July 27, 2021

Micro Therapeutics, Inc. d/b/a ev3 Neurovascular
% Marianne Grunwaldt
Senior Director of Quality Assurance and Regulatory Affairs
InNeuroCo, Inc.
19700 Sterling Road, Suite 1
Pembroke Pines, Florida 33332

Re: K211990
Trade/Device Name: Rist 071 Radial Access Guide Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: DQY, QJP
Dated: June 25, 2021
Received: June 28, 2021

Dear Marianne Grunwaldt:

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)*
K211990

Device Name
Rist™ 071 Radial Access Guide Catheter

Indications for Use *(Describe)*
The Rist™ 071 Radial Access Guide Catheter is indicated for the introduction of interventional devices into the peripheral, coronary, 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

510(k) Number	**K211990**
Date Summary Prepared	**June 25, 2021**
Sponsor	Micro Therapeutics, Inc. d/b/a ev3 Neurovascular 9775 Toledo Way Irvine, CA 92618 Establishment Registration: 2029214
Sponsor Contact	Amnon Talmor E-mail Address: amnon.talmor@medtronic.com
Prepared By	Marianne Grunwaldt E-mail Address: marianne@inneuroco.com
Trade Name:	Rist™ 071 Radial Access Guide Catheter
Regulation Number:	21 CFR 870.1250
Device Common or Classification Name:	Percutaneous Catheter
Product Class:	Class II
Product Panel:	Cardiovascular, Neurovascular
Product Code:	DQY, QJP
Predicate Devices:	RIST™ Cath Radial Access Long Sheath (K191551)

A) Device Description

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 catheter has a nominal outer diameter of 0.084 inches and a nominal inner diameter of 0.071 inches. It is available in three working lengths: 95 cm, 100 cm, and 105 cm. 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.

B) Indications for Use

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

C) Technological Characteristics and Basis for Substantial Equivalence

The Rist™ 071 Radial Access Guide Catheter, is substantially equivalent in its intended use/indications for use, technology and principle of operation, materials, sterilization method and performance to the predicate device, the RIST™ Cath Radial Access Long Sheath 510(k) #K191551. A comparison of the technological characteristics of the subject device and the predicate device, is summarized in Table C.1 below.

Table C.1 Technological Characteristics Comparison

Parameter	Predicate Device RIST™ Cath Radial Access Long Sheath	Subject Device Rist™ 071 Radial Access Guide Catheter
510(k) Number	K191551	K211990
Classification	Class II	Same
Product Code	DQY	DQY, QJP
Review Panel	Cardiology	Cardiology, Neurology
Indications for Use	The RIST™ Cath Radial Access Long Sheath 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.

Table C.1 Technological Characteristics Comparison

Parameter	Predicate Device RIST™ Cath Radial Access Long Sheath	Subject Device Rist™ 071 Radial Access Guide Catheter
Catheter Shaft Outer Jacket	Chronoflex AL 75A, Polyblend 55A blend	Chronoflex AL 75A, Polyblend 55A blend with revised Polyolefin
	Chronoflex C 85A	Chronoflex C 85A purchased from a new vendor resulting in a polyurethane soft block change
	Chronoflex C 45D	Same
	Pebax	Same
	Vestamid/72D Coextrusion	Same
Liner	Etched PTFE	Same
Catheter Shaft Reinforcement	Stainless Steel Flat Wire Nitinol Round Wire	Same
Marker Band	90% Platinum/10% Iridium	Same
Hub Material	Polycarbonate (Makrolon)	Same
Strain Relief	Polyolefin	Same
Coating	Hydrophilic Coating	Same
Catheter Working Length	95, 100, 105* cm	95, 100, 105 cm
Catheter Inner Diameter	0.079 inches	0.071 inches
Catheter Outer Diameter	0.093 inches	0.084 inches
Dilator Working Length	115 cm	Same
Dilator - ID	0.037 inches	0.040 inches
Dilator - OD	0.072 inches	0.068 inches
Dilator - Material	Pebax 72D with $BaSO_4$ with polycarbonate (Makrolon hub)	Same
Accessories	Dilator*	Same

Table C.1 Technological Characteristics Comparison

Parameter	Predicate Device RIST™ Cath Radial Access Long Sheath	Subject Device Rist™ 071 Radial Access Guide Catheter
Packaging	Tyvek/Nylon pouch	Tyvek/Nylon pouch with revised Anti-blocking agent.
	Polyethylene support tube	Polyethylene support tube with revised additive package antioxidant
	Packaging card	Same
	Solid Bleached Sulfate (SBS) carton	Same
Sterilization	Ethylene Oxide	Same
Number of Uses	Single Use	Same
* Since the clearance of the RIST™ Cath Radial Access Long Sheath two changes were made and documented as per the FDA guidance document "Deciding When to Submit a 510(k) for a Change to an Existing Device." The two changes were the removal of the hemostasis valve originally included as an accessory, and the addition of a catheter with 105 cm working length.		

D) Performance Data

Design verification and validation were performed to ensure that the Rist™ 071 Radial Access Guide Catheter meets its performance specifications and to support substantial equivalence to the predicate device. Based on the risk analysis, it was determined that certain tests conducted for the predicate device could apply to the subject device, and certain tests should be repeated. The summary of tests performed on the subject Rist™ 071 Radial Access Guide Catheter is included in Table D.1, and a summary of the prior tests deemed applicable to the subject device is included in Table D.2.

Table D.1 List of Tests Conducted on the Rist™ 071 Radial Access Guide Catheter

Test Performed	Test Method / Applicable Standard	Results
Biocompatibility	Cytotoxicity (ISO MEM Elution)	The test article is considered non-cytotoxic under the conditions of this test. No abnormal events such as pH change or debris were noted.
	Sensitization (ISO Magnusson-Kligman Method)	Under the conditions of this protocol, the test article did not elicit a sensitization response.
	Irritation (ISO Intracutaneous Toxicity)	No significant dermal reactions were observed at the injected test and control sites in any of the test subjects.
	Acute Systemic Toxicity (ISO Systemic Injection)	None of the study subjects were observed with abnormal clinical

Table D.1 List of Tests Conducted on the Rist™ 071 Radial Access Guide Catheter

Test Performed	Test Method / Applicable Standard	Results
		signs indicative of toxicity during the test period.
	Pyrogenicity (Material Mediated Pyrogenicity)	The test article extracts did not cause a pyrogenic response and all validity criteria were met during the assay.
	Hemocompatibility (Complement Activation, SC5b-9 Assay)	The test article results in the Sc5b-9 assay were not statistically significant ($p>0.05$) when compared to the reference material and comparison article.
	Hemocompatibility (ASTM Hemolysis - Direct Contact and Indirect Method)	For Direct Contact method and Indirect method, the test article returned a blank corrected percent hemolysis above the negative control of 0.0%.
	Hemocompatibility (Platelet & Leukocyte Count)	Under the conditions of this protocol, the platelet count was within specification.
	Hemocompatibility (Partial Thromboplastin Time (PTT)	The test article did not create any more material mediated coagulation abnormalities in the intrinsic pathway when compared to the predicate.
Sterilization Validation	Testing was performed per ANSI/AAMI/ISO 11135:2014 and AAMI TIR 28:2016	Product was sterile.
Packaging	The packaging was tested to ensure the sterile barrier was not compromised.	All units met all the packaging acceptance criteria.
Catheter and Dilator Tensile Strength	Testing was completed per ISO 10555-1:2013/Amd. 1:2017(E). Using a force gauge, test samples were pulled until failure.	All units met the tensile strength acceptance criteria.
Catheter PTFE Delamination	Samples of the proximal and distal sections of the catheter were tested to evaluate the adhesion of the etched PTFE layer to the catheter shaft.	All units met the catheter PTFE delamination acceptance criteria.
Torque	The distal end of the unit was held rigid while the proximal end was turned until failure.	All units met the torque acceptance criteria.
Catheter Burst Pressure	Testing was completed per ISO 10555-1:2013/Amd. 1:2017(E) by clamping the distal end and pressurizing the assembly was pressurized and peak pressure was recorded.	All units met the catheter burst pressure acceptance criteria.
Particulate Testing	Particulate testing was performed in a tortuous model and particulate count was evaluated per USP <788>.	All units met the particulate testing acceptance criteria.
Coating Integrity	Catheter samples were inspected under magnification before and after conditioning and being passed through a tortuous path for surface irregularities.	All units met the coating integrity acceptance criteria.
Leak (Liquid)	Testing was completed per ISO 10555-1:2013/Amd. 1:2017(E) by connecting the catheter to test equipment, sealing the distal end of the catheter, pressurizing the	All units met the liquid leak test acceptance criteria.

Table D.1 List of Tests Conducted on the Rist™ 071 Radial Access Guide Catheter

Test Performed	Test Method / Applicable Standard	Results
	catheter, holding the pressure, and ensuring there was no leakage.	
Leak (Air)	Testing was conducted per ISO 10555-1:2013/Amd. 1:2017(E) to ensure no air leaks into the product assembly.	All units met the air leak test acceptance criteria.
Catheter Dimensional Inspection	The ID, OD, and working length were measured to ensure the acceptance criteria were met.	All units met the catheter dimensional inspection acceptance criteria.
Dilator Dimensional Inspection	The ID and OD of the dilator were measured to ensure the acceptance criteria were met.	All units met the dilator dimensional inspection acceptance criteria.
Chemical Compatibility	Samples of catheter and accessories were exposed to saline, dextrose, heparin, and radiocontrast and then inspected for any signs of degradation and ensure the ID had no obstruction.	All units met the chemical compatibility acceptance criteria.
Visual Inspection of Catheter and Dilator	The catheter and dilator were inspected to ensure smooth tip transition points and no surface defects were present.	All units met the visual inspection acceptance criteria.
Catheter Coating Length	Catheter samples were inspected under magnification after hydrating the coating, and the length of the catheter covered with the hydrophilic coating was measured to ensure specification was met.	All units met the catheter coating length acceptance criteria.
Kink Resistance	Test units were wrapped around progressively smaller diameter pegs and mandrels until a kink was observed.	All units met the kink resistance acceptance criteria.
In vitro Simulated Use Study	The Rist™ 071 Radial Access Guide Catheter was prepared per the IFU. A simulated interventional procedure was performed by physicians in order to verify the product's performance. Predicate devices were evaluated in order to establish a baseline for trackability and support ratings.	All acceptance criteria were met.

Table D.2 List of Tests Applied from the Predicate RIST™ Cath Radial Access Long Sheath (K191551)

Test Performed	Test Method / Applicable Standard	Results
Corrosion	Testing was conducted per ISO 10555-1:2013/Amd. 1:2017(E)	All units met the corrosion acceptance criteria.
Hub Compatibility	Catheter luers were tested per ISO 594-1:1986 and ISO 594-2:1998.	All units met the hub compatibility acceptance criteria.
Radiopacity	Physicians were shown fluoroscopic images of the RIST Cath Radial Access Long Sheath and asked to identify the location of the distal tip, the shape of the catheter, and the location of each curve along the shape of the catheter.	All acceptance criteria were met.
Label Content	Product label content is reviewed to ensure the information included is accurate.	All units met the acceptance criteria for label content.

Table D.2 List of Tests Applied from the Predicate RIST™ Cath Radial Access Long Sheath

Test Performed	Test Method / Applicable Standard	Results
Label Legibility	Labeling was inspected to ensure it remained legible after transportation and environmental conditioning.	All units met the acceptance criteria for label legibility.
Barcode	Barcode was scanned on randomly selected carton and pouch to ensure the scan matches the appropriate information.	All units met the acceptance criteria for barcode.
Dilator Working Length	The dilator length was measured to ensure it met the dilator specification.	All units met the acceptance criteria for dilator working length.
Useability (as part of Design Validation)	Evaluators representative of the intended user population evaluated the RIST™ Cath Radial Access Long Sheath as per the Instructions for Use.	All acceptance criteria were met.

E) Shelf-Life Testing

The labeled shelf life for the Rist™ 071 Radial Access Guide Catheter is 6 months. Shelf-life testing (product and packaging) to support the labeled shelf life was performed. All acceptance criteria were met.

F) Conclusion

Based on the verification and validation testing conducted for the subject device and the tests applied from the predicate, as well as the comparison of indications for use, operating principle and technological characteristics, Rist™ 071 Radial Access Guide Catheter is substantially equivalent to the predicate device RIST™ Cath Radial Access Long Sheath (K191551).