K080863
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510(k) Summary

APR 17 2008

Trade Name:	Traxcess 0.014" Hydrophilic Guidewire
Generic Name:	Guidewire
Classification:	Class II, 807.1330
Submitted By:	MicroVention, Inc. 75 Columbia, Suite A Aliso Viejo, CA 92656
Contact:	Kevin E. Daly
Predicate Devices:	Runthrough NS (K063695) Transend EX Platinum Guidewire (K971254) Radifocus Glidewire GT with Gold Coil (K955801)

Device Description:

The Traxcess 0.014" Hydrophilic 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. The Guidewire is available in a variety of coil tip and overall lengths to suit the needs of the clinician.

Indications for Use:

The Traxcess 0.014" Hydrophilic Guidewire 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.

Nonclinical Testing:

Nonclinical testing was completed in accordance with the FDA guidance document entitled "Coronary and Cerebrovascular Guidewire Guidance, January 1995". In summary, physical tests were performed to characterize that the tensile strength, torque strength, torqueability, tip flexibility, coatings, biocompatibility, and catheter compatibility were suitable for its intended use. In addition, animal testing was performed to confirm guidewire performance.

Summary:

Based upon the technical and performance attributes of the Traxcess 0.014" Hydrophilic Guidewire, this device is substantially equivalent to the cited predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 17 2008

Regulatory Technology Services LLC
c/o Mr. Mark Job
Responsible Third Party Official
1394 25th Street NW
Buffalo, MN 55313

Re: K080863
Traxcess 0.014" Hydrophilic Guidewire
Regulation Number: 21 CFR 870.1330
Regulation Name: Catheter Guide Wire
Regulatory Class: Class II (two)
Product Code: DQX
Dated: March 27, 2008
Received: March 28, 2008

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 such 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); 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.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. 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/cdrh/industry/support/index.html.

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): K080863

Device Name: Traxcess 0.014" Hydrophilic Guidewire

Indications for Use:

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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)

Susan R. Mitchell

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K080863