexion Spiral™ Variable Radius Catheter was performed to support substantial equivalence. Results of the testing demonstrates that the Reflexion Spiral™ Variable Radius Catheter design meets product specifications and intended uses.

**Statement of Equivalence:**

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



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

AUG 22 2007

St. Jude Medical  
c/o Ms. Laura Moen-Ftacek  
Regulatory Affairs Specialist  
14901 Deveau Place  
Minnetonka, MN 55345

Re: K072012

Trade/Device Name: Reflexion Spiral Variable Radius Catheter  
Regulation Number: 21 CFR 870.1220  
Regulation Name: Electrode recording catheter or electrode recording probe  
Regulatory Class: Class II  
Product Code: DRF  
Dated: July 20, 2007  
Received: July 23, 2007

Dear Ms. Moen-Ftacek:

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.

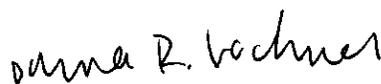
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 Office of Compliance at 240-276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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

## INDICATIONS FOR USE

510(K) Number (if known): K072012

Device Name: Reflexion Spiral™ Variable Radius Catheter

### Indications for Use:

The Reflexion Spiral catheter can be used for recording intracardiac signals and for cardiac stimulation during electrophysiology studies. The Reflexion Spiral catheter is to be used to map the atrial regions of the heart.

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

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

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Dwight R. Veitch  
(Division Sign-Off)  
Division of Cardiovascular Devices

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