510(k) SUMMARY

K061363

Submitter's Name:	St. Jude Medical
Address:	14901 DeVeau Place Minnetonka, MN 55345
Tel:	952-933-4700
Fax:	952-930-9481
Contact Person:	Glenn Jacques
Date of Summary Preparation:	May 15, 2006
Device Common Name:	Introducer, Catheter
Device Trade Name:	Agilis NxT Steerable Introducer
Device Classification Name:	21 CFR 870.1340 Classification: Class II Product Code: DYB
Predicate Devices:	Agilis Steerable Catheter Introducer K042623 Livewire Electrophysiology Diagnostic Catheter K022380

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Device Description

The Agilis™ device is an 8.5 F steerable catheter introducer. The device has a small curl or medium curl at the distal tip which can deflect 90° in the counterclockwise direction and 180° in the clockwise direction. The device is indicated for introducing various cardiovascular catheters into the heart, including the left side of the heart through the interatrial septum. The proximal end of the device is fitted with a hemostasis valve to minimize blood loss during catheter introduction and exchange over a guidewire. A sideport with a three-way stopcock is provided for air or blood aspiration, fluid infusion, blood sampling, and pressure monitoring. The sheath is filled with radiopaque material for visualization under fluoroscopy. A plastic dilator and stainless steel guidewire are packaged with the introducer and are designed to facilitate the introduction and passage of the introducer through the vasculature.

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 Device

The Agilis NxT introducer has similar design, materials, and technical requirements as the predicate devices.

Summary of Testing

Testing has demonstrated that the new device is substantially equivalent to the predicate devices.

Conclusion

The proposed modifications are equivalent to the predicates with respect to intended use, technological characteristics, and performance specifications.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 12 2006

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

Re: K061363
Agilis NxT Steerable Introducer
Regulation Number: 21 CFR 870.1340
Regulation Name: Introducer Catherter
Regulatory Class: II
Product Code: DYB
Dated: June 19, 2006
Received: June 20, 2006

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 (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 (301) 443-6597 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: K061363

Device Name: Agilis NxT Steerable Introducer

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.

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 IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardio

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