510(k) Summary

Product Name:	Headway 17 Advanced Microcatheter
Generic Name:	Percutaneous Catheter
Classification:	Class II, 21 CFR 870.1250
Submitted By:	MicroVention, Inc 1311 Valencia Avenue Tustin, California U.S.A. 714-247-8000
Contact:	Naomi Gong
Date Prepared:	February 26, 2010

AUG 0 6 2010

Predicate Devices:

Number	Description	Clearance Date
K083343	MicroVention - Headway 17 Microcatheter	December 4, 2008
K042568	Boston Scientific, Excelsior SL-10 Preshaped Microcatheter	October 15, 2004

Device Description:

The Headway 17 Advanced 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. The catheters are packaged individually with a variety of preshaped tips.

Indication For Use:

The Headway 17 Advanced 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.

Standards Used for Device Testing:

- ISO 10555-1, Sterile, single-use, intravascular catheters
- ISO 10993-1, Biological evaluation of medical devices

Testing Summary:

Bench Testing	Result
Surface and physical attributes	Met same specifications as predicate
Tensile strength	Met same specifications as predicate
Tip shape and retention	Met same specifications as predicate
Leakage (liquid and air)	Met same specifications as predicate
Static and dynamic burst pressure	Met same specifications as predicate
Simulated use	Met same specifications as predicate
Compatibility with devices	Met same specifications as predicate
Kink resistance	Met same specifications as predicate
Catheter flexural fatigue	Met same specifications as predicate
Catheter stiffness	Met same specifications as predicate
Hydrophilic coating	Met same specifications as predicate
Particulate measurement analysis	Met same specifications as predicate
Packaging testing	Met same specifications as predicate
Insertion tool performance	Met specification - previously tested on predicate
Flow rate	Met specification - previously tested on predicate
Hub testing	Met specification - previously tested on predicate
Corrosion resistance	Met specification - previously tested on predicate
Animal Testing	**Result**
Device performance was evaluated in an acute animal study compared to predicate device	Comparable performance to predicate device
Biocompatibility Testing (ISO 10993-1)	**Result**
Cytotoxcitiy (ISO 10993-5)	Pass
Sensitization/Irritation (ISO 10993-10)	Pass
Hemocompatibility (ISO 10993-4)	Pass
Systemic Toxicity (ISO 10993-11)	Pass

Technological comparison:

	Predicate Device (K833434)	510(k) Subject Device
Intended Use	The Headway 17 Advanced microcatheter is intended for general intravascular use, including the peripheral, coronary and neurovasculature- for the infusion of diagnostic and therapeutic agents.	Same
Size	Proximal = 2.4Fr Distal = 1.9Fr	Proximal = Same Distal = 1.7 Fr
Material	Catheter body: polyether block amide, stainless steel, nylon, PTFE Marker band: Pt/Ir Hub: nylon Strain relief: polyether block amide Introducer sheath: polyether block amide Shaping mandrel: stainless steel	Same with barium sulfate incorporated in polyether block amide segment
Distal Shaft Length (Shapeable Length)	11 cm	Same
Proximal ID/OD	ID = .0170" min OD = .031"	Same
Distal ID/OD	ID = .0170" min OD = .025"	ID = Same OD = .022"
No. of Markers	2	Same
Coating	Hydrophilic Coating	Same
Effective Length	150 cm	Same
Tip Configuration	Straight – Steam Shapeable by physician prior to use	Same
		Same as K042568- Boston Scientific Excelsior SL-10: Preshaped tips –with the option of secondary shaping for proper adjustment to the anatomy prior to use.
Guidewire compatibility	0.014 " wires or smaller	Same
Method of supply	Sterile and single use	Same

Summary of Substantial Equivalence:

The data presented in this submission demonstrates the technological similarity and equivalency of the Headway 17 Advanced Microcatheter when compared with the predicate devices, MicroVention-Headway 17 Microcatheter (K083343) and Boston Scientific-Excelsior SL-10 Preshaped Microcatheter (K042568).

The devices,

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

In summary, the Headway 17 Advanced Microcatheter as described in this submission is substantially equivalent to the predicate devices

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

AUG 17 2010

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

Re: K101542
Trade Name: Headway 17 Advanced Microcatheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II (two)
Product Code: DQY
Dated: July 20, 2010
Received: July 21, 2010

Dear Mr. Job:

This letter corrects our substantially equivalent letter of August 6, 2010.

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" (21 CFR 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

Indications for Use

510(k) Number (if known): K101542

AUG 06 2010

Device Name: Headway 17 Microcatheter

Indications For Use:

The Headway 17 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.

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 K101542