K083343

510(k) Summary

Trade Name: Headway 17 Microcatheter

Generic Name: Percutaneous Catheter

Classification: Class II, 21 CFR 870.1250

DEC 0 4 2008

Submitted By: MicroVention, Inc.
75 Columbia
Aliso Viejo, California U.S.A.

Contact: Florin Truuvert

Predicate Device:

Number	Description	Predicate For	Clearance Date
K013789	Boston Scientific Excelsior SL-10 Microcatheter.	Headway 17 Microcatheter	Dec 06, 2001

Device Description

The Headway Microcatheter is a single lumen catheter designed to be introduced over a steerable guidewire to access small, tortuous vasculature. The semi-rigid proximal section transitions to a flexible distal tip to facilitate advancement through vessels. Dual radiopaque markers at the distal end facilitate fluoroscopic visualization. The outer surface of the Microcatheter is coated with a hydrophilic polymer to increase lubricity. A luer fitting on the Microcatheter hub is used for the attachment of accessories.

Indication For Use

The Headway Microcatheter is intended for general intravascular use, including the peripheral, coronary and neuro vasculature for the infusion of diagnostic agents, such as contrast media, and therapeutic agents, such as occlusion coils.

Verification and Test Summary Table

Bench Testing	Result
Separation Force	Met established criteria
Unscrewing Torque	Met established criteria
Ease of Assembly	Met established criteria
Resistance to Overriding	Met established criteria
Stress Cracking	Met established criteria
Durability/Lubricity of Hydrophilic Coating -	Met established criteria
Tip Shape and Tip Retention	Met established criteria
Simulated Use	Met established criteria
Compatibility with Embolic Agents	Met established criteria
Dynamic Burst Pressure	Met established criteria
Radio-Detectability	Met established criteria
Flow Rate	Met established criteria
kink Resistance	Met established criteria
Catheter Stiffness	Met established criteria
Package Integrity	Met established criteria
Catheter Flexural Fatigue	Met established criteria
Catheter Particle Measurement	Met established criteria
Biocompatibility	Met established criteria

Summary of Substantial Equivalence

The data presented in this submission demonstrates the technological similarity and equivalency of the Headway 17 Microcatheter compared with the predicate device Boson Scientific Excelsior SL-10(K013789).

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 processes.

In summary, the Headway 17 Microcatheter 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
9200 Corporate Boulevard
Rockville MD 20850

DEC 0 4 2008

Microvention, Inc.
c/o Mr. Mark Job
Regulatory Technology Services, LLC
1394 25th Street, NW
Buffalo, MN 55313

Re: K083343
Headway 17 Microcatheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous catheter
Regulatory Class: Class II (two)
Product Code: DQY
Dated: December 2, 2008
Received: December 2, 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 Biometrics' (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,

Anna R. Voss

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): K083343

Device Name: Headway 17 Microcatheter

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)

Donna R. Lo Monaco

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K083343