510(K) SUMMARY

JAN 3 1 2014

1. Administrative Information

Name:	St. Jude Medical
Address:	5050 Nathan Lane North Plymouth, MN 55442
Phone:	651-756-2706
Fax:	651-756-5355
Contact Person:	Blair Schwartz Regulatory Affairs Specialist II
Date:	April 01, 2013

2. Device Information

Name of Device:	EnligHTN Renal Guide Catheter
Common Name:	Guide Support Catheter
Classification Name:	Catheter, Percutaneous (870.1250)
Product Code:	DQY

3. Predicate Device Information

1) Vista Brite Tip IG Guide Catheter (Cordis) – K971572 cleared July 1997

4. Device Description

The EnligHTN Renal Guiding Catheter consists of two primary components, the guiding catheter assembly and the dilator. The guide catheter assembly is the renal access device and has a usable length of 55cm. The outside diameter (OD) of the catheter shaft is 8F (2.7mm) with a distal tip inner diameter (ID) of 0.089 inches. The device is single use and packaged sterile via Ethylene oxide (EO) sterilization. The dilator fits inside the guiding catheter providing support during advancement through the vasculature and placement near the renal ostia. At the proximal end of the guiding catheter is a molded hub equipped with a hemostasis valve that is secured by an ultrasonically welded cap. The hub has a side port feature with an extension tubing and stopcock assembly attached. The distal end of the guiding catheter is formed to match the RDC-1 curve common to the industry and incorporates a radiopaque marker band. The dilator lumen is designed to accommodate a guidewire with an outside diameter of 0.035" or less.

5. Intended Use

The EnligHTN™ Renal Guiding Catheter system is indicated for percutaneous use through an introducer sheath to facilitate a pathway to introduce interventional and diagnostic devices into the renal arterial vasculature.

6. Technological Characteristics

The EnligHTN Renal Guiding Catheter is substantially equivalent to the Cordis Guide Catheter (K971572, July 14, 1997). The EnligHTN Renal Guiding Catheter has substantially equivalent indication for use, principles of operation and materials of construction as the Cordis Guide Catheter.

EnligHTN and Cordis guide catheters have the similar intended indications. Both of the devices are used for the delivery of interventional and diagnostic devices in the vascular system. The EnligHTN Renal Guiding Catheter's indication is specific to the renal arterial vasculature while the Cordis Guide Catheter intended use encompasses coronary, peripheral and neurovasculature. The EnligHTN Renal Guiding Catheter indications for use falls within the scope of the indications for use of the Cordis Guide Catheter. Specifically, the EnligHTN Renal Guiding Catheter's renal arterial vasculature indication falls within the general peripheral vasculature indication of the Cordis Guide Catheter and therefore substantially equivalent for the purpose of this submission.

The EnligHTN Renal Guiding Catheter also has substantially equivalent materials and technological characteristics to the Cordis Guide Catheter with the exception of the hemostasis seal. St. Jude Medical has no information on the materials of composition for the hemostasis seal of the Cordis Guide Catheter.

Although technologically substantially equivalent, the EnligHTN Renal Guiding Catheter and the Cordis Guide Catheter differ in materials of construction including the radiopaque marker band and dilator, dilator length, and distal tip inner diameter. The minor differences between the two devices outlined in the body of this 510(k) do not raise new questions in safety of effectiveness.

The EnligHTN Renal Guiding Catheter system includes the following design aspects:

- 55cm Usable Length
- Renal double curve (RDC-1) at the distal end to assist in engagement of renal ostium
- Radiopaque marker band at the distal tip to aid in visualization under fluoroscopy
- Hub with hemostasis valve
- Extension tube with 3-way stopcock
- Compatible Dilator

7. Summary of Non-clinical Testing

Performance testing of the EnligHTN Renal Guiding Catheter consists of bench and animal testing. Results of the testing demonstrate that the guide catheters design meets product specifications and intended uses and that the device is as safe, as effective, and performs at least as safely and effectively as the Cordis Guide Catheter. A summary of the bench and performance testing conducted is listed below:

Performance Testing Summary

Item	Tests	
Device performance	– Catheter Dimensions – Kink Resistance – Torque manipulation and Strength – Air Leak – Seal Manipulation – Dilator Dimensions – Hemostasis Performance – Renal Double Curve Maintenance – Tensile Test – Corrosion Resistance	
Biocompatibility	Biological Test	– Cytotoxicity – Sensitization – Intracutaneous Reactivity – Acute Systemic Toxicity – Pyrogenicity
	Hemocompatibility	– Hemolysis – Partial Thromboplastin Time – Complement Activation – In vivo Thromboresistance
	Chemical Characterization	– Gas Chromatography with Mass Spectrometry (GC/MS) Static and Dynamic – Inductively Coupled Plasma Spectroscopy (ICP) – Fourier Transform Infrared Spectroscopy (FTIR) – Physicochemical – Non Volatile Residue (NVR)
Sterilization/ Microbiology	– Sterilization – Ethylene Oxide Residuals – Bioburden – LAL endotoxin	
Packaging	– Bubble Leak Test – Visual Inspection – Pouch Seal Strength	

Item	Tests
Shelf Life	– 13 Month Accelerated Aging – 13 Month Real Time Aging (In-process)
Animal Testing	Fit of the Dilator and Catheter, Visualization, Engagement, Seal Performance, and Withdrawal Performance

8. Substantial Equivalence Conclusion

The EnligHTN Renal Guiding Catheter is substantially equivalent to the legally marketed device; Cordis Guide Catheter (K971572, July 14, 1997).

The EnligHTN Renal Guiding Catheter is substantially equivalent in indication for use, materials, technological characteristics and principles of operations as the Cordis Guiding Catheter. The minor differences between the two devices do not raise new questions in safety of effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

January 31, 2014

St. Jude Medical
c/o Mr. Mark Job
Regulatory Technology Services, LLC
1394 25th Street NW
Buffalo, MN 55313

Re: K131592
Trade/Device Name: EnligHTN™ Renal Guiding Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous catheter
Regulatory Class: II
Product Code: DQY
Dated: December 19, 2013
Received: December 20, 2013

Dear Mr. Job:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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 (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 contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

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

ST. JUDE MEDICAL

Indications for Use

510(k) Number (if known):

Device Name: EnligHTN™ Renal Guiding Catheter

Indications For Use:

The EnligHTN™ Renal Guiding Catheter system is indicated for percutaneous use through an introducer sheath to facilitate a pathway to introduce interventional and diagnostic devices into the renal arterial 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)

Kenneth J. Cavanaugh -S