



January 2, 2025

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

Re: K241388

Trade/Device Name: Rist 079 Radial Access Guide Catheter; Rist 071 Radial Access Guide Catheter;  
Rist Radial Access Selective Catheter

Regulation Number: 21 CFR 870.1250

Regulation Name: Percutaneous Catheter

Regulatory Class: Class II

Product Code: QJP, DQY, DQO

Dated: December 3, 2024

Received: December 4, 2024

Dear Vesselina Clayton:

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 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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at <https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system>.

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](mailto: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 and

Physical Medicine Devices

Office of Product Evaluation and Quality

Center for Devices and Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known)

K241388

Device Name

Rist™ 079 Radial Access Guide Catheter

Rist™ 071 Radial Access Guide Catheter

Rist™ Radial Access Selective Catheter

Indications for Use (Describe)

The Rist™ 079 Radial Access Guide Catheter is indicated for the introduction of interventional devices into the peripheral, coronary, and neuro vasculature.

The Rist™ 071 Radial Access Guide Catheter is indicated for the introduction of interventional devices into the peripheral, coronary, and neuro vasculature.

The Rist™ Radial Access Selective Catheter is indicated for the introduction of interventional devices into the peripheral, coronary, and neuro vasculature. It can be used to facilitate introduction of diagnostic agents in the neuro vasculature. It is not intended to facilitate introduction of diagnostic agents in coronary or peripheral arteries.

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 K241388

<b>510(k) Owner:</b>	Micro Therapeutics, Inc. d/b/a ev3 Neurovascular 9775 Toledo Way Irvine, CA 92618, USA Establishment Registration: 2029214
<b>Contact Person:</b>	Vesselina Clayton Senior Regulatory Affairs Specialist Telephone: (651) 707-5314 Email: vessa.clayton@medtronic.com

<b>Date Summary Prepared:</b>	30 December 2024
<b>Trade Name of Devices:</b>	Rist™ Radial Access Selective Catheter Rist™ 071 Radial Access Guide Catheter Rist™ 079 Radial Access Guide Catheter
<b>Common Name of Device:</b>	Percutaneous Catheter, Neurovasculature
<b>Review Panel:</b>	Neurovascular
<b>Medical Specialty:</b>	Cardiovascular
<b>Product Code:</b>	QJP, DQY – Applicable to Rist™ 079 Radial Access Guide Catheter, Rist™ Radial Access Selective Catheter, Rist™ 071 Radial Access Guide Catheter DQO - Applicable to Rist™ Radial Access Selective Catheter
<b>Regulation Number:</b>	21 CFR 870.1250, 21 CFR 870.1200
<b>Regulation Name:</b>	Percutaneous Catheter; Diagnostic Intravascular Catheter
<b>Device Classification</b>	Class II
<b>Predicate Devices:</b>	K191551 (RIST Cath Radial Access Long Sheath) K211990 (Rist™ 071 Radial Access Guide Catheter) K201682 (RIST Radial Access Catheter)

### Device Description:

The Rist™ Radial Access Selective Catheter is a flexible, single lumen catheter, with a radiopaque stainless-steel braid reinforced shaft to provide support. The distal tip of the catheter is shaped to have a smooth, rounded tip and is offered in two different distal segment shapes: Simmons 2 (SIM2) and Berenstein (BER). The braided, tapered shaft of the catheter is visible under fluoroscopy and has a luer connector in its proximal end for the attachment of accessories and the infusion of fluids. The Rist™ Radial Access Selective Catheter has no hydrophilic coating. The Rist™ Radial Access Selective Catheter is supplied sterile, non-pyrogenic, and intended for single use only.

The Rist™ 079 Radial Access Guide Catheter is a single lumen, variable stiffness catheter with a stainless steel and nitinol reinforced shaft to provide support. The catheter has a radiopaque marker band on the distal end to aid in visualization. The distal 25 cm of the Rist™ 079 Radial Access Guide Catheter has a hydrophilic coating which reduces the insertion force and allows the catheter to traverse the vasculature more easily. The Rist™ 079 Radial Access Guide Catheter has a PTFE-lined lumen to reduce friction with other devices introduced through the lumen. It is intended to provide access to the target site via transradial access and, once in place, provides a reinforcing conduit for other intravascular devices. A radial access dilator is included as an accessory. The Rist™ 079 Radial Access Guide Catheter is supplied sterile, non-pyrogenic, and intended for single use only.

The Rist™ 071 Radial Access Guide Catheter is a single lumen, variable stiffness catheter with a stainless steel and nitinol reinforced shaft to provide support. The embedded stainless-steel flat wire cross coil is in the proximal section of the catheter, which transitions to a nitinol round wire single coil in the distal end. The catheter has a radiopaque platinum/iridium marker band on the distal end to aid in visualization. The distal 25 cm of the Rist™ 071 Radial Access Guide Catheter has a hydrophilic coating which reduces the insertion force and allows the catheter to traverse the vasculature more easily. The Rist™ 071 Radial Access Guide Catheter has a PTFE-lined lumen to reduce friction with other devices introduced through the lumen. It is intended to provide access to the target site via transradial access and, once in place, provides a reinforcing conduit for other intravascular devices. A radial access dilator is included as an accessory. The Rist™ 071 Radial Access Guide Catheter is supplied sterile, non-pyrogenic, and intended for single use only.

Indications for Use

<b>The Rist™ Radial Access Catheters Device Family Indications for Use</b>		
<b>Customer Facing Numbers (CFNs)</b>	<b>Trade Name</b>	<b>Indications for Use</b>
105F-BER-120	Rist™ Radial Access Selective Catheter	The Rist™ Radial Access Selective Catheter is indicated for the introduction of interventional devices into the peripheral, coronary, and neuro vasculature. It can be used to facilitate introduction of diagnostic agents in the neuro vasculature. It is not intended to facilitate introduction of diagnostic agents in coronary or peripheral arteries.
105F-BER-130		
105F-SIM-120		
105F-SIM-130		
106F-071-095	Rist™ 071 Radial Access Guide Catheter	The Rist™ 071 Radial Access Guide Catheter is indicated for the introduction of interventional devices into the peripheral, coronary, and neuro vasculature.
106F-071-100		
106F-071-105		
107F-079-095	Rist™ 079 Radial Access Guide Catheter	The Rist™ 079 Radial Access Guide Catheter is indicated for the introduction of interventional devices into the peripheral, coronary, and neuro vasculature.
107F-079-100		
107F-079-105		

Proposed Change:

Micro Therapeutics, Inc. d/b/a ev3 Neurovascular requests clearance for commercialization of the Rist™ Radial Access Selective Catheter, Rist™ 071 Radial Access Guide Catheter and Rist™ 079 Radial Access Guide Catheter with revised labeling that introduces additional Warnings, Precautions, and Complications to the Instructions for Use, as well as clarifications throughout the Directions for Use.

Device Comparison:

Design Feature	Legally Marketed Predicate Devices (K191551, K211990, K201682)			Subject Devices (K241388)
Indications for Use	Rist™ 079 Radial Access Guide Catheter (K191551): The Rist™ 079 Radial Access Guide Catheter is indicated for the introduction of interventional devices into the peripheral, coronary, and neuro vasculature.			Same
	Rist™ 071 Radial Access Guide Catheter (K211990): The Rist™ 071 Radial Access Guide Catheter is indicated for the introduction of interventional devices into the peripheral, coronary, and neuro vasculature.			
	Rist™ Radial Access Selective Catheter (K201682): The Rist™ Radial Access Selective Catheter is indicated for the introduction of interventional devices into the peripheral, coronary, and neuro vasculature. It can be used to facilitate introduction of diagnostic agents in the neuro vasculature. It is not intended to facilitate introduction of diagnostic agents in coronary or peripheral arteries.			
Design Feature	Rist™ 079 Radial Access Guide Catheter (K191551)	Rist™ 071 Radial Access Guide Catheter (K211990)	Rist™ Radial Access Selective Catheter (K201682)	Subject Devices (K241388)
Outer Diameter (OD)	7F 0.093” 2.37 mm	6F Max 0.087” 2.21 mm	5.5F 0.070” 1.78 mm	Same
Inner Diameter (ID)	0.079” 2.00 mm	0.071” 1.80 mm	0.040” 1.02 mm	Same
Effective Length	95 cm 100 cm 105 cm	95 cm 100 cm 105 cm	120 cm 130 cm	Same
Tip Shape	N/A		Berenstein (BER) Simmons2 (SIM2)	Same
Compatible Catheter OD	6F 0.078” 1.99 mm	5.5F 0.070” 1.78 mm	N/A	Same
Compatible Radial Introducer Sheath ID	7F 0.093” 2.37 mm	6F 0.087” 2.21 mm	N/A	Same

Dilator Max. Guidewire	0.037" 0.94 mm	0.038" 0.97 mm	N/A	Same
Compatible Guide Catheter ID	N/A		0.070" 1.78 mm	Same
Max. Guidewire	N/A		0.038" 0.97 mm	Same
Catheter Body	Polyether Block Amide (PEBAX) and BaSO <sub>4</sub>			Same
Catheter Reinforcement Layer	Stainless Steel Coil (Proximal) Nitinol Wire Coil (Distal)		Stainless Steel Braid	Same
Strain Relief	Polyolefin Hub; Polycarbonate			Same
Marker Band	Platinum/Iridium Radiopaque Marker Band			Same
Coating	Hydrophilic Coating; distal 25 cm		N/A	Same
Packaging Configuration	Nylon/Tyvek® pouch, polyethylene support tube, packaging card, SBS carton			Same
Radial Dilator	Yes		No	Same
Sterilization Method	Ethylene Oxide (EO)			Same
Pyrogenicity	Non-pyrogenic			Same
Shelf Life	36 Months			Same

**Biocompatibility:**

There is no change to the biocompatibility of the products associated with the proposed labeling changes.

**Performance Data – Bench:**

Non-clinical bench testing was conducted to evaluate the performance of the Rist™ Radial Access Selective Catheter and the Rist™ 079 Radial Access Guide Catheter in a clinically representative radial access model. 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 respective predicate devices.

The following non-clinical bench tests were conducted:

<b>Design Validation</b>		
<b>Test</b>	<b>Test Method Summary</b>	<b>Results</b>
In-vitro Simulated Use Study - Bench	The devices were evaluated per ANSI/AAMI HE75:2009/(R) 2018.	The devices met the acceptance criteria.

**Performance Data – Animal:**

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

Performance Data – Clinical:

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

Conclusion:

There is no change to the indications for use, design, materials, fundamental scientific technology, or principles of operations of the Rist™ Radial Access Selective Catheter, Rist™ 071 Radial Access Guide Catheter, and Rist™ 079 Radial Access Guide Catheter in comparison to the respective predicate devices. The revised labeling which introduces additional Warnings, Precautions, and Complications to the Instructions for Use, as well as clarifications throughout the Directions for Use do not raise new questions of safety and effectiveness as demonstrated through non-clinical bench testing. The information provided in this submission supports a determination of substantial equivalence of the Rist™ Radial Access Selective Catheter, Rist™ 071 Radial Access Guide Catheter, and Rist™ 079 Radial Access Guide Catheter to the respective predicate devices.