

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

**A. Submitter Information**

Submitter's Name: St. Jude Medical  
 Address: 14901 DeVeau Place  
 Minnetonka, Minnesota 55345-2126 U.S.A.  
 Telephone Number: 1-800-328-3873  
 Fax Number: (952) 930 - 9481  
 Contact Person: Glenn Jacques  
 Date Submission Prepared: September 23, 2005

**B. Device Information**

Trade Name: Swartz™ Braided Transseptal Guiding Introducer  
 Common or Usual Name: Transseptal Catheter Introducer  
 Classification Name: Catheter Introducer (per 21CFR 870.1340)  
 Predicate Devices: Fast-Cath™ (Two-Piece AMAS) Transseptal Catheter  
 Introducers (K964518)  
 Agilis™ Steerable Catheter Introducer (K042623)  
 Device Description: The Swartz™ Braided Transseptal Guiding Introducer  
 set consists of a fixed compound curve, dilator, and  
 guidewire. The fixed curve Swartz introducer is fitted  
 with a hemostasis valve to minimize blood loss during  
 catheter introduction and/or exchange. A sideport with  
 three-way stopcock is provided for air or blood  
 aspiration, fluid infusion, blood sampling and pressure  
 monitoring. The introducer features distal vent holes to  
 facilitate aspiration and minimize cavitation, and a  
 radiopaque tip marker to improve fluoroscopic  
 visualization. The device is provided sterile and is  
 intended for single-use only.  
 Intended Use: The St. Jude Medical Transseptal Catheter Introducer  
 Set is used for introducing various cardiovascular  
 catheters into the left side of the heart through the  
 interatrial septum.

**C. Comparison of Required Technological Characteristics**

All technological characteristics of the Swartz™ Braided Transseptal Guiding Introducer are substantially equivalent to the predicate devices including product design, packaging, biocompatibility, sterilization, and labeling. Where dimensional and material differences exist between the proposed device and the predicate devices, mechanical testing demonstrated that these differences do not adversely affect safety and effectiveness.

**D. Support of the Substantial Equivalence**

St. Jude Medical considers the Swartz™ Braided Transseptal Guiding Introducer to be substantially equivalent to the predicate devices, Fast-Cath™ (Two-Piece AMAS) Transseptal Catheter Introducer and the Agilis™ Steerable Catheter Introducer.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

DEC 5 2005

St. Jude Medical  
c/o Mr. Glenn Jacques  
Regulatory Affairs Manager  
14901 Deveau Pl.  
Minntonka, MN 55345

Re: K052644  
Swartz™ Braided Transseptal Guiding Introducer  
Regulation Number: 21 CFR 870.1340  
Regulation Name: Catheter introducer  
Regulatory Class: II  
Product Code: DYB  
Dated: September 23, 2005  
Received: September 26, 2005

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.

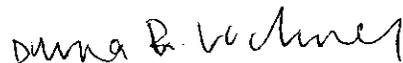
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Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other 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 (if known): K052644

Device Name: Swartz™ Braided Transseptal Guiding Introducer

Indications for Use: The St. Jude Medical Transseptal Catheter Introducer Set is used for introducing various cardiovascular catheters into the left side of the heart through the interatrial septum.

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)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

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Diana R. V. Jones  
(Division Sign-Off)  
Division of Cardiovascular Devices

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