

FEB 24 2006

K053277

**PREMARKET NOTIFICATION [510(K)] SUMMARY**

Date Prepared: November 21, 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 Direct™ SL Outer Catheter  
Common Name: Catheter, Percutaneous  
Classification: Class II, 21 CFR 870.1250

Legally marketed device  
to which your firm is  
claiming equivalence:

Medtronic Attain™ LDS (K021587) Attain Access (K021589),  
Guidant Rapido™ Cut-Away/Advance (K031505)

**Device Description:**

The outer catheter is an introducer that is used to cannulate the Coronary Sinus (CS).

The CPS Direct SL outer catheter will have 7 different curves configurations. The catheters will be available in 47 and 54cm working lengths and are radiopaque. The inner diameter of the sheath shall be PTFE lined and to ensure additional lubricity the inside and outside surfaces of the sheath shall be coated with a lubricious coating. The sheath shall have a proximal split away hub which interfaces with the hemostasis valve.

The catheter functions as an outer catheter and can work with an inner guide catheter as a system.

**Intended Use of the Device:**

The St. Jude Medical Slittable Direct™ Outer Guide Catheter is designed for intracardiac access 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 implantable left heart leads and delivery tools, and support of fluids where minimizing blood loss is essential. In addition, the outer guide catheters can work with inner catheters as a system.

CPS Direct™ SL Outer Catheter  
Traditional 510(k)  
St. Jude Medical, CRM

**Technological Characteristics of the Device Compared to the Predicate Device:**

The CPS Direct™ SL Outer Catheters use similar technology, have similar intended uses, functions, materials and methods of operation as the following predicate devices.

- Medtronic Attain™ LDS/Access, K042194, K021589
- Guidant Rapido™ Cut-Away/Advance, K031505

**Summary of Studies:**

Device comparison testing was performed to support equivalency of the CPS Direct™ SL Outer Catheter to the predicate devices. Verification was also performed which included mechanical, functional and biocompatibility testing with the CPS Direct 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 Direct™ SL Outer Catheter and have been found to be biocompatible.

**Sterilization Validation:**

The CPS Direct™ SL Outer Catheters are sterilized using a validated Ethylene Oxide (EtO) sterilization process.

**Conclusion:**

St. Jude Medical considers the CPS Direct™ SL Outer Catheter 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.

CPS Direct™ SL Outer Catheter  
Traditional 510(k)  
St. Jude Medical, CRM

**STATEMENT OF INDICATIONS FOR USE**

510(k) Number (if known):

Device Name: CPS Direct™ SL Outer Catheter

Indications for Use:

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Prescription Use   X                        AND/OR                      Over-The-Counter Use \_\_\_\_\_  
(Part 21 CFR 801 Subpart D)                      (21 CFR 801 Subpart C)

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OF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

FEB 24 2006

Ms. Deanna L. Hughes  
Regulatory Affairs  
St. Jude Medical, CRMD  
15900 Valley View Court  
Sylmar, CA 91342

Re: K053277  
Trade Name: CPS Direct™ SL Outer Catheter  
Regulation Number: 21 CFR 870.1250  
Regulation Name: Percutaneous Catheter  
Regulatory Class: Class II (two)  
Product Code: DQY  
Dated: November 21, 2005  
Received: November 23, 2005

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,



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**

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(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

  
\_\_\_\_\_  
(Division Sign-Off)  
Division of Cardiovascular Devices  
510(k) Number   K053277