1C093397

DEC 17 2009

510(k) Summary

Trade Name: Traxcess 14EX Guidewire and Traxcess Docking Wire

Generic Name: Guidewire

Classification: Class II, 21 CFR 807.1330

Submitted By: MicroVention, Inc
1311 Valencia Avenue
Tustin, California U.S.A.

Contact: Naomi Gong

Predicate Devices:

Number	Description	Clearance Date
K080863	Traxcess 0.014" Hydrophilic Guidewire	April 7, 2008
K080563	Runthrough NS Extension Wire	March 20, 2008

Device Description:

The Traxcess 14EX Guidewire consists of a 0.014" stainless steel shaft and a tapered nitinol tip contained within 0.012" platinum and stainless steel coils. The distal coil section contains a lubricious hydrophilic coating, and the proximal shaft section is coated with PTFE and silicone.

The Traxcess Docking Wire is an accessory used to extend the Traxcess guidewire. It consists of a stainless steel shaft with a nitinol pipe and is coated with PTFE and silicone.

Indication For Use:

The Traxcess Guidewire and Traxcess Docking Wire is intended for general intravascular use, including the neuro and peripheral vasculature. The wire can be steered to facilitate the selective placement of diagnostic or therapeutic catheters. This device is not intended for use in coronary arteries.

Verification and Test Summary Table

Bench Testing	Result
Physical attributes	Pass
Distal tip tensile strength	Pass
Tip flexibility	Pass
Distal tip torque strength	Pass
Coating adherence	Pass
Torqueability	Pass
Attachment with docking wire	Pass
Docking wire tensile strength	Pass

Summary of Substantial Equivalence

The data presented in this submission demonstrates the technological similarity and equivalency of the Traxcess 14EX Guidewire and Traxcess Docking Wire when compared with the predicate devices.

The devices,

- Have the same intended use,
- Use the same operating principle,
- Incorporate the same basic design,
- Use similar construction and material,
- Are packaged and sterilized using same material and processes.

In summary, the Traxcess 14EX Guidewire and Traxcess Docking Wire described in this submission is, in our opinion, 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 W-O66-0609
Silver Spring, MD 20993-0002

Microvention Inc.
c/o Ms. Naomi Gong
Regulatory Affairs Project Manager
1311 Valencia Avenue
Tustin, CA 92780

DEC 17 2009

Re: K093397
Trade Device Name: Traxcess 14EX Guidewire
Regulation Number: 21 CFR 870.1330
Regulation Name: Catheter Guide wire
Regulatory Class: Class II (two)
Product Code: DQX
Dated: December 11, 2009
Received: December 14, 2009

Dear Ms. Gong:

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 (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Bram 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): K093397

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Indications For Use:

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Prescription Use ____X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 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 K093397