DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

March 26, 2015

MicroVention, Inc.
Ms. Cynthia Valenzuela
Sr. International Regulatory Affairs
1311 Valencia Avenue
Tustin, California 92780

Re: K142449
Trade/Device Name: Headway 27 Microcatheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: DQY
Dated: January 19, 2015
Received: February 27, 2015

Dear Ms. Valenzuela,

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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 contact the Division of Industry and Consumer Education 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. 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 Industry and Consumer Education 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,

Carlos L. Pena -S

Carlos L. Peña, PhD, MS
Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K142449

Device Name
Headway 27 Microcatheter

Indications for Use *(Describe)*
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.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

1.3. 510(k) Summary

510(k) Summary

Trade Name:	Headway 27 Microcatheter
Generic Name:	Percutaneous Catheter
Classification:	Class II, 21 CFR 870.1250 (DQY), 21CFR 870.1200 (DQO)
Submitted By:	MicroVention, Inc. 1311 Valencia Avenue Tustin, California U.S.A.
Contact:	Cynthia Valenzuela (714) 247 8053 or (949) 413-0071
Date:	2014 AUG 06
Predicate Device:	Headway 27 Microcatheter (K110813)

Device Description:

The Headway 27 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. An introducer sheath and shaping mandrel are also provided.

Indications 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.

Technological Comparison:

	Headway 27 (predicate)	**Headway 27** (proposed)
Intended Use	The Headway microcatheter is intended for general intravascular use, including the peripheral, coronary and neurovasculature- for the infusion of diagnostic and therapeutic agents.	Same
Material Catheter Body Marker Hub Strain Relief Introducer Shaping Mandrel	 Outer layer of polyurethane elastomer (Polyblend and Pellethane), polyether block amide (Pebax) and polyamide (Grilamid); inner layer of stainless steel braid/coil, PTFE and polyolefin elastomer Platinum/Iridium Nylon Pebax Pebax Stainless steel	Same

Technological Comparison (conti.):

Proximal ID/OD	ID = .027" min OD = .040"	ID = .0278" min OD = .040"
Distal ID/OD	ID = .027" min OD = .034"	ID = .027" min OD = .035"
Effective Length	150 cm	156 cm
Coating	Hydrophilic coating (Hydak® – same)	Same
Tip Configuration	Straight – Steam Shapeable by physician prior to use	Same
Guidewire Compatibility	0.018" wires or smaller	0.014"/0.016"/0.018"/0.021"
Accessories	Introducer sheath and shaping mandrel	Same
Method of Supply	Sterile and single use	Same
Sterilization Method	Ethylene Oxide	Same
Packaging Configuration	Catheter placed into a HDPE dispenser tube. Dispenser tube, introducer and shaping mandrel placed on a polyethylene packaging card that is inserted into a Tyvek® pouch. Pouch and IFU placed in bleached sulfate carton box.	Same

Verification and Test Summary:

Bench Testing		**Acceptance Criteria**	**Result**
Surface Contamination	• Liquid on surface • Particulate on external surface • Surface defects/sharp edges	• Free from uncured hydrophilic coating. • No surface particulate > .02 mm² per tappi chart • Free from surface defect/no sharp edges • Embedded particulate acceptable if OD is in specification • Free from damage	Passed
Dimensional Attributes	• Catheter effective length • Catheter lumen • Catheter outer diameter • Length of distal OD (2.2Fr section)	• 150 ± 2 cm • .027" (0.69 mm) • nominal .040"/.034-.028" (1.0/.86--.71 mm) • ≥ 6cm	Passed
Force at break	Device shall not break during use	≥ 1.12 lbs (5.0 N) for outer diameters from .030" to .045" (.76 to 1.1 mm)	Passed

Bench Testing		Acceptance Criteria	Result
Freedom from Leakage (Liquid)	(low pressure - long duration) Device shall not leak fluids	No liquid leaking from hub and catheter shaft at 46 psi (317.2 kPa) for 30 second duration	Passed
Freedom from Leakage (air)	(high pressure - short time) Device shall not leak fluids	No liquid leaking from hub and catheter shaft at 300 psi/2068 kPa (rated burst pressure) for 10 second duration	
Burst Pressure of Catheter	Air shall not leak into device	No air leaking into syringe for 15 seconds	Passed
Dynamic Burst Pressure	Microcatheter will not burst statically below rated burst pressure.	Microcatheter: will not burst below 300 psi (2068 kPa)	Passed
Durability and Lubricity of Hydrophilic Coating- Verification that hydrophilic coating does not delaminate during use		Rated 3 or higher (simulated use)	Passed
Tip Shape and Tip Retention		Tip retain better than 55% of its original shape	Passed
Simulated Use		Rated 3 or higher in tested categories	Passed
Compatibility with agents		Rated 3 or higher in tested applicable categories	Passed
Flow Rate		Reference data	N/A
Kink Resistance		Equivalent to or better kink resistance than competitive	Passed
Catheter Stiffness		Document stiffness using Tinius Olsen - reference data only	N/A
Catheter Flexural Fatigue		The catheter must have acceptable results per the following conditions: – Flexural fatigue: simulated use, tip shaping testing – Hoop stress fatigue: flow rate, dynamic burst, liquid leakage, air leakage testing	Passed

.

Bench Testing	Acceptance Criteria	Result
Catheter Particle Testing	Per USP <788> - less than 25 particles greater than 10 microns and less than 3 particles greater than 25 micron	Passed
Dead Space	Reference data	N/A
Torque Test	50 rotations without catheter breakage or equivalent to competitive product catheters.	Passed
DMSO Test	Functional performance and chemical stability	Passed

Biocompatibility	Results	Conclusion
Cytotoxicity ISO 10993-5 MEM Elution Test	Cell culture tested with test article exhibited slight reactivity (Grade 1)	Non-toxic
Cytotoxicity ISO 10993-5 Cell Culture Agar Overlay	Grade 2: zone limited to under specimen	Non-toxic
Sensitization ISO 10993-10 Guinea Pig Maximization Test	Grade 0: No visible change	Non-irritant
Irritation ISO 10993-10 Intracutaneous Reactivity Evaluation Test	Comparative between control and test article <1.0	Non-irritant
Hemocompatibility – Rabbit Blood Direct Contact (ISO10993-4)	0.1% hemolysis	Non-hemolytic
Hemocompatibility – Unactivated Partial Thromboplastin Time Assay Direct Contact (ISO10993-4)	Test article = 12.6 seconds (Normal PT clotting range = 10-14 seconds)	No effect on coagulation
Hemocompatibility - Complement Activation Assay (ISO10993-4)	C3a = 17.7% SC5b-9= 1.6 %	No effect on complement activation
Hemocompatibility – Thrombogenicity Study in Dogs (ISO10993-4)	Minimal to moderate thrombus formation, clotting ability was not compromised	Similar thromboresistance compared to control
Systemic toxicity – Systemic Injection Test (ISO10993-11)	No decrease in body weight of >10%. No reaction found.	Non-toxic effects
Systemic toxicity - Rabbit Pyrogen Test (ISO10993-11)	Temperature increases was 0.0°C from baseline.	Non-pyrogenic

Summary of Substantial Equivalence:

The data presented in this submission demonstrates the technological similarity and equivalency of the Headway 27 Microcatheter when compared with the predicate device, Headway 27 Microcatheter (K110813).

The devices,

- Have the same intended use,
- Use the same operating principle,
- Incorporate the same basic design,
- Are packaged and sterilized using same methods.

In summary, the Headway 27 Microcatheter described in this submission was found to have a safety and effectiveness profile that is similar to the predicate devices.