510(k) Summary

As required by 21 CFR 807.92(c)

510(k) Number: K070417

JUN - 5 2007

Date Prepared: May 4, 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:	ACross™ Transseptal Access System
Common Name:	Trocar and Catheter Introducer
Classification Name:	Trocar and Catheter Introducer
Class:	Class II, 21 CFR 870.1390, Product Code DRC and Class II, 21 CFR 870.1340, Product Code DYB

Predicate Device:

1. St. Jude Medical Swartz™ Braided Transseptal Guiding Introducer (K052644)
2. Thomas Medical Products, Inc. Transseptal Needle (K011727)

Device Description:

The St. Jude Medical ACross™ Transseptal Access System consists of three main components; (1) a radiopaque sheath, (2) a radiopaque dilator, (3) a transseptal luminal stainless steel needle with a solid stainless steel stylet. Each component has a specially curved distal portion to accommodate positioning against the atrial septum. The proximal ends of each component interlock to form a handle. The product is also packaged with a compatible guidewire.

The sheath is fitted with a seal to provide hemostasis during catheter introduction and/or exchange. The seal housing is fitted with a side-port and three-way stopcock to provide for aspiration, fluid infusion, blood sampling, and pressure monitoring. The transseptal needle consists of a Brockenbrough style curved distal tip to accommodate positioning in the cardiac anatomy and a standard female luer fitting for air aspiration, fluid infusion, blood sampling, and pressure monitoring.

Indications for Use:

The St. Jude Medical ACross™ Transseptal Access System is used both to puncture the interatrial septum during a transseptal catheterization procedure and to introduce various cardiovascular catheters into the left side of the heart.

Comparison to Predicate Devices:

The ACross™ Transseptal Access System has the same general intended use and similar technology characteristics as the predicate devices. The addition of the proximal handle features does not affect the intended use or the scientific technology of the device.

Summary of Non-Clinical Testing:

Non-clinical testing of the ACross™ Transseptal Access System includes in vitro bench testing, animal evaluation, biocompatibility testing, shelf-life and packaging testing, and sterilization validation. Results of the testing demonstrates that the ACross™ Transseptal Access System design meets product specifications and intended uses.

Statement of Equivalence:

The St. Jude Medical ACross™ Transseptal Access System has the same general indications for use and technological characteristics of other legally marketed devices. Based on this and the design and engineering data provided in the pre-market notification, SJM's ACross™ Transseptal Access System has been shown to be substantially equivalent to other legally marketed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN - 5 2007

St. Jude Medical
c/o Ms. Laura Moen-Ftacek
Regulatory Affairs Specialist
14901 DeVeau Place
Minnetonka, MN 55345-2126

Re: K070417
ACross™ Transseptal Access System
Regulation Number: 21 CFR 870.1390
Regulation Name: Trocar
Regulatory Class: II (two)
Product Code: DYB
Dated: May 4, 2007
Received: May 7, 2007

Dear Ms. Moen-Ftacek:

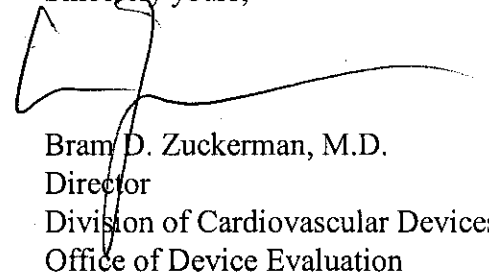
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 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): _____

Device Name: ACoss™ Trasseptal Access System

Indications for Use:

The St. Jude Medical ACross™ Transseptal Access System is used both to puncture the interatrial septum during a transseptal catheterization procedure and to introduce various cardiovascular catheters into the left side of the heart.

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
510(k) Number K070417