



Food and Drug Administration
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December 29, 2015

MicroVention, Inc.
Ms. Sapna Singh
Regulatory Affairs Project Manager
1311 Valencia Avenue
Tustin, California 72780

Re: K153053
Trade/Device Name: Traxcess Pro 14 Guidewire
Regulation Number: 21 CFR 870.1330
Regulation Name: Catheter Guide Wire
Regulatory Class: Class II
Product Code: MOF, DQX
Dated: December 3, 2015
Received: December 4, 2015

Dear Ms. Sapna Singh:

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,

William J. Heetderks -S

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

Enclosure

Indications for Use

510(k) Number (if known)

K153053

Device Name

Traxcess® Pro 14 Guidewire

Indications for Use (Describe)

The Traxcess® Pro 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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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

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510(k) SUMMARY

This 510(k) summary of safety and effectiveness for the Traxcess[®] Pro 14 Guidewire is submitted in accordance with the requirements of 21 CFR 807.87(h) and 807.92 and following the recommendations outlined in FDA Guidance, *The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)]*, dated 28 July, 2014.

I. SUBMITTER [807.92(a)(1)]

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Date Prepared: October 19, 2015

II. DEVICE [807.92(a)(2)]

Name of Device: Traxcess[®] Pro 14 Guidewire
Common or Usual Name: Guidewire
Classification Name: Catheter Guidewire
Product Code: MOF, DQX
Regulatory Class: Class II
Submission Type: Special 510(K)
Regulation Number: 21 CFR 870.1330
Reviewing Product Branch: Division of Cardiovascular Devices (Office of Device Evaluation, CDRH)

III. PREDICATE DEVICE [807.92(a)(3)]

Traxcess 14 Guidewire (K133725)

IV. DEVICE DESCRIPTION [807.92(a)(4)]

The Traxcess[®] Pro 14 Guidewire is a coiled wire that is designed to fit inside a percutaneous catheter for the purpose of directing the catheter through a blood vessel. The core wire proximal

coated section is 0.014" stainless steel wire, and the distal coated section is tapered nitinol wire, contained within a 0.012" outer diameter wire coil.

The wire coil is 400 mm in length. The distal 30 mm coil section is constructed of platinum/nickel for maximum radiopacity, and the balance, 370mm of the coil is constructed of stainless steel. The distal 14 mm section of the guidewire is shapeable by the physician.

The coil section of the guidewire and the distal stainless steel section is coated with a hydrophilic coating, while the proximal stainless steel section is coated with Polytetrafluoroethylene (PTFE). The purpose of these surface coatings is to provide lubricity when the MicroVention guidewire is passed through percutaneous catheters. A shaping mandrel, torque device, and insertion tool are included with the device.

V. INDICATIONS FOR USE [807.92(a)(5)]

The Traxcess® Pro 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.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS [807.92(a)(6)]

The Traxcess® Pro 14 Guidewire has the following similarities to the predicate device, Traxcess 14 Guidewire (K133725):

1. Have the same intended use
2. Use the same operating principle
3. Incorporate the same basic guidewire design
4. Incorporate the same guidewire construction material
5. Are packaged and sterilized using the same materials and processes

The change in the distal tip of the guidewire and the application of PTFE coating on the proximal stainless steel section of the guidewire does not change the indications for use of the Traxcess guidewires and is not a change to the fundamental scientific technology. The performance data below shows the device will perform as well as the previously marketed device.

The **Table I** states the comparison between Traxcess 14 Guidewire (Predicate Device, K133725) and Traxcess® Pro 14 Guidewire (Subject Device).

Table I: Predicate Device vs Subject Device Comparison Table

	Traxcess 14 Guidewire (Predicate Device, K133725)	Traxcess® Pro 14 Guidewire (Subject Device)
Intended Use		
Intended Use Statement	The Traxcess 14 Guidewire is	Same

	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.	
Performance		
Function	The steerable guidewire is used to facilitate the selective placement of diagnostic or therapeutic catheters.	Same
Anatomical Location	General intravascular use, including the neuro and peripheral vasculature.	Same
Design		
Overall Length	200 cm	Same
Diameter	Proximal = 0.014" Distal = 0.012"	Same
Coil Length	40 cm	Same
Platinum/Nickel Coil Length (Radiopaque)	3 cm	Same
Stainless Steel Coil Length	37 cm	Same
Distal Shaft Length (Shapeable Length)	1.4 cm	Same
Distal tip thickness (core wire)	0.037 mm	Same
Proximal end configuration	Compatible with Traxcess docking wire	Same
Material		
Material	Core wire (proximal): Stainless steel Core wire (distal): Nickel titanium (Nitinol) alloy Coil: Platinum nickel alloy and Stainless steel Other: Brazing material and solder	Same
Coating Material	Coil and distal/proximal stainless steel section: Hydrophilic Coating [SLIP-COAT by Argon Medical]	Coil and distal stainless steel section: Hydrophilic Coating [SLIP-COAT by Argon Medical]

		Proximal Stainless steel section: PTFE
Coating Length	Hydrophilic Coating = 1450 mm	Hydrophilic coating = 980 mm PTFE = 1000 mm
Other Attributes		
Method of supply	Sterile and single use	Same
Sterilization method	Ethylene oxide gas	Same
Accessories	Shaping mandrel, Torque device, and Insertion tool	Same
Package configuration	Placed into a Dispenser hoop, Tyvek pouch, and Carton box	Same

VII. PERFORMANCE DATA [807.92(b)]

Results of the verification and validation testing (**Table II**) indicate that the product meets established performance requirements, and is safe and effective for its intended use.

Table II: Design Verification and Validation Test Summary

Bench Testing	Result	Conclusion
Dimensional attributes	Test articles met specified dimensional requirements for guidewire OD, overall length, length of Pt/Ni coil section, length of SS section, length of PTFE coated section, length of hydrophilic coated section, length of proximal docking section and accessory devices	Device met established dimensional specifications
Tip shapeability	≥71% average for tip shape percent angle retention	Device met established tip shapeability
Tensile strength	Tensile strength of distal ≥ 3N Tensile strength of proximal ≥ 70N	Device met established tensile strength
Torque strength	Equivalent or better than predicate (turns to failure)	Device torque strength comparable to predicate
Torqueability	Torque response was equal to or better than predicate	Device torque response comparable to predicate
Tip flexibility	Demonstrated force to deflect the distal tip is ≤ predicate	Device tip flexibility is ≤ predicate
Fracture resistance and Flexing test	No portion of the guidewire should show signs of defect, fracture or other damage. There should be no coating flaking off the guidewire	No defects, fractures, damage or signs of coating flaking

Bench Testing	Result	Conclusion
Particle Testing	Particle count of test articles ≤ 25 particles (≥ 10 microns) and ≤ 3 particles (≥ 25 microns)	Device does not generate particles under use
Radiopacity	Distal coil section visible under fluoroscopy	Device radiopacity was comparable to predicate
Coating adherence	Coating adherence maintained after advance/retract cycles	Durability and lubricity of coating was maintained after advance/retract cycles
n-vitro simulated use testing	Test articles achieved rating ≥ 3 for prep of device, introduction, and tracking	Device performed as intended under simulated use

Biocompatibility	Result	Conclusion
Cytotoxicity – MEM Elution Test (ISO 10993-5)	Cell culture exhibited a biological reactivity grade of 0 (on a scale of 0 to 4). No cytotoxic effect	Non-cytotoxic
Sensitization/Irritation – Kligman Maximization Test (ISO10993-10)	Extracts of test article exhibited 0% sensitization	Non-sensitizer
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 above the negative control of 0.77% (direct contact) and 0.23% (indirect contact)	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 of human plasma
Hemocompatibility – Complement Activation (ISO 10993-4)	The concentration of C3a and SC5b-9 in plasma exposed to test article was not statistically increased than the plasma exposed to negative and untreated controls.	Not considered to have activated the complement system in human plasma
Hemocompatibility – In Vitro Hemocompatibility Test (Direct Contact) (ISO 10993-4)	No effect on the WBCs, Platelet concentration and other hematological parameters in comparison to control	No effect on selected hematological parameters
Hemocompatibility – Dog Thrombogenicity (ISO 10993-4)	Minimal thrombosis for test article and control sites (Grade 0-1)	No significant thrombosis
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

VIII. CONCLUSIONS

Based on the 510(k) summary and information provided herein, we conclude the subject device, the Traxcess[®] Pro 14 Guidewire, is substantially equivalent in its intended use, design, guidewire material, performance, and the underlying fundamental scientific technology used, to the predicate Traxcess 14 Guidewire (K133725).