K093610

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

FEB 17 2011

General Information

Trade Name	Captix™ Retriever
Common Name	Endovascular Retriever
Classification	Percutaneous Catheter, 21CFR 870.1250 – Class II
Submitter	Concentric® Medical, Inc. 301 E. Evelyn Avenue Mountain View, CA 94041 Tel 650-938-2100 Fax 650-237-5230
Contact	Kirsten Valley Senior Vice President, Technology and Regulatory Affairs

Intended Use

The intended use for the Captix Retriever is the same as the intended use for the predicate Retriever:

The Captix Retriever is indicated for use in the retrieval of foreign bodies misplaced during interventional radiological procedures in the neuro, peripheral and coronary vasculature.

Predicate Device

K030476 - Modified Concentric Retriever Model 90037

Device Description

Like the predicate device, the Captix Retriever consists of a flexible, tapered core wire with a shaped section at the distal end. A platinum coil at the distal end allows fluoroscopic visualization. Retriever dimensions are indicated on the product label. The Retriever has a hydrophilic coating to reduce friction during use. A torque device and an insertion tool are provided with the Retriever.

Materials

The materials used in the Captix Retriever are the same as the materials used in the predicate device.

All materials used in the manufacture of the Captix Retriever are suitable for the intended use of the device and have been used in numerous previously cleared products.

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K093610

Testing Summary

Results of design verification and validation testing performed on the Captix Retriever confirm that the device conforms to the pre-determined specifications. The test results were comparable to those of the predicate Concentric Medical foreign body retriever establishing substantial equivalence to the predicate device.

- Simulated anatomy/concomitant device use – the device was evaluated in a simulated anatomy model and the following were assessed: catheter compatibility, deliverability and deployment, and accessory compatibility.
- Kink resistance – the device's resistance to kinking was evaluated in simulated anatomy demonstrating that the device appropriately resisted kinking under simulated use conditions.
- Torque/tensile – the device's ability to withstand torque and tensile loads was evaluated demonstrating the device's mechanical strength and durability for the specified number of retrieval attempts.
- Radiopacity – the visibility of the device under fluoroscopy was evaluated demonstrating the device's ability to be seen during clinical procedures.
- Tensile – the tensile strength of the device was determined demonstrating the device's mechanical integrity.
- Retrievability – the ability of the device to retrieve foreign bodies in a simulated anatomy model was evaluated and demonstrated that the device meets the user needs without loss of mechanical integrity.
- In-vivo animal testing – simulated use testing was performed in an animal model demonstrating that the device meets the user needs and is atraumatic to the blood vessel.

Summary of Substantial Equivalence

The Captix Retriever is substantially equivalent to the predicate device with regard to intended use, operating principal, design concept, materials, shelf life, packaging and sterilization processes.

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

Concentric Medical, Inc.
c/o Ms. Kirsten Valley
Senior Vice President, Technology and Regulatory Affairs
301 East Evelyn Avenue
Mountain View, CA 94041

Re: K093610
Trade/Device Name: Captix® Retriever
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: NRY
Dated: January 25, 2011
Received: January 27, 2011

FEB 17 2011

Dear Ms. Valley:

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,

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological,
and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K093610

Device Name: Captix™ Foreign Body Retriever

Indications for Use: The Captix Foreign Body Retriever is indicated for use in the retrieval of foreign bodies misplaced during interventional radiological procedures in the neuro, peripheral and coronary vasculature.

Prescription Use _X_ (Per 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)

JOE HUTTER

(Division Sign-Off)
Division of Ophthalmic, Neurological and Ear, Nose and Throat Devices

510(k) Number K093610