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

September 14, 2020

Re: K202318
Trade/Device Name: Marathon Flow Directed Micro Catheter
Regulation Number: 21 CFR 870.1210
Regulation Name: Continuous Flush Catheter
Regulatory Class: Class II
Product Code: KRA, QJP
Dated: August 12, 2020
Received: August 17, 2020

Dear Elizabeth Campion:

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)*
K202318

Device Name
Marathon™ Flow Directed Micro Catheter

Indications for Use *(Describe)*
The Marathon™ Flow Directed Micro Catheter is intended to access the peripheral and neuro vasculature for the controlled selective infusion of physician-specified therapeutic agents such as embolization materials and of diagnostic materials such as contrast media.

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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K202318

510(k) Summary [21 CFR 807.92]

510(k) Owner:	Micro Therapeutics, Inc. d/b/a ev3 Neurovascular 9775 Toledo Way Irvine, CA 92618 Establishment Registration: 2029214
Contact Person:	Elizabeth Campion Regulatory Affairs Specialist Telephone: (949) 701-7710 Email: elizabeth.c.campion@medtronic.com

Date Summary Prepared:	September 8, 2020
Trade Name of Device:	Marathon™ Flow Directed Micro Catheter
Common Name of Device:	Vascular Microcatheter
Review Panel:	Neurology
Product Code:	KRA, QJP
Regulation Number:	21 CFR 870.1210
Regulation Name:	Continuous Flush Catheter
Device Classification	Class II
Predicate Device:	Marathon™ Flow Directed Micro Catheter 510(K)s: K093750

Predicate Device

Marathon™ Flow Directed Micro Catheter (K093750)

Reference Device

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

Device Description

The Marathon™ Flow Directed Micro Catheters are single-lumen, endhole catheters designed for the sub selective infusion of physician-specified therapeutic agents such as embolization materials and diagnostic materials such as contrast media in tortuous, distal vessels. The catheter has a semi-rigid proximal shaft and a highly flexible distal shaft to facilitate the advancement of the catheter in the anatomy. The proximal end of the catheter incorporates a standard luer adapter to facilitate the attachment of accessories. The catheter has a radiopaque marker at the distal end to facilitate fluoroscopic visualization. The outer surfaces of the catheter are coated to increase lubricity. Microcatheter may be used with stylet, guidewire or introducer sheath to increase the rigidity of the distal section during introduction into the guiding catheter.

Indications for Use Statement

The Marathon™ Flow Directed Micro Catheter is intended to access the peripheral and neuro vasculature for the controlled selective infusion of physician-specified therapeutic agents such as embolization materials and of diagnostic materials such as contrast media.

Technical Comparison with Predicate Device:

A comparison of the Marathon™ Flow Directed Micro Catheter to the predicate device is provided in the table below:

Table 1: Technical Comparison with Predicate Device		
Attribute	Predicate: Marathon™ Flow Directed Micro Catheter (K093750)	Subject: Marathon™ Flow Directed Micro Catheter
Indication for Use (IFU) Statement	The Marathon™ Flow Directed Micro Catheter is intended to access the peripheral and neuro vasculature for the controlled selective infusion of physician-specified therapeutic agents such as embolization materials and of diagnostic materials such as contrast media.	Same
Proximal Tubing	Grilamid and Pebax with stainless steel helical coil	Same
Proximal Tubing	Adhesive, UV Cure	N/A
Proximal Tubing and hub	Adhesive, Loctite	Dymax UV Adhesive
Outer Strain Relief Adhesive	Adhesive, Loctite	Same
Strain Relief	Inner: Elvax Outer: Dynaflex	Same
Inner lining	PTFE	Same
Outer Coating	Proprietary Hyaluronic acid, acrylic resin binder	Same
Hub	Polypropylene	Trogamid
Marker Bands	Platinum-Iridium Alloy	Same
Usable Length	165±2.5cm	Same
Proximal Section OD (hub)	2.7 F	Same
Distal Section OD (at tip)	1.3 F	Same
Distal Section ID (at tip)	.13”	Same
Carton	Natural, PTFE Tubing	Same
Pouch	High-Density Polyethylene (HDPE)	Same
Shelf Life	3 Year	1 year
Sterilization	Ethylene Oxide (EO)	Same
Use	Single-Use	Same

Biocompatibility

Biocompatibility data was 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. Additionally, no other chemicals were added, and the Dymax UV adhesive is non-patient contacting. While biocompatibility testing was not required, hemocompatibility and cytotoxicity were performed and passed required acceptance criteria. See Table 2 for test summary.

Table 2: Summary of Biocompatibility Testing		
Test Category	**Summary of Results**	**Conclusion**
Cytotoxicity	The test article extract showed no evidence of causing cell lysis or toxicity in any of the test wells. The test article met the requirements of the test since the test article was non-cytotoxic.	The Marathon™ Flow Directed Micro Catheter is considered non-cytotoxic.

Table 2: Summary of Biocompatibility Testing		
Test Category	**Summary of Results**	**Conclusion**
Hemocompatibility	The test article showed no evidence of color and was free of particulates. The test article met the test requirements and was non-hemolytic.	The Marathon™ Flow Directed Micro Catheter is considered non-hemolytic.

Performance Data- Bench

The following non-clinical bench testing was performed to evaluate the performance of the Marathon™ Flow Directed Micro Catheter. The successful 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.

Table 3: Summary of Performance Data- Bench		
Bench Testing	Test Method Summary	Summary of Results
Dimension- Useable Length	**Dimension- Useable Length:** Marathon™ Flow Directed Micro Catheter should measure 165 ± 2.5cm.	The Marathon™ Flow Directed Micro Catheter met the acceptance criteria for useable length.
Dynamic Burst	**Dynamic Burst:** The Marathon™ Flow Directed Micro Catheter was evaluated per ISO 10555-1 2014/A1:2017 Annex G	The Marathon™ Flow Directed Micro Catheter met the acceptance criteria for dynamic burst.
Static Burst	**Static Burst:** The Marathon™ Flow Directed Micro Catheter was evaluated per ISO 10555-1 2014/A1:2017 Annex F	The Marathon™ Flow Directed Micro Catheter met the acceptance criteria for static burst.
Static Burst Post Plug & Push	**Static Burst Post Plug & Push:** The Marathon™ Flow Directed Micro Catheter was evaluated per ISO 10555-1 2014/A1:2017 Annex F	The Marathon™ Flow Directed Micro Catheter met the acceptance criteria for static burst, post plug and push.
Hub Tensile	**Hub Tensile:** The Marathon™ Flow Directed Micro Catheter was evaluated per ISO 10555-1 2013/A1:2017 Annex B	The Marathon™ Flow Directed Micro Catheter met the acceptance criteria for hub tensile.
Hub Tensile Post Plug & Push	**Hub Tensile Post Plug & Push Conditioning:** The Marathon™ Flow Directed Micro Catheter was evaluated per ISO 10555-1 2014/A1:2017 Annex F	The Marathon™ Flow Directed Micro Catheter met the acceptance criteria for hub tensile post plug and push.
Deadspace	**Deadspace:** The Marathon™ Flow Directed Micro Catheter deadspace should be ≤ 0.27 ³ and ≥ 0.23 ml, without Syringe adapter	The Marathon™ Flow Directed Micro Catheter met the acceptance criteria for deadspace.
Visual Inspection	**Visual Inspection:** The Marathon™ Flow Directed Micro Catheter Hub should be clear and free from defects and crazing	The Marathon™ Flow Directed Micro Catheter met the acceptance criteria for visual inspection.

Table 3: Summary of Performance Data- Bench		
Bench Testing	Test Method Summary	Summary of Results
Standard Luer Hub Requirements	**Standard Luer Hub Requirements:** The Marathon™ Flow Directed Micro Catheter was evaluated per ISO 80369-7:2016 and ISO 80369-20:2015	The Marathon™ Flow Directed Micro Catheter met the acceptance criteria for standard luer hub requirements.
Hub Air Leak	**Hub Air Leak:** The Marathon™ Flow Directed Micro Catheter was evaluated per ISO 10555-1 2014/A1:2017 Annex D	The Marathon™ Flow Directed Micro Catheter met the acceptance criteria for hub air leak.

Performance Data- Animal:

No animal testing was conducted as there is no change to the Indication for Use (IFU) Statement for the Marathon™ Flow Directed Micro Catheter in comparison to the legally marketed predicate device. The differences in technological characteristics do not raise new questions of safety and effectiveness as demonstrated through non-clinical bench testing using well-established acceptable scientific methods.

Performance Data – Clinical:

No clinical testing was conducted as there is no change to the Indication for Use (IFU) Statement for the Marathon™ Flow Directed Micro Catheter in comparison to the legally marketed predicate device. The differences in technological characteristics do not raise new questions of safety and effectiveness as demonstrated through non-clinical bench testing using well-established acceptable scientific methods.

Conclusion

There is no change to the Indication for Use (IFU) Statement for the Marathon™ Flow Directed Micro Catheter in comparison to the legally marketed predicate device. In addition, the differences in technological characteristics do not raise new questions of safety and effectiveness as demonstrated through non-clinical bench testing using well- established acceptable scientific methods. The information provided in this submission supports the proposal of substantial equivalence for the Marathon™ Flow Directed Micro Catheter.