DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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September 30, 2016

MicroVention, Inc.
Sapna Singh, MS, RAC
Regulatory Affairs Project Manager
1311 Valencia Avenue
Tustin, California 92780

Re: K161803
Trade/Device Name: Traxcess .007" Mini Guidewire
Regulation Number: 21 CFR 870.1330
Regulation Name: Catheter Guide Wire
Regulatory Class: Class II
Product Code: MOF, DQX
Dated: September 1, 2016
Received: September 2, 2016

Dear Ms. 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,

Carlos L. Pena -S

Carlos L. Peña, Ph.D., M.S.
Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
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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)*
K161803

Device Name
Traxcess .007" Mini Guidewire

Indications for Use *(Describe)*
Traxcess .007" Mini Guidewire is indicated 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 indicated 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.

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510(k) SUMMARY [K161803]

This 510(k) summary for Traxcess .007" Mini 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.

SUBMITTER [807.92(a)(1)]

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Date Prepared: September 30, 2016

DEVICE [807.92(a)(2)]

Name of Device:	Traxcess .007" Mini Guidewire
Common or Usual Name:	Traxcess 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 Neurological and Physical Medicine Devices (Office of Device Evaluation, CDRH)

PREDICATE DEVICE [807.92(a)(3)]

Traxcess® 14 SELECT Guidewire (K153053)

DEVICE DESCRIPTION [807.92(a)(4)]

Traxcess .007" Mini Guidewire is a coiled wire that is designed to fit inside a percutaneous microcatheter for the purpose of directing the catheter through a blood vessel. It consists of a

proximal coated Stainless Steel core wire, and a distal coated Nitinol core wire. The distal core wire is tapered at the distal tip and is contained within a Platinum/Nickel coil. The Platinum/Nickel coil is 6 cm in length. The distal 1.4 cm of the guidewire is shapeable by the physician.

Traxcess .007" Mini Guidewire distal and proximal sections are coated with hydrophilic coating. The purpose of the hydrophilic coating is to provide lubricity when the MicroVention guidewire is passed through microcatheters. A shaping mandrel, insertion tool, and torque device are also included with the device

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

Traxcess .007" Mini Guidewire is indicated 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 indicated for use in coronary arteries.

CONTRAINDICATION

The device is not indicated to be used in coronary arteries.

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

Traxcess .007" Mini Guidewire has the following similarities to the predicate device, Traxcess® 14 SELECT Guidewire (K153053):

1. Same intended use
2. 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 small distal tip of the guidewire and the application of hydrophilic coating on the distal and proximal sections 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 SELECT Guidewire (Predicate Device, K153053) and Traxcess .007" Mini Guidewire (Subject Device, K161803).

Table I: Predicate Device vs Subject Device Comparison Table

	Traxcess 14 SELECT Guidewire (Predicate Device, K153053)	**Traxcess .007" Mini Guidewire (Subject Device, K161803)**
Indications for Use		

Indications for Use Statement	Traxcess 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.	Traxcess .007" Mini Guidewire is indicated 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 indicated 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	210 cm
Diameter	Proximal = 0.014" Distal = 0.012"	Proximal = Same Distal = 0.007"
Core wire configuration	60 cm Nitinol welded to Stainless Steel	Same
Coil Length	40 cm	6 cm
Coil Configuration	3cm Platinum Nickel alloy and 37cm Stainless Steel	6cm Platinum Nickel alloy
Distal Shaft Length (Shapeable Length)	1.4 cm	Same
Docking Wire Compatibility	Yes	No
Material		
Material	Core wire (proximal): Stainless steel Core wire (distal): Nickel titanium (Nitinol) alloy Coil: Platinum nickel alloy and Stainless steel	Core wire (proximal): Same Core wire (distal): Same Coil: Platinum nickel alloy. No Stainless steel
Coating Material	Coil and distal stainless steel section: Hydrophilic Coating [SLIP-COAT by Argon Medical]	Coil and distal stainless steel section: Same No PTFE Coating

	Proximal Stainless Steel Section: PTFE	
Hydrophilic Coating Length	98 cm	158 cm
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

PERFORMANCE DATA [807.92(b)]

Performance Bench Testing and Animal Testing: Results of the performance bench testing and animal testing (**Table II**) indicate that Traxcess .007" Mini Guidewire (subject device, K161803) meets established performance requirements, and is substantially equivalent for its intended use.

Table II: Performance Bench Testing and Animal Testing Summary

Performance Bench Testing		
Tests	**Acceptance Criteria**	**Conclusion**
Dimensional Inspection (Visual): The dimensional attributes of the test samples were inspected.	Test article should meet specified dimensional requirements for: • OD (Distal and Proximal) • Overall Length • Length of distal Pt/Ni coil section • Length of hydrophilic coated section	Device met established dimensional specification.
Tip Shapeability: The test evaluates the shapeability and retention before and after simulated application of intraprocedural stresses.	Test article should be greater than or equal to existing tip shapeability specification.	Device met established tip shapeability specification.

Performance Bench Testing		
Tests	**Acceptance Criteria**	**Conclusion**
Durability/Lubricity of Hydrophilic Coating: The durability/lubricity of the coated test samples are inspected by passing the sample through two silicone clamp pads. Machine starts pulling the coated sample up through the clamping pads, recording the coating lubricity friction (in grams) until the sample is completely through.	Test article should meet existing durability/lubricity of hydrophilic coating specification.	Device met established durability/lubricity of hydrophilic coating specification.
Tensile Strength: The tensile strength of the distal tip and proximal section (nitinol and stainless steel weld) of the guidewire was measured to make sure it is sufficiently strong to withstand normal tensile loading for its intended use.	Test article should be greater than or equal to existing tensile strength specification for distal tip and proximal joint section.	Device met established distal tip and proximal joint tensile strength specification.
Corrosion Resistance: The corrosion resistance of the guidewire is tested to make sure if the guidewire is corrosion resistance.	Test article should be corrosion resistant.	Device met established corrosion resistance.
Surface Contamination and Defects: The surface contamination and defect results of the guidewire is tested to make sure it is free from contamination and defects.	Test article when examined at magnification, should meet existing surface contamination and defects specification.	Device met established surface contamination and defects specification.
Torque Strength: The Torque Strength test was performed to count the number of turns to guidewire failure.	Test article should be greater than or equal to existing torque strength specification.	Device met established torque strength specification.
Torqueability: The Torqueability test was performed to measure the difference in input angle (turn at the proximal end at a set amount) vs. the output angle and measure how much the distal end turns.	Test article should be equal to, or better than predicate device.	Subject device torque response better than predicate device.

Performance Bench Testing		
Tests	**Acceptance Criteria**	**Conclusion**
Fracture resistance: The Fracture Resistance Test was performed to test for fracture on the guidewire after winding the guidewire around a cylindrical former, then unwound and examined for fracture of the guidewire and the coating as well.	Test article should not show signs of fracture. There should be no coating flaking off the guidewire.	Device met established fracture resistance specification.
Flexing test: The Flexing test was performed to test the guidewire (distal and proximal sections) under repeated reverse bending and straightening (flexing) and examined for defects or damage.	Test article should not show signs of defect, fracture or other damage. There should be no coating flaking off the guidewire.	Device met established flexing test specification.
Distal Tip flexibility: The distal tip flexibility testing was performed to demonstrate the force required to deflect the distal tip of the guidewire.	Test article should be less than existing distal tip specification to deflect the distal tip of guidewire.	Device met established distal tip flexibility specification.
Particle Testing: The particle testing analysis was performed to quantify particulate matter in injections of the guidewire after advancement/retraction procedures.	Test article should meet established particle testing specification.	Device met established particle test specification.
Radiopacity: The guidewire is placed under fluoroscopy and digital images are visually assessed for device visibility.	Test article should be visible under fluoroscopy.	Device met established radiopacity specification.
***In-Vitro* Simulated Use Testing:** Samples underwent simulated use testing that included introduction into and movement within the catheter, tracking guidewire/microcatheter system in the model, system maximum distal reach, overall performance and any particles detected.	Test article should meet rating of 3 or greater when tested with compatible microcatheters.	Device met established simulated use testing specification.
Performance Animal Testing		

Performance Bench Testing		
Tests	**Acceptance Criteria**	**Conclusion**
Trackability, friction and handling of the guidewire to the target location	Equal to or better than the predicate device.	Both subject device and predicate device were able to reach desired location in the animal study with no issues. No friction during insertion. Subject device trackability, friction and handling equivalent to predicate device.
Radiopacity	Must be visible under fluoroscopy.	Both subject device and predicate device were visible under fluoroscopy.
Compatibility with Microcatheter	Must be compatible with microcatheters.	Both subject device and predicate device were compatible with microcatheters.
Overall Assessment	Equal to or better than the predicate device.	Performance of both subject device and predicate device was satisfactory. Subject device overall assessment is equivalent to predicate device.

Biocompatibility: The biocompatibility studies were not repeated on the subject device, Traxcess .007" Mini Guidewire since it is made from the same material, same manufacturing processes, same sterility assurance level and same packaging configuration as those utilized in the fabrication of predicate device, Traxcess® 14 SELECT Guidewire (K153053). The results from biocompatibility testing conducted on predicate device showed that the acceptance criteria were met. **Table III** summarizes the biocompatibility testing conducted on Traxcess® 14 SELECT Guidewire.

Table III: Biocompatibility Test Summary

Biocompatibility Test (ISO Standard)	**Acceptance Criteria**	**Conclusion**
Cytotoxicity – L929 MEM Elution Test (ISO 10993-5)	Test article meets the requirements of the test if it does not show greater than a mild reactivity (Grade 2).	Test article exhibited a biological reactivity grade of 0 (on a scale of 0 to 4). (Non-cytotoxic).
Sensitization/Irritation – Kligman Maximization Test (ISO10993-10)	Test article meets the requirements of the test if it does not show a positive response in atleast 10% of the test animals.	Test article exhibited 0% sensitization. (Non-sensitizer).

Biocompatibility Test (ISO Standard)	**Acceptance Criteria**	**Conclusion**
Sensitization/Irritation - Intracutaneous Injection Test (ISO 10993-10)	Test article meets the requirements of the test if it does not produce irritation after intracutaneous injection in New Zealand White rabbits.	Test article did not show a significantly greater biological reaction than sites injected with the control article. The difference of the overall mean score between the test article and the control article was 0.0. (Non-irritant).
Hemocompatibility – Hemolysis - Direct and Indirect (ISO 10993-4)	Test article meets the requirements of the test if the hemolytic index above the negative control article is <5%.	Hemolysis index was above the negative control of 0.77% via direct contact method and 0.23% via indirect contact method. (Non-hemolytic).
Hemocompatibility – Unactivated Partial Thromboplastin Time (UPTT) Assay - Direct Contact (ISO 10993-4)	Test article meets the requirements of the test if no statistical decrease is found between UPTT of the plasma exposed to the test article and that of plasma exposed to negative control or untreated control.	No statistical decrease is found between UPTT of the plasma exposed to the test article and that of plasma exposed to negative control or untreated control. (Not considered to have an effect on coagulation of human plasma).
Hemocompatibility – C3A and SC5B-9 Complement Activation Test - Direct Contact (ISO 10993-4)	Test article meets the requirements of the test if the concentration of C3A and SC5B-9 in plasma exposed to test article does not statistically increase than the plasma exposed to negative and untreated controls.	The concentration of C3A and SC5B-9 in plasma exposed to test articles were not statistically increased than the plasma exposed to negative and untreated controls. (Not considered to activate the complement system in human plasma).
Hemocompatibility – In Vitro Hemocompatibility Test - Direct Contact (ISO 10993-4)	Test article meets the requirements of the test if no statistical decrease (or increase/decrease for hematocrit and Mean corpuscular values) is found between blood exposed to test article and blood exposed to negative control or untreated control.	Test article did not have an effect on the WBCs, Platelet concentration and other hematological parameters in comparison to negative control and untreated control. (No effect on selected hematological parameters).
Hemocompatibility – Dog Thrombogenicity (ISO 10993-4)	Test article meets the requirements of the test if there is minimal thrombosis for test article (Grade 0-2).	Minimal thrombosis (Grade 0-1) for test article and control sites. (No significant thrombosis).
Systemic toxicity – Systemic Injection Test (ISO 10993-11)	Test article meets the requirements of the test if it does not induce a significantly greater biological reaction than the animal treated with the control articles when injected into albino mice	Test article did not induce a significantly greater biological reaction than the control extracts when injected into albino mice. (No toxic effects).

Biocompatibility Test (ISO Standard)	Acceptance Criteria	Conclusion
Systemic toxicity – Rabbit Pyrogen Test (ISO 10993-11)	Test article meets the requirements of the test for the absence of pyrogens, if no rabbit shows an individual temperature rise of 0.5°C or more above the baseline temperature.	Temperature increases for the test animals were all 0.0° C from baseline. (Non-pyrogenic).

Packaging: The packaging validation, T=3 years accelerated aging was performed on predicate device, Traxcess® 14 SELECT Guidewire (K153053) and included testing devices via visual inspection, simulated use testing, sterile pouch seal strength testing, dye penetration testing and shipper box testing. The results from packaging testing conducted on predicate device showed that the acceptance criteria were met. The testing was not repeated on the subject device, Traxcess .007" Mini Guidewire since there is no change in the packaging material, packaging configuration, and method of supply or sterilization. The packaging still provides the same protection and sterile barrier requirements.

Sterilization: A product adoption study was performed on predicate device, Traxcess® 14 SELECT Guidewire (K153053). The device is sterilized using 100% Ethylene Oxide (EtO) gas, per Cycle 11 to a sterility assurance level of 10^{-6} in the same manner as our existing Headway 17 Microcatheter (K083343). The bacterial endotoxin testing was conducted on predicate device and found to be less than 0.011 EU/ml and met the acceptance criteria of no more than 2.15 EU/device. The sterilization testing was not repeated on subject device, Traxcess .007" Mini Guidewire since it is sterilized using 100% Ethylene Oxide (EtO) gas in the same manner as predicate device, Traxcess® 14 SELECT Guidewire (K153053). There are no changes in materials or other design attributes made to the subject device.

Shelf Life: The shelf life testing, T=3 years accelerated aging was performed on predicate device, Traxcess® 14 SELECT Guidewire (K153053) and included testing devices via simulated use, dimensional inspection, durability/lubricity of hydrophilic and PTFE coating, tensile strength, surface defects and contamination, torque response and particle testing. The results from shelf life testing conducted on predicate device showed that the acceptance criteria were met. The shelf life testing was not repeated on the subject device, Traxcess .007" Mini Guidewire since no new materials are added to the subject device. Therefore, there will be no impact on device shelf life as material degradation rate is the same.

The conclusions drawn from the performance bench testing, animal testing, biocompatibility, packaging, sterilization and shelf-life testing demonstrate compliance with the established testing acceptance criteria. Therefore, we can conclude that proposed device is substantially equivalent to legally marketed predicate device, Traxcess 14 SELECT Guidewire (K153053).

CONCLUSIONS

Based on the 510(k) summary and information provided herein, we conclude the subject device, Traxcess .007" Mini Guidewire, is substantially equivalent in its intended use, design, guidewire

material, performance, and the underlying fundamental scientific technology used, to the predicate device, Traxcess® 14 SELECT Guidewire (K153053).