K111490

SEP 16 2011

8. 510(k) Summary

SUMMARY OF SAFETY AND EFFECTIVENESS

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR 807.92(c).

Submitted by:
Chestnut Medical Technologies, Inc., an ev3 Company
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Contact Person: Daniel Cher, M.D.

Date summary prepared: May 12, 2011

Trade Name: Marksman™ Catheter

Common Name: Catheter

Classification Name: Catheter, Continuous Flush (21 CFR 870.1210, Product Code KRA)

Device Description:

The Marksman™ Catheter is a variable stiffness, single lumen catheter designed to access small, tortuous vascular areas. The outer surface of the catheter's distal segment is coated with a hydrophilic material to provide lubricity during use. The catheter also incorporates a PTFE liner to facilitate movement of introduction devices passed through its lumen. The Marksman™ Catheter has a radiopaque marker at the distal tip to facilitate fluoroscopic visualization. The distal tip of the catheter is shapeable. The Marksman™ Catheter is provided with various working lengths. The Marksman™ Catheter is for single use only.

Indications for Use:

The Marksman™ Catheter is indicated for the introduction of interventional devices and infusion of diagnostic or therapeutic agents into the neuro, peripheral and coronary vasculature.

Substantial Equivalence Determination

The information presented in this Special 510k shows that the Marksman™ Catheter with the alternative Biocoat™ coating is substantially equivalent to the predicate Marksman™ Catheter in regards to the following aspects:

Design:	**SAME:** The subject and predicate device are substantially equivalent with respect to design characteristics.
Function:	**SAME:** The subject and predicate device are substantially equivalent with respect to functional characteristics.
Manufacturing:	The subject and predicate device are the **same** with respect to technological manufacturing processes with the exception of the hydrophilic coating.
Materials:	The subject and predicate devices are composed of exactly the **same** materials, with the exception of the hydrophilic coating. All the materials have an extensive clinical history of safe use in medical devices.
Indications:	**SAME:** The subject and predicate device maintain the same indication.
Packaging:	**SAME:** The subject and predicate devices utilize the same packaging configurations.
Sterilization:	**SAME:** The subject and predicate devices are both sterilized utilizing the same Ethylene Oxide sterilization cycle validated in accordance with ISO 11135 - *Medical Devices - Validation and Routine Control of Ethylene Oxide Sterilization.*
Labeling:	**SAME:** Both the subject and predicate devices have the same labeling.
Shelf life:	**SAME:** The subject and predicate device maintain the same shelf life indication.
Biocompatibility:	**SAME:** Biocompatibility testing of the Marksman™ Catheter was performed according to the relevant sections of standard EN ISO 10993-1: 2009. Tests were performed by Toxikon (Bedford, MA), a laboratory certified to EN/ISO/IEC 17025:2005 (Title: General Requirements for the Competence of Testing and Calibration Laboratories). When evaluated according to the above listed biocompatibility standards, the Marksman™ Catheter utilizing the alternative hydrophilic Biocoat™ is not toxic (local or systemic),

	sensitizing, locally irritating or otherwise harmful. All test results obtained were acceptable for the device's intended use. The Marksman™ Catheter with Biocoat™ coating meets the requirements for biocompatibility. The Biocoat™ coating is a widely used coating in the industry Micro Therapeutics, Inc./ev3 Inc.'s Rebar Micro Catheter's coating (Ref. 510K # K993672) & (Ref. Special 510k # K001966-Rebar Micro Catheter).
Risk:	**SAME:** A risk evaluation was conducted to show that no new risks were identified and that the safety and effectiveness profile is similar to the well-established predicate device cleared for the market. As an alternative coating, Biocoat™, the team has determined that no new risks have been identified. This well-established coating is currently used by many of our products for the same purpose and confirmatory tests show there we no new risks specifically associated with coating of the Marksman™ Catheter.
Safety and Performance Verification Tests:	**SAME:** Verification testing for changes implemented in the Marksman™ Catheters included dimensional inspection, material and component verification, access/tractability /coating durability, and particulate testing. These tests yielded acceptable results substantially equivalent to the predicate device.

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

Ev3, Inc.
c/o Dr. Daniel Cher
Vice President of Clinical and Regulatory Affairs
173 Jefferson Drive
Menlo Park, CA 94025

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Re: K111490
Trade/Device Name: Marksman™ Catheter
Regulation Number: 21 CFR 870.1210
Regulation Name: Continuous flush catheter
Regulatory Class: II
Product Code: KRA
Dated: August 25, 2011
Received: August 26, 2011

Dear Dr. Cher:

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,

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

Enclosure

Indications for Use

510(k) Number (if known): K111490

Device Name: Marksman™ Catheter.

Indications for Use:

The Marksman™ Catheter is indicated for the introduction of interventional devices and infusion of diagnostic or therapeutic agents into the neuro, peripheral and coronary 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 OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K111490