MAR 8 2006

K053217

PREMARKET NOTIFICATION [510(K)] SUMMARY

Date Prepared:	November 16, 2005
Submitter:	St. Jude Medical, CRMD
Address:	15900 Valley View Court Sylmar, CA 91324
Phone:	818 493-2629
Fax:	818 493-3615
Contact Person:	Deanna Hughes
Trade Name/Proprietary Name:	CPS Aim™ Inner Catheter
Common Name:	Catheter, Percuatenous
Classification:	Class II, 21 CFR 870.1250
Legally marketed device to which your firm is claiming equivalence:	Medtronic Attain™ Select (K042194), Guidant Rapido™ (K021455)

Device Description:

The inner catheter is an introducer that shall be used to primarily subselect a coronary sinus vein branch in the venous system.

The CPS Aim™ Inner Catheters will have eight different curve configurations. The catheters will have a working length of 71 cm, are radiopaque, and have a flexible distal tip. The inner diameter of the catheter is lined with polytetrafluoroethylene (PTFE) to ensure additional lubricity. The catheters function as an inner catheter and can work with an outer guide catheter as a system.

Intended Use of the Device:

The St. Jude Medical CPS Aim™ Inner Catheter is designed for intracardiac access of the coronary sinus and subselection of the venous system of the heart, and to serve as a conduit during implantation for the delivery of contrast medium and St. Jude Medical devices, including guidewires. In addition, the inner catheters can work with outer guide catheters as a system.

Technological Characteristics of the Device Compared to the Predicate Device:

The CPS Aim™ Inner Catheters use similar technology, have similar intended uses, functions, materials and method of operation of the following predicate devices.

- Medtronic Attain Select™, K042194
- Guidant Rapido™ Inner Catheter, K021455

Summary of Studies:

Device comparison testing was performed to support equivalency of the CPS Aim™ Inner Catheters to the predicate devices. Verification was also performed which included mechanical, functional and biocompatibility testing with the CPS Aim™ meeting all specified design and performance specifications.

Biocompatibility Information:

St. Jude Medical has performed biocompatibility testing on the patient tissue contacting materials used in the CPS Aim inner catheter and have been found to be biocompatible.

Sterilization Validation:

The CPS Aim™ Inner Catheters are sterilized using a validated Ethylene Oxide (EtO) sterilization process.

Conclusion:

St. Jude Medical considers the CPS Aim™ Inner Catheters to be substantially equivalent to the legally marketed predicate and referenced devices. The results of the tests provide reasonable assurance that the device has been designed and tested to assure conformance to the requirements for its indications for use.

K053217
page 2 of 2

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 8 2006

St. Jude Medical
c/o Ms. Deanna Hughes
Sr. Regulatory Affairs Specialist
15900 Valley View Court
Sylmar, CA 91324

Re: K053217
Trade Name: CPS Aim™ Inner Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II (two)
Product Code: DQY
Dated: February 06, 2006
Received: February 07, 2006

Dear Ms. Hughes:

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,

B Zimmerman for

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

STATEMENT OF INDICATIONS FOR USE

510(k) Number (if known):

Device Name: CPS Aim™ Inner Catheter

Indications for Use:

The St. Jude Medical CPS Aim™ Inner Catheter is designed for intracardiac access of the coronary sinus and subselection of the venous system of the heart, and to serve as a conduit during implantation for the delivery of contrast medium and St. Jude Medical devices, including guidewires. In addition, the inner catheters can work with outer guide catheters as a system.

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 K053217