510(k) Summary
(As required by 21 CFR 807.92)

A. Submitter Information

Submitter's Name:	St. Jude Medical, Daig Division, Inc.
Address:	14901 DeVeau Place Minnetonka, Minnesota 55345-2126 U.S.A.
Telephone Number:	(952) 238-9356
Contact Person:	Glenn Jacques
Date Submission Prepared:	January 22, 2004

B. Device Information

Common or Usual Name:	Reflexion Cannulator™ Steerable Electrophysiology Catheter with Lumen
Classification Name:	Steerable Catheter
Predicate Device:	6F Reflexion™ Bidirectional Electrophysiology Catheter St. Jude Medical, Daig Division, Inc
Device Description:	7F Unidirectional Reflexion Cannulator™ Steerable Electrophysiology Catheter with Lumen is a catheter that will enable electrical mapping and pacing from endocardial and intravascular sites. Additionally, the Reflexion Cannulator™ with lumen can provide access to the vascular system by either over the wire, or by steerable access to the vasculature for guidewire positioning and contrast media injection through the lumen. The catheter includes a hemostasis valve, Cath-Lock and sideport with a 3-way stopcock,. The catheters are provided sterile, and are intended for single-use only.
Intended Use:	The Reflexion Cannulator™ Steerable Electrophysiology Catheter with Lumen can be used in the evaluation of a variety of cardiac arrhythmias from endocardial and intravascular sites when minimizing blood loss is essential.

C. Comparison of Required Technological Characteristics

All technological characteristics of the Reflexion Cannulator™ Steerable Electrophysiology Catheter with Lumen are substantially equivalent to the predicate device including product design, packaging, sterilization, and labeling.

D. Support of the Substantial Equivalence

St. Jude Medical, Daig Division, Inc. considers the Reflexion Cannulator™ Steerable Electrophysiology Catheter with Lumen, to be substantially equivalent to the predicate device, Reflexion™ Bidirectional Electrophysiology catheter.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 1 2 2004

St. Jude Medical
Daig Division, Inc.
c/o Mr. Glenn Jacques
Sr. Regulatory Affairs Specialist
14901 DeVeau Place
Minnetonka, MN 55345

Re: K040165
Trade Name: Reflexion Cannulator™ Steerable Electrophysiology Catheter with Lumen
Regulation Number: 21 CFR 870.1280
Regulation Name: Steerable Catheter
Regulatory Class: II (two)
Product Code: DRA
Dated: April 66, 2004
Received: April 08, 2004

Dear Mr. Jacques:

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 (301) 594-4648. 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 (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Anna R. Vachner

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): K040165

Device Name: Reflexion Cannulator™ Steerable Electrophysiology Catheter with Lumen

Indications for Use:

The St. Jude Medical (SJM) Reflexion Cannulator™ Steerable Electrophysiology Catheter with Lumen can be used in the evaluation of a variety of cardiac arrhythmias from endocardial and intravascular sites when minimizing blood loss is essential.

Prescription Use X AND/OR Over-The-Counter Use _____
(Per 21 CFR 801 Subpart D) (Per 21 CFR 807 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 K040165