February 16, 2021

Micro Therapeutics, Inc. d/b/a ev3 Neurovascular
Catherine Chiou
Associate Regulatory Affairs Specialist
9775 Toledo Way
Irvine, California 92618

Re: K210114
Trade/Device Name: Rebar Micro Catheter
Regulation Number: 21 CFR 870.1210
Regulation Name: Continuous Flush Catheter
Regulatory Class: Class II
Product Code: KRA, QJP
Dated: January 15, 2021
Received: January 19, 2021

Dear Catherine Chiou:

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,

Naira Muradyan, Ph.D.
Assistant 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K210114

Device Name
Rebar™ Micro Catheter

Indications for Use *(Describe)*
The Rebar™ Micro Catheter is intended for the delivery of interventional devices or contrast media into the vasculature of the peripheral and neuro anatomy.

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 [21 CFR 807.92]

K210114

510(k) Owner:	Micro Therapeutics, Inc. d/b/a ev3 Neurovascular 9775 Toledo Way Irvine, CA 92618 Establishment Registration: 2029214
Contact Person:	Catherine Chiou Associate Regulatory Affairs Specialist Telephone: (562)286-3057 Email: catherine.chiou@medtronic.com

Date Summary Prepared:	February 15, 2021
Trade Name of Device:	Rebar™ Micro Catheter
Common Name of Device:	Vascular Microcatheter
Review Panel:	Cardiovascular; Neurovascular
Product Code:	KRA; QJP
Regulation Number:	21 CFR 870.1210; 21 CFR 870.1250
Regulation Name:	Continuous Flush Catheter
Device Classification	Class II
Predicate Device:	Rebar™ Micro Catheter 510(K)s: K093750

Predicate Device

Rebar™ Micro Catheter (K093750)

Reference Device

Marathon™ Flow Directed Micro Catheter (K202318)

Riptide™ Aspiration System (React 71 Catheter) (K182101)

Device Description

The Rebar™ Micro Catheter is an endhole, single-lumen catheter designed to be introduced over a steerable guidewire into the vasculature. The proximal end of the catheter incorporates a standard luer adapter to facilitate the attachment of accessories. The catheter has a semi-rigid proximal shaft which transitions into the flexible distal shaft to facilitate the advancement of the catheter in the anatomy. Single or dual radiopaque markers at the distal end facilitate fluoroscopic visualization. The outer surface of the catheter is coated to increase lubricity.

Indications for Use Statement

The Rebar™ Micro Catheter is intended for the delivery of interventional devices or contrast media into the vasculature of the peripheral and neuro anatomy.

Technical Comparison with Predicate Device:
A comparison of the Rebar™ Micro Catheter to the predicate device is provided in the table below:

Attribute	Predicate: Rebar™ Micro Catheter (K093750)	Subject: Rebar™ Micro Catheter
Indication for Use (IFU) Statement	The Rebar Micro Catheter is intended for the controlled selective infusion of physician-specified therapeutic agents or contrast media into the vasculature of the peripheral and neuro anatomy.	The Rebar Micro Catheter is intended for the delivery of interventional devices or contrast media into the vasculature of the peripheral and neuro anatomy.
Principles of Operations	The Rebar™ Micro Catheter is inserted within a guide catheter that has already been advanced to the desired location. The user connects a hemostatic side arm adapter to the guide catheter to prevent backflow of blood during insertion of the micro catheter. The user also connects a one-way stopcock to the hemostatic side arm adapter to continuously flush the guide catheter with saline. The outer surface of the catheter must be hydrated, and the catheter lumen must be flushed with heparinized saline by attaching a saline filled syringed to the catheter hub. The user selects an appropriate steerable guidewire, inserts it into the hub of the micro catheter and advances the guidewire in the lumen. The stopcock is closed, and the hemostatic valve loosened. The guidewire and micro catheter are introduced as a unit through the hemostatic port of the hemostatic sidearm adapter into the lumen of the guiding catheter. The guidewire/catheter assembly is advanced to the distal tip of the guiding catheter or until the desired site has been reached. The valve around the micro catheter is tightened enough to prevent backflow but allowing some movement through the valve by the micro catheter. The stopcock is then opened. When ready to infuse, the user withdraws the guidewire completely from the micro catheter. A syringe with the desired infusate is connected to the hub of the micro catheter. The user infuses the site as required and then removes and discards the micro catheter.	Same
Proximal Tubing	Pebax with stainless steel helical coil	Same
Distal Tubing	Adhesive, UV Cure	Same
Adhesive	Adhesive, Loctite	Dymax UV Adhesive
Adhesive	Adhesive, Loctite	Same

Attribute	Predicate: Rebar™ Micro Catheter (K093750)	Subject: Rebar™ Micro Catheter
Strain Relief	Inner: Elvax Outer: Dynaflex	Same
Inner lining	PTFE	Same
Outer Coating	Pebax	Same
Hub Resin	Polypropylene	Trogamid
Marker Bands	Platinum-Iridium Alloy	Same
Usable Length	Rebar™ 18: 105-5081-130: 130 cm 105-5081-153: 153 cm 105-5083-153: 153 cm Rebar™ 27: 105-5082-130: 130 cm 105-5082-145: 145 cm	Same
Proximal Section OD (hub)	Rebar™ 18: 2.7F – 0.035" Maximum Rebar™ 27: 2.8F – 0.043" Maximum	Same
Distal Section OD (at tip)	Rebar™ 18: 2.4F – 0.037" Maximum Rebar™ 27: 2.8F – 0.043" Maximum	Same
Distal Section ID (at tip)	Rebar™ 18: 0.020" Minimum Rebar™ 27: 0.026" Minimum	Same
Carton	Natural, PTFE Tubing	Same
Pouch	High-Density Polyethylene (HDPE)	Same
Shelf Life	2 years	Same
Sterilization	Ethylene Oxide (EO)	Same
Use	Single-Use	Same

Performance Data- Bench

The following non-clinical bench testing was performed to evaluate the performance of the Rebar™ Micro Catheter. The passing results of the testing demonstrated that the changes do not raise new questions of safety and effectiveness, supporting the substantial equivalence to the predicate device.

Bench Testing	Test Method Summary	Results Summary
Safety Visual Inspection	**Safety Visual Inspection:** External surface of catheter should be free from process and surface defects and extraneous matter.	The Rebar™ Micro Catheter met the acceptance criteria for visual inspection.

Bench Testing	Test Method Summary	Results Summary
Catheter Hub Integrity A	**Catheter Hub Integrity A:** Catheter hub transition section shall be approximately 6° angle and length ≥ 0.5”	The Rebar™ Micro Catheter met the acceptance criteria for Catheter Hub Integrity A.
Catheter Hub Integrity B	**Catheter Hub Integrity B:** Catheter shall be made of a clear thermal plastic material without internal ledges and voids	The Rebar™ Micro Catheter met the acceptance criteria for Catheter Hub Integrity B.
Catheter Hub Integrity C	**Catheter Hub Integrity C:** Per ISO 80369-7:2018, the hub must meet ISO gauging requirement of 6% luer taper	The Rebar™ Micro Catheter met the acceptance criteria for Catheter Hub Integrity C.
Catheter Hub Integrity D (Liquid Leak)	**Catheter Hub Integrity D (Liquid Leak):** The Rebar™ Micro Catheter was evaluated per ISO 10555-1: 2013 Annex C	The Rebar™ Micro Catheter met the acceptance criteria for Catheter Hub Integrity D (Liquid Leak).
Catheter Hub Integrity E (Air Aspiration)	**Catheter Hub Integrity E (Air Aspiration):** The Rebar™ Micro Catheter was evaluated per ISO 10555-1: 2013 Annex D	The Rebar™ Micro Catheter met the acceptance criteria for Catheter Hub Integrity E (Air Aspiration).
Catheter Pressurization (Dynamic Burst)	**Catheter Pressurization Dynamic Burst:** Catheter shall withstand a dynamic pressure of ≥ 700 psi without rupturing/leaking	The Rebar™ Micro Catheter met the acceptance criteria for Catheter Pressurization (Dynamic Burst).
Catheter Pressurization (Static Burst)	**Catheter Pressurization Static Burst:** Catheter shall withstand a static pressure of ≥ 400 psi without rupturing/leaking	The Rebar™ Micro Catheter met the acceptance criteria for Catheter Pressurization (Static Burst).
ISO 80369-7:2016 Dimensional Testing	**ISO 80369-7:2018 Dimensional Testing:** The Rebar™ Micro Catheter was evaluated per ISO 80369-7:2016	The Rebar™ Micro Catheter met the acceptance criteria for ISO 80369-7:2016 Dimensional Testing.
ISO 80369-7:2016 Performance Testing	**ISO 80369-7:2018 Performance Testing:** The Rebar™ Micro Catheter was evaluated per ISO 80369-7:2016	The Rebar™ Micro Catheter met the acceptance criteria for ISO 80369-7:2016 Performance Testing.

Bench Testing	Test Method Summary	Results Summary
Tensile Strength	**Tensile Strength:** The Rebar™ Micro Catheter was evaluated per ISO 10555-1: 2013	The Rebar™ Micro Catheter met the acceptance criteria for Tensile Strength.

Biocompatibility

Biocompatibility test results for subject Rebar Micro Catheter will be leveraged and adopted for the design change to the hub. The new hub material is Trogamid, which is found within other cleared Medtronic Neurovascular product lines, and is considered indirect patient contact. Biocompatibility data can be leveraged per ISO 10993-1 from the React™ 71 Catheter (K182101), as the modified hub has the same nature and duration of contact, has similar geometry, and is identical in formulation, processing, and sterilization. Slight dimensional changes that were made to the inside of the hub, outside of the hub, and luer thread are minor and do not impact biocompatibility data. Additionally, the new UV adhesive included in the manufacturing process for the hub is non-patient contacting, thereby not impacting biocompatibility results of subject Rebar™ Micro Catheter. Both materials were found to be non-hemolytic and non-cytotoxic per Marathon™ Flow Directed Micro Catheter (K202318).

Performance Data- Animal:

Animal testing was not included in the subject submission. The differences in technological characteristics do not raise new questions of safety and effectiveness as demonstrated through non-clinical bench testing using well-established scientific methods.

Performance Data – Clinical:

Clinical testing was not included in the subject submission. The differences in technological characteristics do not raise new questions of safety and effectiveness as demonstrated through non-clinical bench testing using well-established scientific methods.

Conclusion

The differences in technological characteristics do not raise new questions of safety and effectiveness as demonstrated through non-clinical bench testing using well-established scientific methods. The information provided in this submission supports the proposal of substantial equivalence for the Rebar™ Micro Catheter.