July 4, 2018

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

Re: K180715
Trade/Device Name: React 68 Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: DQY
Dated: June 4, 2018
Received: June 6, 2018

Dear Ryan Kenney:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820);

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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/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 -S

for Carlos L. Peña, PhD, MS
Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
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)*
K180715

Device Name
React 68 Catheter

Indications for Use *(Describe)*
The React™ 68 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.

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510(k) Summary: K180715

510(k) Owner:	Micro Therapeutics, Inc. d/b/a ev3 Neurovascular 9775 Toledo Way Irvine, CA 92618 Establishment Registration No.: 2029214
Contact Person:	Ryan Kenney Senior Regulatory Affairs Specialist Telephone: (949) 297-5489 Email: ryan.j.kenney@medtronic.com

Date Summary Prepared:	June 25, 2018
Trade Name of Device:	React™ 68 Catheter
Common Name of Device:	Percutaneous Catheter
Review Panel:	Neurology
Product Code:	DQY
Regulation Number:	21 CFR 870.1250
Regulation Name:	Percutaneous Catheter
Device Classification:	Class II
Predicate Device(s):	AXS Catalyst™ Distal Access Catheter 510(k)#: K151667
	ReFlex™ Guide Catheter 510(k)#: K110055

Device Description:
The React™ 68 Catheter is a single lumen, flexible, variable stiffness composite catheter with a nitinol structure that is jacketed with a durable polymer outer layer. A lubricous, polytetrafluoroethylene liner is used to create a structure that has both proximal stiffness and distal flexibility, and an encapsulated radiopaque distal platinum-iridium markerband which is used for visualization under fluoroscopy. The React™ 68 Catheter is introduced into the vasculature through the split y-introducer sheath. The proximal end of the React™ 68 Catheter is designed with a thermoplastic elastomer strain relief and a clear hub. The distal end of the React™ 68 Catheter is designed with a hydrophilic coating.

Indications for Use:
The React™ 68 Catheter is indicated for the introduction of interventional devices into the peripheral and neuro vasculature.

Device Comparison:

	AXS Catalyst™ Distal Access Catheter (K151667)	ReFlex™ Guide Catheter (K110055)	React™ 68 Catheter
Indication for Use (IFU) Statement	The AXS Catalyst™ Distal Access Catheter is indicated for the insertion and guidance of appropriately sized interventional devices into a selected blood vessel in the peripheral and neurovascular systems. The AXS Catalyst™ Distal Access Catheter is also indicated for use as a conduit for retrieval devices.	The ReFlex™ Guide Catheter is indicated for the introduction of interventional devices into the peripheral and neuro vasculature.	Same as K110055
Materials			
Hub	Nylon	Trogamid®	Same as K110055
Strain Relief	Thermoplastic Rubber	Santoprene	DynaFlex®
Inner Layer	PTFE	Same	Same
Reinforcement	Stainless Steel with Nitinol and Polymer Fiber	Nitinol	Same as K110055
Outer Jacket	Pebax®	Polymeric	Grilamid™ Pebax®
Markerband	Platinum/ Iridium	Same	Same
Adhesive	Cyanoacrylate	Same	Same
Coating	Hydrophilic	Same	Same
Dimensions			
Working Length	132 cm	130 cm	Same as K151667
Inner Diameter (ID)	0.060”	0.072”	0.068”
Proximal Outer Diameter (OD)	0.079”	0.084”	0.083”
Distal Outer Diameter (OD)	0.071”	0.084”	0.083”
Packaged Accessories			
Peelable Sheath	Yes	Same	Same
Rotating Hemostasis Valve	Yes	No	Same as K110055
Packaging			
Packaging Card	Polyethylene	Same	Same
Packaging Hoop	Polyethylene	Same	Same

	AXS Catalyst™ Distal Access Catheter (K151667)	ReFlex™ Guide Catheter (K110055)	React™ 68 Catheter
Other			
Sterilization	Ethylene Oxide (EO)	Same	Same

Biocompatibility:
Biocompatibility was conducted for the React™ 68 Catheter. The React™ 68 Catheter is categorized as a limited exposure (< 24 hours), external communicating device contacting circulating blood. The following biocompatibility was conducted for the React™ 68 Catheter:

Test Description	Results	Conclusions
Cytotoxicity (Elution Method)	The test article extract showed no evidence of causing cell lysis or toxicity and had a grade of zero (no reactivity). The test article extract met the requirements of the test since the grade was less than a grade two (mild reactivity).	The React™ 68 Catheter is considered non-cytotoxic.
Sensitization (Guinea Pig Maximization Test)	The test article extracts showed no evidence of causing delayed dermal contact sensitization in the guinea pig.	The React™ 68 Catheter does not elicit a sensitization response.
Irritation (Intracutaneous Reactivity)	The difference between each test article extract overall mean score and corresponding control extract overall mean score was 0.0 and 0.0 for the sodium chloride and sesame oil test article extracts, respectively.	The React™ 68 Catheter is considered a non-irritant.
Acute Systemic Toxicity (Systemic Toxicity)	There was no mortality or evidence of systemic toxicity from the extracts injected. All animals were clinically normal throughout the study.	The React™ 68 Catheter does not indicate signs of toxicity.
Hemocompatibility (Hemolysis)	The hemolytic index for the test article in direct contact with blood was 0.9%, and the hemolytic index for the test article extract was 0.0%.	The React™ 68 Catheter is considered non-hemolytic.
Hemocompatibility (Complement Activation)	The concentration of SC5b-9 in the sponsor provided control sample was not	The control and test article samples are not considered to

Test Description	Results	Conclusions
	statistically higher than the activated normal human serum control or the negative control. The concentration of SC5b-9 in the test article sample was not statistically higher than the activated normal human serum control, the negative control or the sponsor provided control.	be potential activators of the complement system.
Hemocompatibility (Thrombogenicity)	The thrombogenic potential of the control article was evaluated in comparison to the test article. Both the control and test articles were determined to have minimal thrombus formation after four (4) hours (±30 minutes) without anticoagulation.	The React™ 68 Catheter demonstrates minimal thrombus formation.
Pyrogenicity (Material Mediated)	Not a single animal showed a temperature rise of 0.5°C or more above its baseline temperature. The total rise of the temperature during three (3) hours was 0.0°C.	The React™ 68 Catheter is considered non-pyrogenic.

The React™ 68 Catheter has been evaluated to meet requirements specified in ISO 10993-1.

Performance Data – Bench:
Non-clinical bench testing was conducted to evaluate the performance of the React™ 68 Catheter. The following non-clinical bench testing was conducted for the React™ 68 Catheter:

Test	Test Method Summary	Results
Microbial		
Ethylene Oxide Residual	The React™ 68 Catheter was evaluated per ISO 10993-7.	The React™ 68 Catheter met the acceptance criteria for ethylene oxide residual.
Ethylene Chlorohydrin Residual	The React™ 68 Catheter was evaluated per ISO 10993-7.	The React™ 68 Catheter met the acceptance criteria for ethylene chlorohydrin residual.
Bioburden	The React™ 68 Catheter was evaluated per ISO 11737-1.	The React™ 68 Catheter met the acceptance criteria for bioburden.

Test	Test Method Summary	Results
Bacterial Endotoxin	The React™ 68 Catheter was evaluated per ANSI/AAMI ST72 and USP <161>.	The React™ 68 Catheter met the acceptance criteria for bacterial endotoxin.
Performance		
Visual Inspection	The React™ 68 Catheter was inspected under x2.5 magnification.	The React™ 68 Catheter met the acceptance criteria for visual inspection.
Dimensional Measurements	The proximal ID, distal ID, proximal OD, distal OD, usable length, total length, coating length, and distal tip length of the React™ 68 Catheter were measured.	The React™ 68 Catheter met the acceptance criteria for dimensional measurements.
Tip Buckling	The React™ 68 Catheter was evaluated for the maximum compressive force.	The React™ 68 Catheter met the acceptance criteria for tip buckling.
Kink Resistance	The React™ 68 Catheter was evaluated for the maximum kink diameter.	The React™ 68 Catheter met the acceptance criteria for kink resistance.
Particulate	The React™ 68 Catheter was evaluated per USP <788>.	The React™ 68 Catheter met the acceptance criteria for particulate evaluation.
Coating Lubricity	The React™ 68 Catheter was evaluated for the average friction forces.	The React™ 68 Catheter met the acceptance criteria for coating lubricity.
Tensile Strength	The React™ 68 Catheter was evaluated per ISO 10555-1. Annex B.	The React™ 68 Catheter met the acceptance criteria for tensile strength at the hub and shaft.
Liquid Leak	The React™ 68 Catheter was evaluated per ISO 10555-1. Annex C.	The React™ 68 Catheter met the acceptance criteria for liquid leak.
Corrosion Resistance	The React™ 68 Catheter was evaluated per ISO 10555-1. Annex A.	The React™ 68 Catheter met the acceptance criteria for corrosion resistance.
Hub Aspiration Resistance	The React™ 68 Catheter was evaluated per ISO 10555-1. Annex D.	The React™ 68 Catheter met the acceptance criteria for hub air aspiration.
Compatibility	The React™ 68 Catheter was inspected for visual damage of the catheter when delivering and retrieving interventional devices.	The React™ 68 Catheter met the acceptance criteria for delivering and retrieving interventional devices.

Test	Test Method Summary	Results
Radiopacity	The markerband length and wall thickness of the React™ 68 Catheter were measured. In addition, radiopacity was confirmed via fluoroscopy.	The React™ 68 Catheter met the acceptance criteria for radiopacity.
Luer Standards	The React™ 68 Catheter was evaluated per ISO 594-1 and ISO 80369-7.	The React™ 68 Catheter met the acceptance criteria for luer standards.
Torque Strength	The React™ 68 Catheter was evaluated for transmission of proximal torque to the distal tip.	The React™ 68 Catheter was able to withstand torsional forces that are typical of clinical use.
Dynamic Pressure	The React™ 68 Catheter was evaluated for the amount of pressure it can withstand.	The React™ 68 Catheter was able to withstand pressures that are typical of clinical use.
Coating Integrity	The React™ 68 Catheter was evaluated for coating coverage and lubricity.	The React™ 68 Catheter remained coated and lubricous.
Usability	The React™ 68 Catheter and predicate device were evaluated for maneuverability and flexibility.	The React™ 68 Catheter met the acceptance criteria for usability.

Performance Data – Animal:
Not Applicable. A determination of substantial equivalence is based upon successful completion of non-clinical bench testing as there is no change to the intended use or fundamental scientific technology.

Performance Data – Clinical:
Not Applicable. A determination of substantial equivalence is based upon successful completion of non-clinical bench testing as there is no change to the intended use or fundamental scientific technology.

Conclusion:
The design modifications incorporated do not alter the intended use or fundamental scientific technology.

Non-clinical bench testing supports a determination that the subject React™ 68 Catheter is substantially equivalent to the predicate device.