K091563

4. 510(k) Summary

Date prepared	July 30, 2009
Name	Reverse Medical Corporation 13900 Alton Parkway Suite 123 Irvine, CA 92618
Contact Person	Amy Eskina Director, Regulatory Quality & Clinical Affairs Reverse Medical Corporation Tel 949-215-0660 ext 234 Fax 949-215-0661
Device name	ReCruit™ Microcatheter
Common name	Foreign Body Remover
Model No.	TBD
Classification name	Percutaneous Retrieval Device
Classification regulation	870.5150 MMX
Predicate devices	K014109; In-Time Retrieval Device; Clearance date: March 12, 2002
Description	The Reverse Medical ReCruit™ Microcatheter consists of a flexible, tapered reinforced composite catheter with a braided mesh retrieval element attached to the distal region of the catheter. The inner lumen can accommodate a guidewire to aid in placement of the catheter. The catheter contains radiopaque markers to facilitate fluoroscopic visualization— a distal tip marker, markers at the proximal and distal end of the retrieval element, and circumferentially placed markers within the retrieval element. The retrieval element is deployed through the advancement of a guidewire or the ReAct™ stylet through the lumen to radially expand the retrieval element. The selection of guidewire sizes in accordance with device compatibility allows for guidewires to be used either for navigation and placement or for deployment of the element. The proximal end of the catheter has a luer fitting to allow attachment of accessories and infusion of liquids through the catheter. The catheter is coated with a hydrophilic coating. The catheter is designed to be used with a guide catheter. The catheter is offered in various retrieval element sizes to accommodate physician preferences and patient anatomy. Each ReCruit™ Microcatheter is packaged with a ReAct™ stylet and torque device. The ReAct™ stylet is a stainless steel wire with a platinum tip that may be used to activate the ReCruit™ Microcatheter's retrieval element. The ReCruit™ Microcatheter can be used in vessel diameters ranging from 2mm to 4mm. Materials used in the Reverse Medical ReCruit™ Foreign Body Retrieval Microcatheter are manufactured from medical grade materials that are commonly used in the industry, are similar or identical to the predicate device, and have historically been demonstrated to be both biocompatible and suitable for this use.

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Indications for Use	The Reverse Medical ReCruit™ Microcatheter is designed for use with a guiding catheter for the retrieval of intravascular foreign objects such as coils, balloons, portions of catheters and/or loop wires misplaced during interventional radiologic procedures in peripheral, neuro and cardiovasculature.
Summary of substantial equivalence	Preclinical studies conducted included in vitro and in vivo laboratory studies to demonstrate that the Reverse Medical ReCruit™ Microcatheter performed as intended under simulated use conditions. Biocompatibility testing was performed to demonstrate that the device meets ISO 10993-1 requirements and FDA requirements. The Reverse Medical ReCruit™ Foreign Body Retrieval Microcatheter has the following similarities to the previously cleared predicate device: • Same indications for use; • Same intended use; • Same intended treatment site; • Similar operating principle; • Similar technological characteristics; • Same packaging methods • Same sterilization methods In summary, the Reverse Medical ReCruit™ Microcatheter as described in this submission is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 30 2009

Reverse Medical Corporation
c/o Mr. Mark Job
Reviewer
Regulatory Technical Services LLC
1394 25th Street NW
Buffalo, MN 55313

Re: K091563
Trade Name: ReCruit Foreign Body Retrieval Microcatheter
Regulation Number: 21 CFR 870.5150
Regulation Name: Percutaneous Retrieval Device
Regulatory Class: Class II
Product Code: MMX
Dated: July 17, 2009
Received: July 21, 2009

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.

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 (240) 276-3150 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

3. Indications for Use

510(k) Number (if known):_____

Device Name: Reverse Medical ReCruit™ Microcatheter

Indications for Use:

The Reverse Medical ReCruit™ Microcatheter is designed for use with a guiding catheter for the retrieval of intravascular foreign objects such as coils, balloons, portions of catheters and/or loop wires misplaced during interventional radiologic procedures in peripheral, neuro and cardiovasculature.

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 IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K091653