DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

December 9, 2016

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

Re: K163154
Trade/Device Name: Traxcess 7 Mini XSoft Guidewire
Regulation Number: 21 CFR 870.1330
Regulation Name: Catheter Guide Wire
Regulatory Class: Class II
Product Code: MOF, DQX
Dated: November 9, 2016
Received: November 10, 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 FDA

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)*
K163154

Device Name
Traxcess 7 Mini XSoft Guidewire

Indications for Use *(Describe)*

Traxcess 7 Mini XSoft 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.

510(k) SUMMARY

This 510(k) summary for Traxcess 7 Mini XSoft 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: December 07, 2016

DEVICE [807.92(a)(2)]

Name of Device:	Traxcess 7 Mini XSoft 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

PREDICATE DEVICE [807.92(a)(3)]

Traxcess® 7 Mini Guidewire (K161803)

REFERENCE DEVICE

Traxcess® 14 SELECT Guidewire (K153053)

DEVICE DESCRIPTION [807.92(a)(4)]

Traxcess 7 Mini XSoft 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 aproximal 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 7 Mini XSoft 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 7 Mini XSoft 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.

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

Traxcess 7 Mini XSoft Guidewire has the following similarities to predicate device, Traxcess 7 Mini Guidewire (K161803).

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 minor change in the distal corewire taper (distal to proximal) does not change the indications for use of the Traxcess 7 Mini XSoft Guidewire 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 devices. The **Table I** states the comparison between subject device, Traxcess 7 Mini XSoft guidewire and predicate device, Traxcess 7 Mini Guidewire (K161803).

Table I: Reference Device vs Predicate Devices vs Subject Device Comparison Table			
	Traxcess® 14 SELECT Guidewire (K153053) **[Reference Device]**	**Traxcess® 7 Mini Guidewire (K161803)** **[Predicate Device]**	**Traxcess 7 Mini XSoft** **[Subject Device]**
Indication For Use			
Indication For Use Statement	Traxcess 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.	Traxcess 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.	Traxcess 7 Mini XSoft 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	Same
Anatomical Location	General intravascular use, including the neuro and peripheral vasculature.	Same	Same
Design			
Overall Length	200 cm	210 cm	210 cm
Diameter	Proximal = 0.014” Distal = 0.012”	Proximal = 0.014” Distal = 0.007”	Proximal = 0.014” Distal = 0.007”
Corewire Configuration	60 cm Nitinol welded to Stainless Steel	Same	Same
Coil Length	40 cm	6 cm	6 cm
Coil Configuration	3 cm Platinum Nickel alloy and 37 cm Stainless Steel	6cm Platinum Nickel alloy	6cm Platinum Nickel alloy
Distal Shaft Length (Shapeable Length)	1.4 cm	Same	Same
Distal Corewire Taper (distal to proximal)	Diameter before flattening is 0.003”	Diameter before flattening is 0.0025”	Diameter before flattening is 0.0020”
	Length of distal ‘paddle’ and taper: 17 ± 1.5 mm	Length of distal ‘paddle’ and taper: 14 ± 1.5 mm	Length of distal ‘paddle’ and taper: 14 ± 1.5 mm
	Thickness of distal ‘paddle’ is 0.037 ± 0.001 mm	Thickness of distal ‘paddle’ is 0.0356 ± 0.001 mm	Thickness of distal ‘paddle’ is 0.0254 ± 0.001 mm
Docking Wire Compatibility	Yes	No	No

Table I: Reference Device vs Predicate Devices vs Subject Device Comparison Table			
Material			
Material	Corewire (proximal): Stainless Steel Corewire (distal): Nitinol Coil: Platinum Nickel alloy and Stainless Steel	Corewire (proximal): Stainless Steel Corewire (distal): Nitinol Coil: Platinum Nickel alloy. No Stainless Steel	Corewire (proximal): Stainless Steel Corewire (distal): Nitinol Coil: Platinum Nickel alloy. No Stainless Steel
Coating Material	Coil and distal stainless steel section: Hydrophilic Coating [SLIP-COAT by Argon Medical] Proximal Stainless Steel section: PTFE	Coil and distal stainless steel section: Hydrophilic Coating [SLIP-COAT by Argon Medical] No PTFE Coating	Coil and distal stainless steel section: Hydrophilic Coating [SLIP-COAT by Argon Medical] No PTFE Coating
Hydrophilic Coating Length	98 cm	158 cm	158 cm
Other Attributes			
Method of supply	Sterile and single use	Same	Same
Sterilization method	Ethylene oxide gas	Same	Same
Accessories	Shaping Mandrel, Torque Device, and Insertion Tool	Same	Same
Package configuration	Placed into a Dispenser Hoop, Tyvek Pouch, and Carton Box.	Same	Same

PERFORMANCE DATA [807.92(b)]

Performance Bench Testing: Results of the performance bench testing (**Table II**) indicate that Traxcess 7 Mini XSoft Guidewire (subject device) meets established performance requirements, and is substantially equivalent for its intended use.

Table II: Performance Bench Testing Summary

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 •Accessory devices present	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.
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.

Table II: Performance Bench Testing Summary		
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 devices.	Subject device torque response better than predicate devices.
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 and must be softer than Traxcess 7 Mini.	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.

Table II: Performance Bench Testing Summary		
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.

There are no differences between the predicate and the reference device which would raise any different questions of safety and effectiveness. One can find the proposed device substantially equivalent to the predicate, Traxcess® 14 SELECT Guidewire (K153053).

Biocompatibility: The biocompatibility studies were not repeated on the subject device, as Traxcess 7 Mini XSoft Guidewire 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 7 Mini Guidewire (K161803). The results from biocompatibility testing conducted on Traxcess® 14 SELECT Guidewire 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 at least 10% of the test animals.	Test article exhibited 0% sensitization. (Non-sensitizer).
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).

Table III: Biocompatibility Test Summary		
Biocompatibility Test (ISO Standard)	**Acceptance Criteria**	**Conclusion**
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).

Table III: Biocompatibility Test Summary		
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: Traxcess 7 Mini XSoft packaging is similar to the FDA cleared predicate device, Traxcess 7 Mini Guidewire (K161803). The packaging validation, T=3 years accelerated aging was performed on the reference 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 Traxcess® 14 SELECT Guidewire showed that the acceptance criteria were met. The testing was not repeated on the subject device, Traxcess 7 Mini XSoft 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: Traxcess 7 Mini XSoft is sterilized using 100% Ethylene Oxide (EtO) gas in the same manner as FDA cleared predicate device, Traxcess 7 Mini Guidewire (K161803) Traxcess 7 Mini XSoft is sold sterile, for single use and single patient only. The product adoption study was performed and is documented. No changes in materials or other design attributes have been made to the subject device. Therefore, it was not necessary to repeat sterilization validation.

Shelf Life: Traxcess 7 Mini XSoft shelf life is same as FDA cleared predicate device, Traxcess 7 Mini Guidewire (K161803). No new materials are added to the Traxcess 7 Mini XSoft. Therefore, there will be no impact on device shelf life since material degradation rate is the same.

The accelerated shelf life testing for Traxcess® 14 SELECT Guidewire has been conducted (T= 3 years accelerated aging) with test results confirmed that all acceptance criteria were met. No new questions of safety or effectiveness are raised. Based on the result, we can conclude that Traxcess 7 Mini XSoft will perform as intended per the Design Specification to recognized standards where applicable. Traxcess 7 Mini XSoft will be labeled for 3-year shelf life.

CONCLUSIONS

Based on the 510(k) summary and information provided herein, we conclude the subject device, Traxcess 7 Mini XSoft Guidewire, is substantially equivalent in its intended use, design, guidewire material, performance, and the underlying fundamental scientific technology used, to the predicate device, Traxcess® 7 Mini Guidewire (K161803).