K061843

ST. JUDE MEDICAL

SECTION 6. 510(K) SUMMARY

6.1 APPLICANT INFORMATION

AUG 0 1 2006

Submitted by: St. Jude Medical
6550 Wedgwood Rd. N.
Suite 150
Maple Grove, MN 55311

Contact Person: Shannon Springer
Telephone: 763-383-0900
Fax: 763-322-8808

Date Prepared: 29 June, 2006

6.2 DEVICE INFORMATION

Trade Name:	Venture Wire Control Catheter
Model:	WCC
Version:	Rapid Exchange (RX)
Common Name:	Steerable Catheter
Classification Name:	Percutaneous Catheter
Classification:	Class II per CFR 870.1250
Product Code:	DQY

6.3 DEVICE DESCRIPTION

The rapid exchange (RX) version of the Venture™ Wire Control Catheter is a single use support catheter consisting of a radiopaque deflectable tip, 30cm long guide wire lumen, and a proximal shaft (hypotube). A rotating knob at the handle controls the tip deflection angle. The tip can be deflected up to 90° from the catheter axis.

The device is compatible with all 0.014" guide wires and 6 Fr or larger guide catheters. It is torqueable and can be used to instantaneously shape and control the curvature of the guide wire during use as well as provide support to the guide wire when needed.

6.4 INTENDED USE

The Venture™ Wire Control Catheter is indicated for directing, steering, controlling, and supporting a guide wire to access discrete regions of the coronary and peripheral vasculature.

6.5 PREDICATE DEVICE COMPARISON / TECHNOLOGICAL CHARACTERISTICS

The Venture Wire Control Catheter included in this Special 510(k) submission is a modification of the current Venture Wire Control Catheter. A rapid exchange version of the Venture catheter was created by incorporating one primary design change; full length guide wire lumen replace with 30 cm guide wire lumen.

The Venture™ Wire Control Catheter device covered by this submission is similar in function, mechanism of action and intended use to market cleared predicate device, Venture™ Wire Control Catheter (*K042910 - November 11, 2004*).

6.6 TEST SUMMARY

The Rapid Exchange Venture Wire Control Catheter passed all verification specification criteria for dimensional, strength, functional, packaging, sterilization, biocompatibility, and shelf life tests. Test results confirm the device performs as intended without raising additional questions of safety and efficacy. Given the scope of the modifications incorporated to create the rapid exchange version of the Venture™ catheter no additional animal or clinical data was deemed necessary.

6.7 SUBSTANTIAL EQUIVALENCE

The Venture™ Wire Control Catheter device covered by this submission is substantially equivalent to the previously cleared Venture™ Wire Control Catheter (*K042910 – November 11, 2004*).

The Venture™ Wire Control Catheter in this submission is substantially equivalent to the predicate device listed above given the similar technological characteristics, principles of operation and intended use.

6.8 CONCLUSION

The Venture™ Wire Control Catheter in this submission has the same fundamental indications for use, principles of operation, and technological characteristics as the previously cleared predicate device. The differences between this device and its predicate device do not raise new questions of safety or efficacy. Therefore, the rapid exchange version of the Venture Wire Control Catheter is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 0 1 2006

St. Jude Medical
c/o Ms. Shannon Springer
Sr. Regulatory Affairs Associate
6550 Wedgwood Road N., Suite 150
Maple Grove, MN 55311

Re: K061843
Venture™ Wire Control Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: II
Product Code: DQY
Dated: June 29, 2006
Received: June 30, 2006

Dear Ms. Springer:

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 Statement

510(k) Number: K061843

Device Name: Venture™ Wire Control Catheter

Indication for Use

The Venture™ Wire Control Catheter is indicated for directing, steering, controlling, and supporting a guide wire to access discreet regions of the coronary and peripheral vasculature.

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 IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Kochman

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K061843