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K122263

5.0 510(k) Summary

SEP 2 8 2012

1. **Sponsor**
Symmetry Surgical
3034 Owen Drive
Antioch, TN 37013

Primary Contact: Hannah Foley
Telephone: 1- 615-964-5509

Date Prepared: July 24, 2012

2. **Device Name and Classification:**

Proprietary Name:	**Symmetry Surgical Single Use Cuffed Catheter Removal Device**
Common/Usual Name:	Percutaneous, Implanted Long-Term Intravascular Catheter
Classification Name:	Percutaneous, Implanted Long-Term Intravascular Catheter (880.5970), Class II
Product Code:	ODY

(NOTE: The Symmetry Surgical Single Use Cuffed Catheter Removal Device is an Instrument and **Not** an Implant of any kind)

3. **Predicate Devices**
This 510(k) submission provides pre-market notification of the Single Use Cuffed Catheter Removal Device. The cuffed catheter removal device's design does not alter the fundamental technology of the predicate device or the devices' intended use.

K063048 – Trans Catheter Extractor

4. **Device Description**
Symmetry Surgical Single Use Cuffed Catheter Removal devices are sold as sterile, single use devices, unless otherwise noted. The **Symmetry Surgical Single Use Cuffed Catheter Removal Device** is a tool for minimizing surgical trauma associated with catheter removal. The device jaws are normally in the closed position. The device is equipped with a trigger, a button located on the handle, actuated feature that opens the jaws. Upon release of the trigger, the jaws return to the normally closed position with a spring assist mechanism. The Single Use Cuffed Catheter Removal Device has no locking mechanism. During use the jaws are opened outside the patient and allowed to close around the catheter. The catheter then serves as a guide for moving the

closed tip down into the catheter tunnel. When cutting the catheter cuff, the jaws may be activated to allow for tissue dissection and release which will then ease the catheter removal. The opening of the jaws in vivo are limited by the constraint of the surrounding tissue tunnel as well as the design limit of no more than a maximum angle of 57°.

5. **Intended Use**
   The **Symmetry Surgical Single Use Cuffed Catheter Removal Device** is a catheter accessory device intended for the minimally invasive removal of tunneled long term catheters. The Cuffed Catheter Removal Device is indicated for use with tunneled, double lumen Permcath catheters with sizes ranging from 6.0 French to 16.0 French

6. **Technological Characteristics**
   The **Symmetry Surgical Single Use Cuffed Catheter Removal Device** was shown to be substantially equivalent to predicate devices through comparison of indications for use, function, operating principles, clinical literature study, animal testing and materials.

7. **Basis for Substantial Equivalence**
   The Symmetry Surgical Single Use Cuffed Catheter Removal Device was evaluated and has been found to be substantial equivalent to the predicate device in terms of the similarity in surgical application, intended use, Indications for use, material, classification, device description, performance and sterility. Clinical data was not required for this device. The animal study and biocompatibility testing includes performance assessment per the following recognized test methods:
   -Code of Federal Regulation (CFR), Title 21, Part 58, Good Laboratory Practice for Nonclinical Laboratory Studies(2008)
   -International Organization (ISO) 10993-2, Biological Evaluation of Medical Devices – Part 2: Animal Welfare Requirements (2006)
   -National research Council, Guide for the Care and Use of Laboratory Animals, Washington, D.C: National Academy Press, 2011
   -Office of Laboratory Animal Welfare (OLAW), Public Health Service Policy on Humane Care and Use of Laboratory Animals
   -International Organization for Standardization (ISO) 13485, Medical Device – Quality Management Systems- Requirements for Regulatory Purpose (2003)
   -AAMI / ANSI HE75:2009 Human Factors Engineering – Design of Medical Devices.
   - ANSI/AAMI/ISO 10993:2010 – Biological evaluation of medical devices. Parts 1, 5,11, 12
   -Code of Federal Regulation (CFR), Title 21, Part 58, Good Laboratory Practice for Nonclinical Laboratory Studies(2008)
   -U.S. Pharmacopeia, Section 88 & 87, Current revision
   -ASTM F756-08 Standard Practice for Assessment of Hemolytic Properties of Material.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

Symmetry Surgical
Ms. Hannah Foley
Quality Assurance & Regulatory Affairs Engineer
3034 Owen Drive
Antioch, Tennessee 37013

SEP 2 8 2012

Re: K122263
Trade/Device Name: Symmetry Surgical Single Use Cuffed Catheter Removal Device
Regulation Number: 21 CFR 880.5970
Regulation Name: Percutaneous, Implanted, Long-Term Intravascular Catheter
Regulatory Class: II
Product Code: ODY
Dated: July 24, 2012
Received: July 27, 2012

Dear Ms. Foley:

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.

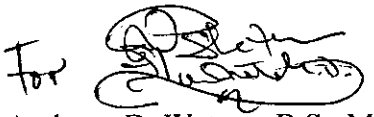
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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 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 (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if Known):

Device Name: Symmetry Surgical Single Use Cuffed Catheter Removal Device

Indications For Use:

The **Symmetry Surgical Single Use Cuffed Catheter Removal Device** is a catheter accessory device intended for the minimally invasive removal of tunneled long term catheters. The Cuffed Catheter Removal Device is indicated for use with tunneled, double lumen Permcath catheters with sizes ranging from 6.0 French to 16.0 French

Prescription Use: X **OR** **Over-The-Counter Use:** _____
(Part 21 CFR 807.109)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

9/24/

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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