July 2, 2020

MicroVention, Inc.
Ganesh Balachandar
Sr. Regulatory Affairs Specialist
35 Enterprise
Aliso Viejo, California 92656

Re: K201487
Trade/Device Name: Traxcess 7 Mini Guidewire
Regulation Number: 21 CFR 870.1330
Regulation Name: Catheter Guide Wire
Regulatory Class: Class II
Product Code: MOF, DQX
Dated: June 1, 2020
Received: June 4, 2020

Dear Ganesh Balachandar:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Xiaolin Zheng, Ph.D., M.S.
Director
DHT5A: Division of Neurosurgical,
Neurointerventional
and Neurodiagnostic Devices
OHT5: Office of Neurological
and Physical Medicine Devices
Office of Product Evaluation and Quality
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K201487

Device Name
Traxcess™ 7 Mini Guidewire

Indications for Use *(Describe)*
Traxcess™ 7 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.

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."

510(k) SUMMARY

This 510(k) summary of safety and effectiveness for the Traxcess™ 7 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.

I SUBMITTER [807.92(a)(1)]

MicroVention Inc.
Tustin, California U.S.A

Telephone: (714)247-8201
Contact Name: Ganesh Balachandar
E-mail address: ganesh.balachander@microvention.com
Date Prepared: 01-June-2020

II DEVICE [807.92(a)(2)]

Name of Device:	Traxcess™ 7 Mini 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 Neurosurgical, Neurointerventional, and Neurodiagnostic Devices (Office of Product Evaluation and Quality)

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

Predicate Device: Traxcess 7 Mini Guidewire (K161803)
Reference Device: Traxcess 14 SELECT Guidewire (K200547)

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

Traxcess™ 7 Mini Guidewire consists of a proximal coated 0.014" stainless steel core wire, and a distal coated 0.007" nitinol core wire. The distal core wire is tapered at the distal tip and is contained within 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 Guidewire distal and proximal sections are coated with hydrophilic coating.

There is no PTFE coating. The purpose of the hydrophilic coating is to provide lubricity when the MicroVention guidewire is passed through microcatheters. Shaping mandrels, insertion tool, and torque device are also included with the device.

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

Traxcess™ 7 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.

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

Traxcess™ 7 Mini Guidewire has the following similarities to the predicate device, Traxcess™ 7 Mini Guidewire (K161803):

- Have the same intended use
- Use the same operating principle
- Incorporate the same basic guidewire design
- Incorporate the same guidewire construction material
- Are packaged and sterilized using the same materials and processes

The change in core wire taper diameter profile for the Traxcess™ 7 Mini guidewire for better support and compatibility with microcatheters does not change the indications for use of the Traxcess™ 7 Mini 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 device.

The **Table 1** states the comparison between Traxcess™ 7 Mini Guidewire (Predicate Device, K161803) and Traxcess™ 7 Mini Guidewire (Subject Device).

Description	**Reference Device (Existing) Traxcess™ 14 SELECT Guidewire (K200547)**	**Predicate Device (Existing) Traxcess™ 7 Mini Guidewire (K161803)**	**Subject Device (Modified) Traxcess™ 7 Mini Guidewire**	**Rationale for Difference (if any)**
Indications for Use	Traxcess™ 14 SELECT 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 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.	Same	No difference
Intended Use	The Traxcess™ 14 SELECT guidewire is used in both diagnostic and interventional procedures where distal access is necessary.	The Traxcess™ 7 Mini Guidewire is used in both diagnostic and interventional procedures where distal access is necessary.	Same	No difference
Function	The steerable guidewire is used to facilitate the selective placement of diagnostic or therapeutic catheters.	The steerable guidewire is used to facilitate the selective placement of diagnostic or therapeutic catheters.	Same	No difference
Anatomical Location	General intravascular use, including the neuro and peripheral vasculature.	General intravascular use, including the neuro and peripheral vasculature.	Same	No difference
Wire Diameter	Proximal = 0.014” Distal = 0.012”	Proximal = 0.014” Distal = 0.007”	Same	No difference with predicate

				device(K161803)
Device Length	200 cm	210 cm	Same	No difference with predicate device(K161803)
Coil Length	40 cm	6 cm	Same	No difference with predicate device(K161803)
Platinum/Nickel Coil Length (Radiopaque)	3 cm	6 cm	Same	No difference with predicate device(K161803)
Distal Shaft Length (Shapeable Length)	1.4 cm	1.4 cm	Same	No difference with predicate device(K161803)
Corewire configuration	N/A	Diameter from 2-6 cm:0.0033” Diameter from16-30 cm: 0.01”	Diameter from 2-6 cm:0.0038” Diameter from 16-30 cm: 0.008”	Change in core wire diameter profile in comparison to the predicate device (K161803)
Docking wire compatibility	Compatible with Traxcess™ docking wire(K093647)	No	Same	No difference with predicate device(K161803)
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	**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	No difference with predicate device(K161803)

Coating Material	**Proximal section:** PTFE **Distal section:** Hydrophilic Coating [SLIP-COAT by Argon Medical]	**Coil and distal/proximal stainless-steel section:** Hydrophilic Coating [SLIP-COAT by Argon Medical]	Same	No difference with predicate device(K161803)
Coating Length	Hydrophilic coating = 980 mm PTFE = 1000 mm	Hydrophilic coating = 1580 mm	Same	No difference with predicate device(K161803)
Method of supply	Sterile and single use	Sterile and single use	Same	No difference with predicate device(K161803)
Sterilization method	Ethylene oxide gas	Ethylene oxide gas	Same	No difference with predicate device(K161803)
Accessories	Shaping mandrel, torque device, and insertion tool	Shaping mandrels, torque device, and insertion tool	Same	No difference with predicate device(K161803)
Package configuration	Placed into a dispenser hoop, Tyvek pouch, and box carton.	Placed into a dispenser hoop, Tyvek pouch, and box carton.	Same	No difference with predicate device(K161803)

VII PERFORMANCE DATA [807.92(b)]

Results of the verification and validation testing in the table below indicate that the product meets established performance requirements and is safe and effective for its intended use.

Bench Testing	**Result**	**Conclusion**
Physical 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.
Surface Contamination	Test article when examined at magnification, should meet existing surface contamination and defects specification.	Device was free from surface defects and contamination.
Corrosion Resistance	Test article should be corrosion resistant.	Device met established corrosion resistance.
Guidewire Coating adherence	Coating adherence maintained after advance/retract cycles.	Durability and lubricity of coating was maintained after advance/retract cycles.
Guidewire fracture resistance	Test article should not show signs of fracture. There should be no coating flaking off the guidewire.	Device met established fracture resistance specification.
Guidewire tip shapeability	Test article should be greater than or equal to existing tip shapeability specification.	Device met established Guidewire tip shapeability specification.
Torque Strength	Test article should be greater than or equal to existing torque strength specification.	Device met established torque strength specification.
Torque Response	Test article should be equivalent to, or better than predicate device.	Subject device torque response equivalent to predicate device.

Flexing test	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	Test article should be less than existing distal tip specification to deflect the distal tip of guidewire.	Device met established distal tip flexibility specification.
Tensile strength	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.
Simulated use testing	Test articles achieved rating ≥ 3 for prep of device, introduction, and tracking.	Device performed as intended under simulated use.
Particulate Testing	Particle count of test articles ≤ 25particles (≥ 10 microns) and ≤ 3 particles (≥ 25 microns).	Device has comparable particulate results to the predicate device.

Biological Evaluation

The biocompatibility studies were not repeated as Traxcess™ 7 Mini 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 the reference device Traxcess™ 14 SELECT Guidewire (K200547). The biocompatibility testing conducted on the Traxcess™ 14 SELECT Guidewire (K200547) provides assurance that the guidewire has a safe biocompatibility profile and are safe to use.

VIII CONCLUSIONS

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