



Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Room - WO66-0609  
Silver Spring, MD 20993-0002

St. Jude Medical  
Cardiac Rhythm Management Division  
% Ms. Colleen Canan  
Senior Regulatory Submission Specialist  
15900 Valley View Court  
Sylmar, California 91342

AUG 07 2009

Re: **K092075**

Trade/Device Name: CPS Direct® SL II Slittable Outer Catheter  
Regulation Number: 21 CFR 870.1250  
Regulation Name: Percutaneous Catheter  
Regulatory Class: II  
Product Code: DQY  
Dated: June 30, 2009  
Received: July 9, 2009

Dear Ms. Canan:

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 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); medical device reporting

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(reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to

<http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,



Bram Zuckerman, M.D.

Director

Division of Cardiovascular Devices

Office of Device Evaluation

Center for Devices and Radiological Health

Enclosure

## Indications for Use Statement

510(k)  
Number  
(if known)

K092075

Device Name CPS Direct® SL II Slittable Outer Catheter

Indications  
for Use

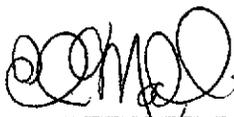
The St. Jude Medical CPS Direct® SL II Slittable Outer Catheters intended use is designed for intracardiac access of the venous system of the heart and to serve as a conduit during implantation for the delivery of contrast medium and St. Jude Medical devices, including implantable left heart leads and 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.

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE  
IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use              
(Per 21 CFR 801. 109)

OR Over-The-Counter Use           



(Division Sign-Off)  
Division of Cardiovascular Devices

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