April 16, 2020

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

Re: K200547
Trade/Device Name: Traxcess™ 14 SELECT Guidewire
Regulation Number: 21 CFR 870.1330
Regulation Name: Catheter Guide Wire
Regulatory Class: Class II
Product Code: MOF, DQX
Dated: March 5, 2020
Received: March 19, 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)*
K200547

Device Name
Traxcess™ 14 SELECT Guidewire

Indications for Use *(Describe)*
The 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 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™14 SELECT 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: 15-April-2020

II DEVICE [807.92(a)(2)]

Name of Device:	Traxcess™ 14 SELECT 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)]

Traxcess 14 SELECT Guidewire (K153053)

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

The Traxcess™ 14 SELECT 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 PTFE. The purpose of these surface coatings is to provide lubricity when the Traxcess™ 14 SELECT 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™ 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 intended for use in coronary arteries.

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

The Traxcess™ 14 SELECT Guidewire has the following similarities to the predicate device, Traxcess™ 14 SELECT Guidewire (K153053):

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 alternative 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 1** states the comparison between Traxcess™ 14 SELECT Guidewire (Predicate Device, K153053) and Traxcess™14 SELECT Guidewire (Subject Device).

Description	**Predicate Device (Existing) Traxcess™ 14 SELECT Guidewire**	**Subject Device (Modified) Traxcess™ 14 SELECT Guidewire (K200547)**	**Rationale for Differences (if any)**
Indications for Use	The Traxcess™ 14 SELECT Guidewire is 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	The 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	**Changed intended to indicated in the Indications for Use statement**

	device is not intended for use in coronary arteries.	device is not intended for use in coronary arteries.	
Intended Use	The Traxcess™ 14 SELECT guidewire is used in both diagnostic and interventional procedures where distal access is necessary.	Same	No differences
Function	The steerable guidewire is used to facilitate the selective placement of diagnostic or therapeutic catheters.	Same	No differences
Anatomical Location	General intravascular use, including the neuro and peripheral vasculature.	Same	No differences
Wire Diameter	Proximal = 0.014" Distal = 0.012"	Same	No differences
Device Length	200 cm	Same	No differences
Coil Length	40 cm	Same	No differences
Platinum/Nickel Coil Length (Radiopaque)	3 cm	Same	No differences
Stainless Steel Coil Length	37 cm	Same	No differences
Distal Shaft Length (Shapeable Length)	1.4 cm	Same	No differences
Distal tip thickness (core wire)	0.037 mm	Same	No differences
Proximal end configuration	Compatible with Traxcess™ docking wire(K093647)	Same	No differences
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	No differences
Coating Material (Distal section)	**Coil and distal/proximal stainless-steel section:** Hydrophilic Coating [SLIP-COAT by Argon Medical]	Same	No differences
Coating Material (Proximal section)	**Proximal Stainless-steel section:** PTFE	**Proximal Stainless-steel section:** PTFE	**Change in Supplier of PTFE coating**
Coating Length (Distal section)	Hydrophilic coating = 980	Same	No differences

	mm		
Coating Length (Proximal section)	PTFE = 1000 mm	Same	No differences
Method of supply	Sterile and single use	Same	No differences
Sterilization method	Ethylene oxide gas	Same	No differences
Accessories	Shaping mandrel, Torque device, and Insertion tool	Same	No differences
Package configuration	Placed into a dispenser hoop, Tyvek pouch, and box carton.	Same	No differences

VII PERFORMANCE DATA [807.92(b)]

Results of the verification and validation testing (**Table 2,3**) indicate that the product meets established performance requirements and is safe and effective for its intended use.

Table 2: Design Verification and Validation Test Summary

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.
Simulated use testing	Test articles achieved rating ≥ 3 for prep of device, introduction, and tracking	Device performed as intended under simulated use
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.
Particulate Testing	Particle count of test articles ≤ 6000 particles (≥ 10 microns) and≤ 600 particles (≥ 25 microns)	Device has comparable particulate results to the predicate device

Table 3: Biocompatibility Test Summary

Biocompatibility	Result	Conclusion
Cytotoxicity Compliance with ISO 10993-5:2009	Scores of grade 0 (no cell lysis) or grade 1 and 2 (slight to mild cytotoxic results) are considered passing and non-cytotoxic.	The test articles are non-cytotoxic (grade 0)
Sensitization Compliance with ISO 10993-10:2010	The test article is considered non-sensitizing if all of the animals receive grades of <1 at all time periods.	The test articles are not a sensitizer (grade <1)
Irritation Compliance with ISO 10993-10:2010	Considered to be non-irritating and passing when the difference between the test article mean score (erythema and edema) is 1.0 or less than that of the negative (vehicle) control score.	The test articles are considered non-irritating (the score ≤1)
Acute Systemic Toxicity Compliance with ISO 10993-11:2017	The test is considered negative and non-acute systemically toxic if none of the animals treated with the test article showed a significantly greater biological reactivity than animals treated with the negative control. If 2 or more test group animals dies or exhibit severe reactions (e.g. convulsions), or if 3 or more test group animals experience weight loss greater than 10% of their original mass, the article does not meet requirements of the test	The test articles meet requirements of the test and it's nontoxic.
Material-mediated Pyrogenicity Compliance with ISO 10993-11:2017	Considered non-pyrogenic if no animal shows an individual rise in temperature of 0.5 °C or more above the baseline temperature	Not pyrogenic ((temperature rise < 0.5 ºC)

Biocompatibility	Result	Conclusion
Haemo-compatibility - Hemolysis Compliance with (ISO) 10993-4: 2017	A score of < 2.0% hemolytic index is classified as "non-hemolytic". Scores of ≥2% to ≤5% hemolytic index are "slightly hemolytic" and scores of >5% are "hemolytic".	The test article is considered non-hemolytic (1.48% hemolysis) Extract Method
	A score of < 2.0% hemolytic index is classified as "non-hemolytic". Scores of ≥2% to ≤5% hemolytic index are "slightly hemolytic" and scores of >5% are "hemolytic".	Test article is consideration-hemolytic (0.96% hemolysis)). Direct Method
Haemo-compatibility - Coagulaton Compliance with ISO 10993-4:2017	Test article meets the requirements of the test and is not considered to have an effect on the PTT, if no statistically significant decrease is found between the PTT of the plasma exposed to the test article and that of the plasma exposed to either the negative control or the untreated control. The biological significance is also considered in the evaluation of the results by comparing to a predicate device.	The test article meets the requirement of the test and not an activator to the coagulation.
Haemo-compatibility – Complement Activation Compliance with ISO 10993-4: 2017	No statistically significant increase in the reported level of C3a or SC5b-9a when compared to both the Normal Human Serum (NHS) and the negative control at 60-minute time point.	The test articles are considered a 'Non-Activator of the Complement System'.
Haemo-compatibility – Thrombus formation Compliance with ISO 10993-4:2017	The mean percentage value of the platelet cell counts is within 80 to 120% of the negative control and is at least 30% above that of the positive control mean percentage value. The test article fails if the platelet count is ≤50% of the negative control and /or a visible clot is produced	The test article meets the requirement of the test and does not cause thrombus formation
Haemo-compatibility – Thrombogenicity Compliance with ISO 10993-4:2017	Considered thromboresistant if the test article has a thrombus formation score of 2 or less	The test articles are considered thromboresistant (score <2).

VIII CONCLUSIONS

Based on the 510(k) summary and information provided herein, we conclude the subject device, the Traxcess™ 14 SELECT Guidewire, is substantially equivalent in its intended use, design, guidewire material, performance, and the underlying fundamental scientific technology used, to the predicate Traxcess™ 14 SELECT Guidewire (K153053).