May 28, 2024

Micro Therapeutics, lnc. d/b/a ev3 Neurovascular
Alexander Abe
Regulatory Affairs Specialist
9775 Toledo Way
Irvine, California 92618

Re: K241177
Trade/Device Name: React 71 Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: DQY, QJP
Dated: April 26, 2024
Received: April 29, 2024

Dear Alexander Abe:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 -S

Naira Muradyan, Ph.D.
Assistant Director
DHT5A: Division of Neurosurgical,
Neurointerventional
and Neurodiagnostic Devices
OHT5: Office of Neurological
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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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K241177

Device Name
React™ 71 Catheter

Indications for Use *(Describe)*
The React™ 71 Catheter is indicated for the introduction of interventional devices into the peripheral and neuro vasculature.

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
K241177

510(k) Owner:	Micro Therapeutics, Inc. d/b/a ev3 Neurovascular 9775 Toledo Way Irvine, CA 92618, USA Establishment Registration: 2029214
Contact Person:	Alexander Abe Regulatory Affairs Specialist Telephone: (949) 490-3814 Email: alex.k.abe@medtronic.com

Date Summary Prepared:	23 May 2024
Trade Name of Device:	React™ 71 Catheter
Common Name of Device:	Percutaneous Catheter
Review Panels:	Neurology, Cardiovascular
Product Codes:	DQY, QJP
Regulation Number:	21 CFR 870.1250
Regulation Name:	Percutaneous Catheter
Device Classification:	Class II
Predicate Device:	K182097 React™ 71 Catheter
Reference Device:	K180715 React™ 68 Catheter

Device Description:

The React™ 71 Catheter is a single lumen, flexible, variable stiffness composite catheter with a nitinol structure that is jacketed with various durable polymer outer layers. A lubricious, polytetrafluoroethylene liner and Engage™ inner layer is used to create a structure that has both proximal stiffness and distal flexibility. The React™ 71 Catheter is also designed with an encapsulated radiopaque distal platinum-iridium marker band which is used for visualization under fluoroscopy. The React™ 71 Catheter is introduced into the vasculature through the Split-Y Introducer Sheath. The proximal end of the React™ 71 Catheter is designed with a green thermoplastic elastomer strain relief and a clear hub. The distal end of the React™ 71 Catheter is coated with a Surmodics Serene™ Coating.

Indications for Use

React™ 71 Catheter Indications for Use		
Model Numbers	**Device Name**	**Indications for Use/Intended Use**
REACT-71-115 REACT-71-125	React™ 71 Catheter	The React™ 71 Catheter is indicated for the introduction of interventional devices into the peripheral and neuro vasculature.

Proposed Change:

Micro Therapeutics, Inc. d/b/a ev3 Neurovascular requests clearance for commercialization of the React™ 71 Catheter models with shortened usable and subsequently shortened overall lengths.

Device Comparison:

Design Feature	Predicate Device: React™ 71 Catheter (K182097)	Subject Device: React™ 71 Catheter (K241177)	Reference Device: React™ 68 Catheter (K180715)
Indications for Use	The React™ 71 Catheter is indicated for the introduction of interventional devices into the peripheral and neuro vasculature.	Same as K182097	The React™ 68 Catheter is indicated for the introduction of interventional devices into the peripheral and neuro vasculature.
CFU(s)/Model Number(S)/SKU(s)	REACT-71	REACT-71-115 REACT-71-125	REACT-68
Materials of Construction			
Hub	Trogamid®	Same as K182097	Same as K182097
Strain Relief	DynaFlex®	Same as K182097	Same as K182097
Inner Layer	PTFE, Polyolefin	Same as K182097	PTFE
Reinforcement	Nitinol	Same as K182097	Same as K182097
Outer Jacket	Polyamide, Polyolefin, Polyurethane	Same as K182097	Grilamid™ Pebax®
Marker Band	Platinum/ Iridium	Same as K182097	Same as K182097
Adhesive	Cyanoacrylate	Same as K182097	Same as K182097
Coating	Hydrophilic	Same as K182097	Same as K182097
Dimensions			
Working Length/Effective Length/Usable Length	132 cm	115 cm 125 cm	Same as K182097
Inner Diameter	0.071”	Same as K182097	0.068”

Design Feature	Predicate Device: React™ 71 Catheter (K182097)	Subject Device: React™ 71 Catheter (K241177)	Reference Device: React™ 68 Catheter (K180715)
Proximal Outer Diameter (OD)	0.0855" (Max)	Same as K182097	0.083"
Distal OD	0.0855" (Max)	Same as K182097	0.083"
Overall Catheter Length* **Measured from Lip of Hub Luer to Distal End of Catheter Tip*	141 cm	121 cm 131 cm	Same as K182097
Packaged Accessories			
Peelable Sheath	Yes	Same as K182097	Same as K182097
Packaging			
Packaging Card	Polyethylene	Same as K182097	Same as K182097
Packaging Hoop	Polyethylene	Same as K182097	Same as K182097
Packaging Pouch	Nylon, Tyvek®	Same as K182097	Same as K182097
Sterilization			
Method	Ethylene Oxide (EO)	Same as K182097	Same as K182097
Sterility Assurance Level (SAL)	10^{-6}	Same as K182097	Same as K182097
Device Compatibility			
Guidewire Compatibility	The maximum diameter recommended for a guidewire is 0.038" (0.97 mm).	Same as K182097	Same as K182097
Guide Sheath Compatibility	When using the React™ 71 Catheter, the minimum inner diameter recommended for a guide sheath is 0.087" (2.21 mm).	Same as K182097	N/A

Biocompatibility:
There are no changes to the materials of construction or to the manufacturing materials for the subject React™ 71 Catheters when compared to the legally marketed predicate device (K182097). Therefore, the biocompatibility evaluation of the legally marketed predicate device was adopted for the subject device.

Sterilization and Shelf-Life:
There are no changes to the packaging configuration or materials for the subject React™ 71 Catheters when compared to the legally marketed predicate device (K182097). Therefore, the sterilization and shelf-life for the legally marketed predicate device was adopted for the subject device.

Performance Data – Bench:
Non-clinical bench testing was conducted to evaluate the performance of the subject device with shorter length compared to the predicate in a clinically representative anatomical model.

The following non-clinical bench tests were conducted:

Design Validation		
Evaluation Criteria	**Test Method Summary**	**Results**
The length of the subject device shall be compatible with minimum length 136 cm guide catheter.	The subject device was evaluated per FDA Guidance 1757 and per FDA Recognized Consensus Standards 5-125 & 5-129.	The subject device met the acceptance criteria.
The subject device should be able to navigate to the distal M1 segment of the MCA over a microcatheter.	The subject device was evaluated per FDA Guidance 1757 and per FDA Recognized Consensus Standards 5-125 & 5-129.	The subject device met the acceptance criteria .

Performance Data – Animal & Clinical:

The determination of substantial equivalence is based upon successful completion of non-clinical bench testing as there is no change to the indication for use statement, fundamental scientific technology, principles of operation, or materials of construction.

Conclusion:

There is no change to the indication for use, fundamental scientific technology, materials of construction, and principles of operation of the subject React™ 71 Catheters in comparison to the legally marketed predicate device (K182097). The shorter usable lengths and subsequently shorter overall lengths of the subject React™ 71 Catheters do not raise different questions of safety and effectiveness. The information provided in this special 510(k) premarket notification supports a determination of substantial equivalence for the subject React™ 71 Catheters.