February 25, 2021

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

Re: K210230
Trade/Device Name: Phenom Catheters
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: DQY, KRA, QJP
Dated: January 27, 2021
Received: January 28, 2021

Dear Prerana Gurubasavaraj:

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)*
K210230

Device Name
Phenom™ Catheters

Indications for Use *(Describe)*

Phenom™ Catheters are intended for the introduction of interventional devices or diagnostic agents into the neuro, peripheral, and coronary vasculatures.

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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K210230

510(k) Summary

510(k) Owner:	Micro Therapeutics, Inc. d/b/a ev3 Neurovascular 9775 Toledo Way Irvine, CA 92618 Establishment Registration: 2029214
Contact Person:	Prerana Gurubasavaraj Specialist, Regulatory Affairs Telephone: (949) 297-5804 Email: prerana.gurubasavaraj@medtronic.com

Date Summary Prepared:	February 24, 2021
Trade Name of Device:	Phenom™ Catheters
Device Classification Name:	Catheter, Percutaneous
Regulation Medical Specialty:	Cardiovascular
510(k) Review Panel:	Cardiovascular
Classification Product Code:	DQY
Subsequent Product Code:	KRA, QJP
Regulation Number:	870.1250 870.1210
Regulation Description:	Percutaneous catheter Continuous flush catheter
Device Classification:	Class II
Predicate Device:	Phenom™ 17 Catheter, Phenom™ 21 Catheter, Phenom™ 27 Catheter, Phenom™ Plus Catheter 510(k): K151638 Phenom™ 27 Catheter 510(k): K180959
Reference Device:	React™ 68 Catheter 510(k): K180715 Navien™ Intracranial Support Catheter 510(k): K161152

Device Description:
The Phenom™ Catheters are variable stiffness, single lumen catheters designed to access small, tortuous vasculature. They are available in a variety of lengths, stiffness and inner and outer diameters. The outer surface of the catheter is coated to enhance navigation in the vessel. The Phenom™ 17, 21, and 27 Catheters have a hydrophilic coating that spans the distal 100cm. The Phenom™ Plus Catheters have a hydrophilic coating that spans the distal 90cm. The catheter also incorporates a liner to facilitate movement of introduction devices passing through its lumen. The distal tip has radiopaque marker(s) to aid visualization and positioning under fluoroscopy. The Phenom™ Catheter is packaged with a shaping mandrel and may be accompanied with a split introducer sheath.

Indication for Use Statement:
Phenom™ Catheters are intended for the introduction of interventional devices or diagnostic agents into the neuro, peripheral, and coronary vasculatures.

Device Comparison:

	Legally Marketed Predicate Devices (K151638 & K180959)				Phenom™ Catheters
Indication for Use Statement	The Phenom™ Catheters are intended for the introduction of interventional devices and infusion of diagnostic or therapeutic agents into the neuro, peripheral, and coronary vasculatures.				Phenom™ Catheters are intended for the introduction of interventional devices or diagnostic agents into the neuro, peripheral, and coronary vasculatures.
Dimensions	Phenom™ 17 (K151638)	Phenom™ 21 (K151638)	Phenom™ 27 (K180959)	Phenom™ Plus (K151638)	
Proximal/Distal Outer Diameter (OD)	2.2 F / 1.8 F	2.6 F / 2.3 F	3.1 F / 2.8 F	4.7 F / 4.2 F	Same
Internal Diameter (ID)	0.017”	0.021”	0.027”	0.0445”	Same
Min. Guiding Catheter ID	≥ 0.035”	≥ 0.038”	≥ 0.0445”	≥ 0.070	Same
Max. Guidewire OD	≤ 0.014”	≤ 0.018”	≤ 0.025”	≤ 0.041	Same
Effective Length (cm)	75 - 170	75 - 170	75 - 160	75 - 150	Phenom 17: 150 Phenom 21: 150, 160 Phenom 27: 150, 160 Phenom Plus: 120
Distal segment length (cm)	6 - 20	6 - 20	6 - 20	6 - 20	Same
Inner Lumen	Inner lumen lined with lubricious PTFE to facilitate movement of guidewires and other devices.				Same
No. of lumens	Single lumen				Same
Shaft	Progressively softer from proximal end to distal tip				Same
Method of delivery/tracking	Coaxial tracking over steerable guidewire				Same
Shaft Materials	PTFE and Pebax				Same
Shaft reinforcement	Metallic (Stainless Steel) reinforced				Same
Inner Liner	PTFE liner				Same
Marker band	Radiopaque marker band				Same

Tip Markers	1 or 2	1 or 2	1	1	Same
Tip Shaping	Steam shapeable straight tip; Pre-shaped 45°, 90° and J		Steam shapeable tip	Steam shapeable tip	Same
Coating	Hydrophilic coating				Same
Packaging					
Pouch Material	PET/Tyvek				NYLON/Tyvek
Pouch Dimensions	11” X 12” (Hoop configuration) 11” X 13.75” (Tray configuration)				13” X 10.94”
Carton	Cardboard, Solid Bleach Sulfate				Same
Accessories					
Shaping Mandrel	Yes				Same
Split Introducer Sheath (Phenom™ 17)	No				Yes
Sterilization					
Method	Ethylene Oxide (EO)				Same
Stability					
Shelf Life	36 Months				12 Months

Performance Data – Bench:

The following non-clinical bench testing was performed to evaluate the performance of the Phenom™ Catheters. 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 devices.

Test	Test Method Summary	Results
Performance		
Compatibility – Guide Catheter	The Phenom™ Catheters were evaluated for compatibility with guide catheters in a simulated tortuous path model.	The Phenom™ Catheters are compatible for use with a guide catheter.
Compatibility – Guide Wire	The Phenom™ Catheters were evaluated for compatibility with guide wires in a simulated tortuous path model.	The Phenom™ Catheters are compatible for use with a guide wire.
Compatibility – RHV	The Phenom™ Catheters were evaluated for compatibility with a standard RHV.	The Phenom™ Catheters are compatible with the standard used RHV.
Coating Lubricity (Friction Force)	The Phenom™ Catheters were evaluated for coating lubricity under simulated clinical conditions.	The Phenom™ Catheters exhibit acceptable friction force under simulated clinical conditions.
Hub Functional & Dimensional	The Phenom™ Catheters were evaluated per ISO 80369-7:2016 and ISO 80369-20: 2015.	The Phenom™ Catheters met the acceptance criteria for hub functional & dimensional requirements.
Torque Strength	The Phenom™ Catheters were evaluated for torsional strength integrity during use in a simulated path model.	The Phenom™ Catheters exhibit acceptable torsional strength integrity.

Test	Test Method Summary	Results
Tensile	The Phenom™ Catheters were evaluated per ISO 10555-1:2013, Annex B.	The Phenom™ Catheters met the acceptance criteria for tensile strength.
Air Aspiration	The Phenom™ Catheters were evaluated per ISO 10555-1:2013	The Phenom™ Catheters met the acceptance criteria for air aspiration.
Liquid Leak	The Phenom™ Catheters were evaluated per ISO 10555-1:2013	The Phenom™ Catheters met the acceptance criteria for liquid leak.
Particulate	The Phenom™ Catheters were evaluated per USP <788>.	The Phenom™ Catheters met the acceptance criteria for particulate.
Design Validation	The Phenom™ Catheters were evaluated per ANSI/AAMI HE75:2009/(R) 2018	The Phenom™ Catheters met the user needs and intended use(s) for which it was designed and tested.

Biocompatibility:

Biocompatibility was conducted for the Phenom™ Catheters. The Phenom™ Catheters are categorized as a limited exposure (< 24 hours), external communicating devices contacting circulating blood. The following biocompatibility endpoint testing was conducted for the Phenom™ Catheters:

Test	Test Method Summary	Results
Cytotoxicity – MEM Elution	Cell culture treated with test sample exhibited slight reactivity (Grade 1).	Non-cytotoxic
Sensitization – Guinea Pig Maximization	Animals treated with test sample exhibited no dermal reactions (Grade 0).	Non-sensitizer
Irritation – Intracutaneous Study in Rabbits	Animals treated with test sample exhibited no dermal reactions (Score 0.0).	Non-irritant
Acute Systemic Toxicity – Systemic Toxicity Study in Mice	Animals treated with test sample exhibited no mortality or evidence of systemic toxicity.	Non-toxic
Material Mediated Pyrogenicity – USP Rabbit Pyrogen Study	Individual animals treated with test sample exhibited no temperature rise above 0.5°C.	Non-pyrogenic
Hemocompatibility – Platelet and Leukocyte Counts	Blood treated with the test sample exhibited platelet and leukocyte counts within the average normalized values and control values.	Non-activator
Hemocompatibility – Partial Thromboplastin Time	Blood treated with the test article exhibited clotting time within the control values.	Non-activator
Hemocompatibility – Hemolysis Direct Contact and Extract Methods	Blood treated with the test sample directly and indirectly exhibited no hemolysis and was within the control values.	Non-hemolytic
Hemocompatibility – Complement Activation	Normal human serum treated with the test sample exhibited complement activation within the control values.	Non-activator

Performance Data – Animal:
No animal testing was conducted. 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. 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 Intended Use for the Phenom™ Catheters 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 a determination of substantial equivalence for the Phenom™ Catheters.