

SEP 18 2009

K 091559

5. 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.
173 Jefferson Drive
Menlo Park, CA 94025
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Contact Person: Daniel Cher, M.D.

Date summary prepared: May 27, 2009

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 intended for the introduction of interventional devices and infusion of diagnostic or therapeutic agents into the neuro, peripheral and coronary vasculature.

Marksman Catheter

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Substantial Equivalence Determination

The information presented in the 510k shows that the Marksman™ Catheter is substantially equivalent to predicate endovascular catheters in regards to the following aspects:

- Design:** The subject and predicate devices are substantially equivalent with respect to design characteristics. The slight variations in flexibility, length of coated segments and lubricity are what differentiate these catheters. Each manufacturer optimizes these design variations towards a more specific application (e.g. infusion of diagnostic and therapeutic agents) or for the introduction of a specific devices such as embolic agents, coils and stents.
- Function:** The subject and predicate devices are substantially equivalent with respect to functional characteristics.
- Manufacturing:** The subject and predicate devices are similar with respect to technological manufacturing processes.
- Materials:** The subject and predicate devices are composed of similar materials, all of which have an extensive clinical history of safe use in medical devices.
- Indications:** The subject and predicate devices maintain similar indications.
- Packaging:** The subject and predicate devices utilize similar packaging configurations.
- Sterilization:** The subject and predicate devices are both sterilized utilizing a Ethylene Oxide sterilization cycle validated in accordance with ISO 11135 - *Medical Devices - Validation and Routine Control of Ethylene Oxide Sterilization*.
- Labeling:** Both the subject and predicate devices have similar labeling.

Clinical evaluation was conducted to show that no new risks were identified and that the safety and effectiveness profile is similar to well-established predicate devices cleared for the market. Evaluation was performed in the more complex and higher risk neurovascular anatomy, which is the worst case representation of the cardiac and peripheral vascular anatomies.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center – WO66-0609
Silver Spring, MD 20993-0002

SEP 18 2009

Chestnut Medical Technologies, Inc.
C/O Daniel Cher, M.D.
173 Jefferson Dr.
Menlo Park, CA 94025

Re: K091559

Trade/Device Name: Marksman™ Catheter
Regulation Number: 21 CFR 870.1210
Regulation Name: Catheter, Continuous Flush
Regulatory Class: Class II
Product Code: KRA
Dated: September 10, 2009
Received: September 11, 2009

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.

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

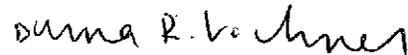
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device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of 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/ucml15809.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" (21 CFR 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): K091559

Device Name: Marksman™ Catheter.

Indications for Use:

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

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (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)

Dennis R. Velmer
(Division Sign-Off)
Division of Cardiovascular Devices

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Marksman Catheter

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