510(k) Summary

JUL 3 1 2014

K133725

Trade Name:	Traxcess 14 Guidewire
Generic Name:	Guidewire
Classification:	Class II, 21 CFR 870.1330
Product Code:	MOF, DQX
Submitted By:	MicroVention, Inc 1311 Valencia Avenue Tustin, California U.S.A. Ph: 714-247-8000 Fax: 714-247-8005
Contact:	Naomi Gong
Date:	December 4, 2013

Predicate Device:

Number	Description	Clearance Date
K080863	Traxcess 0.014" Hydrophilic Guidewire	April 7, 2008

Device Description:

The Traxcess 14 Guidewire consists of a 0.014" stainless steel shaft and a tapered nitinol tip contained within 0.012" platinum and stainless steel coils. The guidewire is coated with a lubricious hydrophilic coating.

Indication For Use:

The Traxcess 14 Guidewire is intended for general intravascular use, including the neuro and peripheral vasculature. The guidewire can be steered to facilitate the selective placement of diagnostic or therapeutic catheters. This device is not intended for use in coronary arteries.

Technological Comparison:

	Predicate	**Traxcess 14**
Intended Use	The Traxcess 14 Guidewire is intended for general intravascular use, including the neuro and peripheral vasculature. The guidewire can be steered to facilitate the selective placement of diagnostic or therapeutic catheters. This device is not intended for use in coronary arteries.	Same
Diameter	Proximal = 0.014" Distal = 0.012"	Same
Overall Length	200 cm	Same
Distal Shaft Length (Shapeable Length)	1.4 cm	Same
Material	**Core wire (proximal):** Stainless steel **Core wire (distal):** Nickel titanium alloy **Coil:** Stainless steel and Platinum nickel alloy **Other:** Brazing material and solder	Same
Coating	Shaft: PTFE/silicone Coil: Hydrophilic Coating (dimethylacramide-glycidyl methacrylate copolymer)	Shaft and Coil: Hydrophilic Coating [SLIP-COAT]
Coating Length	Hydrophilic coating (distal) = 400 mm PTFE/silicone (proximal) ≈1600 mm	Hydrophilic Coating = 1450 mm
Coil Length	40 cm	Same
Radiopaque Length	3 cm	Same
Distal tip thickness (core wire)	0.037 mm	Same
Proximal end configuration	Tapered to be compatible with Traxcess docking wire	Same

Verification and Test Summary Table:

Bench Testing	**Result**	**Conclusion**
Physical and dimensional attributes	Test articles met specified dimensional requirements for OD, overall length, length of coil section, length of SS section, length of docking section.	Device met established dimensional and physical specifications.
Tensile strength (distal and proximal)	Tensile strength of distal ≥ 3N and of proximal ≥ 70N	Device met established tensile strength
Tip flexibility	Demonstrated force to deflect the distal tip is ≤ predicate	Device tip flexibility is ≤ predicate

Bench Testing	Result	Conclusion
Torque strength	Equivalent or better than predicate (turns to failure)	Equivalent to predicate
Coating adherence	Coating adherence maintained after advance/retract cycles	Durability and lubricity of coating was comparable to predicate
Torqueability	Torque response was equal to or better than predicate	Torque response was equal to or better than predicate
Flexing and fracture resistance test	No damage to test articles or coating after flexing and fracture test	Device able to withstand forces and stress during navigation in vasculature.
Radiopacity	Distal coil section visible under fluoroscopy	Device radiopacity equivalent or better than predicate
Tip shapeability	Test articles able to maintain tip shape	Device tip shapeability equivalent or better than predicate
In-vitro simulated use testing	Test articles achieved rating $\geq$ 3 for prep of device, introduction, and tracking	Device performed as intended under simulated use.
Attachment with docking wire	Pull force of attachment was equivalent or better than predicate	Device is compatible with docking wire
Particulate Testing	Particle count of test articles $\leq$ 25 particles ($\geq$ 10 microns) and $\leq$ 3 particles ($\geq$ 25 microns)	Device does not generate particles under use.

Biocompatibility	Result	Conclusion
Cytotoxicity – MEM Elution Test (ISO 10993-5)	Cell culture exhibited slight reactivity (Grade 1)	Non-cytotoxic
Sensitization/Irritation – Kligman Maximization Test (ISO10993-10)	Extracts of test article elicited no reaction at challenge (0%) following induction phase. (Grade 1)	Weak allergenic potential
Sensitization/Irritation - Intracutaneous Injection Test (ISO 10993-10)	Extracts of test article did not show a significantly greater biological reaction than sites injected with the control	Non-irritant
Hemocompatibility – Hemolysis (Direct and Indirect) (ISO 10993-4)	Hemolysis index was 4.69% (direct) and 0.0% (indirect)	Non-hemolytic
Hemocompatibility – Unactivated Partial Thromboplastin Assay (ISO 10993-4)	No statistically significant difference found between plasma exposed to test article, negative control, and untreated control.	No effect on coagulation
Hemocompatibility – Complement Activation (ISO 10993-4)	C3a and SC5b-9 in plasma exposed to test article was not statistically higher than the plasma exposed to negative and untreated controls.	No effect on complement system
Hemocompatibility – Dog Thrombogenicity (ISO 10993-4)	Minimal thrombosis for test article and control sites (Grade 1-2)	No significant thrombosis

Biocompatibility	Result	Conclusion
Systemic toxicity – Systemic Injection Test (ISO 10993-11)	Extracts of test article did not induce a significantly greater biological reaction than the control extracts when injected into albino mice.	No toxic effects
Systemic toxicity – Rabbit Pyrogen Test (ISO 10993-11)	Temperature increase 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 Traxcess 14 Guidewire when compared with the predicate device.

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 14 Guidewire 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 Center - WO66-G609
Silver Spring, MD 20993-0002

July 31, 2014

MicroVention, Inc.
Ms. Naomi Gong
Sr. Regulatory Affairs Project Manager
1311 Valencia Ave.
Tustin, CA 92780

Re: K133725
Trade/Device Name: Traxcess 14 Guidewire
Regulation Number: 21 CFR 870.1330
Regulation Name: Neurovasculature Catheter Guide Wire
Regulatory Class: Class II
Product Code: MOF, DQX
Dated: June 27, 2014
Received: June 30, 2014

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. 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)*
K133725

Device Name
Traxcess 14 Guidewire

Indications for Use *(Describe)*
The Traxcess 14 Guidewire is intended for general intravascular use, including the neuro and peripheral vasculature. The guidewire can be steered to facilitate the selective placement of diagnostic or therapeutic catheters. This device is not intended for use in coronary arteries.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Carlos L. Pena -S

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

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