510(k) Summary

As required by 21 CFR 807.92(c)

510(k) Number: K083402

Date Prepared: November 17, 2008

DEC 15 2008

Submitter Information:

Submitter's Name/ Address:	St. Jude Medical 14901 DeVeau Place Minnetonka, MN 55345-2126 Establishment Registration Number: 2182269
Contact Person:	Mac McKeen Director, Regulatory Management Tel: 952-351-1544 Fax: 952-930-9481 mmckeen@sjm.com

Device Information:

Trade Name:	Agilis™ NxT Steerable Introducer
Common Name:	Catheter Introducer
Classification Name:	Introducer, Catheter
Class:	Class II, 21 CFR 870.1340, Product Code DYB

Predicate Device:

Agilis™ NxT Steerable Introducer (K061363)

Device Description:

The Agilis NxT Steerable Introducer consists of a steerable sheath, plastic dilator and stainless steel guidewire, which is indicated for introducing various cardiovascular catheters into the heart, including the left side of the heart through the interatrial septum. It is an 11F asymmetrical bi-directional steerable introducer with a small and medium curl at the distal tip and a useable length of 71 cm. The proximal end of the device sheath is fitted with a hemostasis valve to minimize blood loss during catheter insertion and/or exchange over a guidewire. A sideport with three-way stopcock is provided for air or blood aspiration, fluid infusion, blood sampling, and pressure monitoring. A handle is equipped with a rotating collar to deflect 90° in the counterclockwise direction and 180° in the clockwise direction. The sheath is filled with radiopaque material for visualization under fluoroscopy.

Indications for Use:

The Agilis™ NxT Steerable Introducer is indicated for introducing various cardiovascular catheters into the heart, including the left side of the heart through the interatrial septum.

Comparison to Predicate Devices:

The Agilis™ NxT Steerable Introducer has the same intended use and fundamental scientific technology as the predicate device. All technological characteristics of the Agilis™ NxT Steerable Introducer are substantially equivalent to the predicate device including packaging, biocompatibility, sterilization, and labeling. Where dimensional 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 Agilis™ NxT Steerable Introducer was performed to verify the device modifications. Results of the testing demonstrate that the Agilis™ NxT Steerable Introducer design meets the product specification and intended use.

Statement of Equivalence:

The St. Jude Medical Agilis™ NxT Steerable Introducer 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 Agilis™ NxT Steerable Introducer 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

St. Jude Medical
c/o Mr. Mac McKeen
Director, Regulatory Management
14901 DeVeau Place
Minnetonka, MN 55345-2126

DEC 15 2008

Re: K083402
Trade/Device Name: Agilis™ NxT Steerable Introducer
Regulation Number: 21 CFR 870.1340
Regulation Name: Introducer, Catheter
Regulatory Class: Class II
Product Code: DYB
Dated: November 17; 2008
Received: November 18, 2008

Dear Mr. McKeen:

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

INDICATIONS FOR USE

510(K) Number (if known): K083402

Device Name: Agilis™ NxT Steerable Introducer

Indications for Use:

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K083402