DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

May 31, 2017

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

Re: K171268
Trade/Device Name: Reverse Micro Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: DQY, KRA, DQO
Dated: April 28, 2017
Received: May 1, 2017

Dear Mr. Elliott:

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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Carlos L. Pena -S

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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K171268

Device Name

Reverse™ Micro Catheter

Indications for Use *(Describe)*

The Reverse™ Micro Catheter is intended for use in neuro, peripheral, and coronary vasculature for the infusion of diagnostic agents, such as contrast media, and therapeutic agents, such as occlusion coils.

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 per 21 CFR 807.92

Submitter's Name and Address	Micro Therapeutics, Inc. d/b/a ev3 Neurovascular 9775 Toledo Way Irvine, CA 92618 U.S.A.
Contact Name and Information	Eric Elliott Principal Regulatory Affairs Specialist Tel: 949.297.5803 E-mail: Eric.Elliott@medtronic.com
Date Prepared	April 28, 2017
Trade Name	Reverse™ Micro Catheter
Common Name	Catheter Percutaneous, Catheter Infusion, Catheter Diagnostic
Classification Name	Catheter, Percutaneous (DQY) has been classified as Class II per 21 CFR 870.1250 Catheter, Infusion (KRA) has been classified as Class II per 21 CFR 870.1210 Catheter, Intravascular Diagnostic (DQO) has been classified as Class II per 21 CFR 870.1200

Predicate Device	Reverse™ Medical Microcatheter	K130858	11-Oct-2013
Reference Device(s)	Navien™ Intracranial Catheter	K161152	12-Oct-2016
	Arc™ Intracranial Catheter	K150107	29-Jul-2015

Description of Device	The Reverse™ Micro Catheter is a single lumen catheter designed to be introduced over a steerable guide wire to access small, tortuous vasculature. The semi-rigid proximal section transitions to a flexible distal tip to facilitate vessel navigation. The micro catheter incorporates a PTFE liner to facilitate movement or introduction of devices passed through its lumen. Dual radiopaque markers at the distal end

Device Description, continued	facilitate fluoroscopic visualization. The outer surface of the catheter body also employs a hydrophilic coating to enhance lubricity and promote deliverability. The Reverse™ Micro Catheter incorporates a standard luer fitting to facilitate the attachment of ancillary devices. The catheter and included accessories (steam shaping mandrel and peel away introducer sheath) are provided sterile, non-pyrogenic, and are intended for single use only. To accommodate physician preference and anatomical variations, the Reverse™ Micro Catheter is available in two models, Reverse 021, with a 0.021" inner diameter (ID) and, Reverse 027, with a 0.027" ID.
Intended Use/Indications for Use	The Reverse™ Micro Catheter is intended for use in neuro, peripheral, and coronary vasculature for the infusion of diagnostic agents, such as contrast media, and therapeutic agents, such as occlusion coils.

Device Technology Characteristics and Comparison to Predicate Device

The Reverse™ Micro Catheter maintains the same fundamental scientific technology and operating principles as the predicate Reverse™ Medical Microcatheter (K130858). Furthermore, dimensions, materials of construction (excluding hydrophilic coating), sterilization method, and indications for use remain unchanged.

The primary difference between the subject and predicate device is the utilization of Serene® hydrophilic coating. This is the same coating as previously cleared with Medtronic's more recent intracranial support catheters, Navien™ (K161152) and Arc™ (K150107). Serene® will replace the predicate's legacy hydrophilic coating, thereby improving consistency across Medtronic Neurovascular's product portfolio and reducing manufacturing redundancy across the organization.

The only remaining design difference between subject and predicate is the elimination of yellow colorant from the split sheath introducer, an accessory packaged with the catheter. Even though the colorant is no longer utilized, the overall design and base formulation remains unchanged. With the two exceptions listed above, all raw materials utilized by the Reverse™ Micro Catheter are identical to those of the predicate (K130858).

In support of a substantial equivalence determination, Medtronic Neurovascular has compared and evaluated the design differences between the subject and predicate device.

Technological Characteristic	Subject Device K171268	Predicate Device K130858
Inner Diameter	Reverse 021: 0.021" Reverse 027: 0.027"	Same
Guidewire Compatibility	Reverse 021: ≤ 0.018" OD Reverse 027: ≤ 0.025" OD	Same
Distal Sheath Outer Diameter	Reverse 021: 2.4 F Reverse 027: 2.8 F	Same
Proximal Sheath Outer Diameter	Reverse 021: 2.75 F Reverse 027: 3.1 F	Same
Usable Length	150 cm	Same
Coating	Hydrophilic Topcoat w/ Polyacrylamide Base	Hydrophilic Topcoat w/ Urethane Base
Peel Away Introducer Sheath	Yes (Colorless)	Yes (Yellow)

Non-clinical performance evaluations, as described below, indicate that the subject device is substantially equivalent to, and at least as safe and effective as the predicate device (Reverse™ Medical Microcatheter, K130858).

Non-Clinical Performance Data

Modifications to the predicate device were assessed according to risk-based failure mode effects and criticality analysis (FMECA), ensuring that the appropriate verification and validation activities were conducted. Determination of substantial equivalence is based on this assessment of non-clinical verification and validation testing.

Non-clinical data includes bench-top verification and validation, packaging verification, and biological safety.

Bench Testing:

Bench testing was performed to evaluate physical integrity, functionality, and overall performance of the catheter relative to the design modifications introduced by the subject device. Comprehensive verification and validation activities were successfully completed; raising no new issues of safety or effectiveness. All testing passed the acceptance criteria. Performance testing encompassed:

- surface inspection
- dimensional requirements
- lubricity/ friction
- particulates
- coating characterization
- simulated use device compatibility
- simulated use navigation and delivery
- shelf-life verification (1 year accelerated aging)

Biological Safety Testing:

The Reverse™ Micro Catheter was subjected to a series of biocompatibility tests in accordance with FDA Guidance, *Use of International Standard ISO 10993-1*.

- MEM Elution Cytotoxicity
- Guinea Pig Maximization Sensitization
- Intracutaneous Reactivity
- Acute System Injection
- Materials Mediated Rabbit Pyrogen
- Hemolysis Direct Contact
- Hemolysis Indirect Extract Method
- Complement Activation
- *In vivo* Thrombogenicity
- Genotoxicity, Ames Assay
- Genotoxicity, *in vitro* Mouse Lymphoma
- Genotoxicity, *in vivo* Mouse Micronucleus
- USP Physicochemical

Testing demonstrated that the Reverse™ Micro Catheter finished device, accessories, and packaging materials have no residual risk of biological hazards; and are therefore considered biocompatible for their intended use.

Non-Clinical Performance Data, continued	Microbial assessments included bioburden, endotoxin, and sterility assurance. Sterilization has been validated and is controlled in accordance with *ISO 11135-1, Medical Devices – Validation and Routine Control of Ethylene Oxide Sterilization* and designed to provide a minimum SAL of 10^{-6}. Validation was conducted using the overkill approach in accordance with ISO 11135-1 Annex B (normative), *Conservative determination of lethal rate of the sterilization process – Overkill approach*. The validated cycle was adopted for the Reverse™ Microcatheter based on fractional results determined from EO comparative resistance testing. Packaging Validation: Visual Inspection, Bubble Leak, and Seal Strength testing was used to evaluate integrity of the packaging configuration. Testing was leveraged from representative product using identical packaging materials after being subjected to Ethylene Oxide sterilization (2x), environmental conditioning, and simulated shipping and distribution. Conclusion: Non-clinical performance evaluations, as described above, indicate that the subject device is substantially equivalent to, and at least as safe and effective as the predicate device, (Reverse™ Medical Microcatheter, K130858).
Clinical Performance Data	Not applicable; determination of substantial equivalence is based on an assessment of non-clinical performance data.
Conclusion	With respect to the predicate, design modifications incorporated by subject device do not alter the fundamental scientific technology or the indications for use. Based on failure mode effects and criticality analysis (FMECA), comprehensive verification and validation activities were successfully completed; raising no new issues of safety or effectiveness. Non-clinical performance data supports a determination that the subject device, Reverse™ Micro Catheter, is substantially equivalent to the predicate device (Reverse™ Medical Microcatheter, K130858); and that it is at least as safe and effective for its intended use.