SEP 13 2007

510(k) Summary

As required by 21 CFR 807.92(c)

510(k) Number: K072278

Date Prepared: August 13, 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 Tel: 952-351-1453 Fax: 952-930-9481 lmoen-ftacek@sjm.com

Device Information:

Trade Name:	BRK™ Transseptal Needle
Common Name:	Transseptal Needle
Classification Name:	Trocar
Class:	Class II, 21 CFR 870.1390, Product Code DRC

Predicate Device:

1. Thomas Medical Products, Inc., Transseptal Needle/Trocar (K011727)
2. St. Jude Medical ACross™ Transseptal Access System (K070417)

Device Description:

The St. Jude Medical Transseptal Needle consists of a luminal stainless steel needle and solid stainless steel stylet. The distal section of the needle is curved to facilitate positioning within the heart when used with a St. Jude Medical Transseptal Introducer set. Within this curved section, there is an abrupt step down in the outer diameter of the needle to mate with the internal diameter of the dilator of the St. Jude Medical Transseptal Introducer set. The distal tip of the needle is beveled to facilitate the puncture process. The proximal end of the needle is configured with a pointer flange and is fitted with a 2-way stopcock to provide needle lumen access for aspiration, fluid injection/infusion, blood sampling, pressure monitoring, and stylet and or guidewire insertion.

Indications for Use:

The St. Jude Medical Transseptal Needle is used to puncture the interatrial septum during a transseptal catheterization procedure to gain left heart access.

Comparison to Predicate Devices:

The BRK™ Transseptal Needle has the same general intended use and fundamental scientific technology as the predicate device.

Summary of Non-Clinical Testing:

Bench testing of the BRK™ Transseptal Needle was performed to support substantial equivalence. Results of the testing demonstrate that the BRK™ Transseptal Needle design meets product specifications and performance requirements.

Statement of Equivalence:

The St. Jude BRK™ Transseptal Needle has similar 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 BRK™ Transseptal Needle 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

SEP 18 2007

St. Jude Medical Inc.
c/o Mr. Mark Job
Regulatory Technology Services LLC
1394 25th Street NW
Buffalo, MN 55313

Re: K072278
Trade/Device Name: BRK™ Transseptal Needle
Regulation Number: 21 CFR 870.1390
Regulation Name: Trocar
Regulatory Class: Class II
Product Code: DRC
Dated: August 15, 2007
Received: August 16, 2007

Dear Mr. Job:

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 Biometric's (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): K072278

Device Name: BRK™ Transseptal Needle

Indications for Use:

The St. Jude Medical Transseptal Needle is used to puncture the interatrial septum during a transseptal catheterization procedure to gain left heart access.

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)

Donna R. Volmer

(Division Sign-Off)
Division of Cardiovascular Devices

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