RIST Neurovascular, Inc.
Vyoma Chikara
Design Quality/Regulatory Affairs
11611 Interchange Circle South
Miramar, Florida 33025

September 28, 2020

Re: K201682
Trade/Device Name: RIST Radial Access Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: QJP, DQO
Dated: August 28, 2020
Received: August 31, 2020

Dear Vyoma Chikara:

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K201682

Device Name
RIST Radial Access Catheter

Indications for Use *(Describe)*
The RIST Radial Access 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.

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510K SUMMARY K201682

Date Summary Prepared: September 23, 2020

Submitter:
RIST Neurovascular, Inc.
11611 Interchange Circle South
Miramar, FL 33025

Primary Submission Contact:
Vyoma Upadhya Chikara
Design Quality & Regulatory Affairs
RIST Neurovascular Inc.
11611 Interchange Circle South
Miramar, FL 33025
Telephone: 1-954-559-1323
Facsimile: 1-954-742-5989
E-Mail: Vyoma@InNeuroCo.com

Secondary Submission Contact:
Marianne Grunwaldt
Director, Quality Assurance & Regulatory Affairs
RIST Neurovascular Inc.
11611 Interchange Circle South
Miramar, FL 33025
Telephone: 1-305-495-3883
Facsimile: 1-954-742-5989
E-Mail: Marianne@InNeuroCo.com

Trade Name: RIST Radial Access Catheter

Regulation Number: 21 CFR 870.1250

Device Common or Classification Name: Percutaneous Catheter

Product Class: Class II

Product Panel: Neurovascular

Product Code: QJP

Secondary Product Code: DQO

Predicate Devices: SOFIA 6F Plus/Distal Access Catheter (K150366)
RIST Radial Access Catheter (K200417)

A) Device Description

The RIST Radial Access Catheter is a flexible, single lumen catheter compatible with 0.035 inch and 0.038-inch guidewires. It is designed to deliver interventional devices into the peripheral, coronary, and neuro vasculature, facilitate introduction of diagnostic agents in the neuro vasculature, and is intended to provide access to the target site via transradial access. The RIST Radial Access Catheter consists of a radiopaque catheter shaft reinforced with stainless steel and has a luer connector at its proximal end for the attachment of accessories and the infusion of fluids. The distal tip of the catheter is shaped to have a smooth, rounded tip and is offered in two different distal segment shapes, namely Simmons 2 (SIM2) and Berenstein (BER). The catheter has a nominal outer diameter of 0.070 inches and a nominal inner diameter of 0.040 inches. It is available in two working lengths: 120 cm and 130 cm. The RIST Radial Access Catheter is compatible with the RIST Cath Radial Access Long Sheath (K191551) and off-the-shelf accessories. The RIST Radial Access Catheter is supplied sterile, non-pyrogenic, and intended for single use only.

B) Indications for Use

The RIST Radial Access 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.

C) Technological Characteristics and Basis for Substantial Equivalence

The RIST Radial Access Catheter, subject of this 510(k) submission, is substantially equivalent in its intended use/indications for use, technology/principal of operation, materials, sterilization method and performance to the predicate devices, the SOFIA 6F Plus/Distal Access Catheter (K150366), and RIST Radial Access Catheter (K200417). A comparison of the technological characteristics of the subject device, the predicate devices, is summarized in Table c.1 below.

Table c.1 Technological Characteristics comparison

Parameter	**Subject Device RIST Radial Access Catheter**	**Predicate Device SOFIA 6Fr PLUS/Distal Access Catheter (K150366)**	**Predicate Device RIST Radial Access Catheter (K200417)**
Indications for Use	The RIST Radial Access 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.	The SOFIA PLUS/Distal Access Catheters are indicated for general intravascular use, including the neuro and peripheral vasculature. It can be used to facilitate introduction of diagnostic and therapeutic agents. It is not intended for use in coronary arteries.	RIST Radial Access Catheter is indicated for the introduction of interventional devices into the peripheral, coronary, and neuro vasculature.
Principles of operation	The device is advanced into the vasculature over a guidewire,	Same	Same

Parameter	Subject Device RIST Radial Access Catheter	Predicate Device SOFIA 6Fr PLUS/Distal Access Catheter (K150366)	Predicate Device RIST Radial Access Catheter (K200417)
	once advanced and placed into the desired vasculature, the inner lumen is used to deliver devices or diagnostic agents.		
Performance Testing	The product performance has been evaluated per ISO10555-1.	Same	Same
Product Code	QJP, DQO	DQY, DQO	QJP, DQY
Classification	Class II	Same	Same
Material	Catheter Body: Outer polymer jacket of Polyether Block Amide (PEBAX) with $BaSO_4$ Inner polymer layer of Polyether Block Amide (PEBAX) with $BaSO_4$	Catheter Body: Outer polymer jacket of Polyamide (Grilamid), Polyether Block Amide (PEBAX), and polyurethane elastomer (Polyblend and Pellethane) Inner polymer layer of PTFE and polyolefin elastomer	Same as subject device
	Reinforcement layer: Stainless Steel Braid	Reinforcement layer: Stainless Steel Braid/Coil	Same as subject device
	Strain Relief: Polyolefin Hub: Polycarbonate (Makrolon)	Strain Relief: Polyurethane Hub: Nylon	Same as subject device
Catheter Shaft Reinforcement Pattern	Braid	Same	Same
Hydrophilic Coating	No	Yes	Same as subject device
Visibility under fluoroscopy	Yes	Same	Same
Working Length	120 and 130 cm	115cm - 135cm	Same as subject device
Outer Diameter	5.5Fr	5Fr and 6Fr	Same as subject device
Inner Diameter	0.040 inches	0.055 inches and 0.070 inches	Same as subject device
Tip Shapes Offered	Yes	Steam Shapeable by user	Same as subject device
Packaging	Pouch & Carton	Same	Same
Sterilization	Ethylene Oxide	Same	Same
Number of Uses	Single Use	Same	Same

D) Performance Data

Design verification and validation were performed to ensure that the RIST Radial Access Catheter meets its performance specifications and demonstrates substantial equivalence to the predicate devices. There are no known performance standards for this device. For this device, the verification and validation test data, including biocompatibility were leveraged from data that had been generated from testing done on a previously cleared device. The summary of these tests is included in Table d.2.

To support the indication for use for the subject device RIST Radial Access Catheter in diagnostic angiography procedures, the following additional testing was performed: Power Injection testing. A summary of this test is presented in Table d.1.

Table d.1 Summary of Additional testing Conducted

Test Performed	Test Method / Applicable Standard	Results
Power Injection	Testing was completed per ISO 10555-1 connecting units to power injector at different flow rates using test fluid.	All units met the power injection acceptance criteria.

Table d.2 Summary of Testing leveraged from previous cleared device

Test Performed	Test Method / Applicable Standard	Results
Testing Leveraged from RIST RADIAL ACCESS Catheter (K200417)		
Tensile Strength	Testing was completed per ISO 10555-1. Using a force gauge, test samples were pulled until failure.	All units met the Tensile Strength acceptance criteria.
Torque Strength	The distal end of the unit was held rigid while the proximal end was turned until failure.	All units met the Torque Strength acceptance criteria.
Particulates	Particulate testing was performed in a tortuous model and particulate count was evaluated per USP <788>.	The acceptance criteria for Particulate testing was met.
Dimensional Verification – ID	The ID was measured to ensure the acceptance criteria was met.	The acceptance criteria for ID Dimensional Verification was met.
Dimensional Verification –OD	The OD was measured to ensure the acceptance criteria was met.	The acceptance criteria for OD Dimensional Verification was met.
Dimensional Verification – Working Length	The working length was measured to ensure the acceptance criteria were met.	The acceptance criteria for Working Length Dimensional Verification was met.
Dimensional Verification – Tip Length	The tip length was measured to ensure the acceptance criteria were met.	The acceptance criteria for Tip Length Dimensional Verification were met.
Kink Resistance	Test units were wrapped around progressively smaller diameter pegs and/or mandrels until a kink was observed.	All units met the Kink Resistance acceptance criteria.
Visual Inspection (Tip Taper/Transitions)	Samples were visually inspected to ensure the acceptance criteria were met.	All units met the Tip Taper/Transition Visual Inspection acceptance criteria
Shape Retention (Catheter Tip Shape)	Samples were individually inspected to ensure that the shape met the specified specification.	All units met the Shape Retention Acceptance criteria.
Radiopacity	Physicians will be shown fluoroscopic images of the RIST Radial Access Catheter 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.

Test Performed	Test Method / Applicable Standard	Results
Testing Leveraged from RIST RADIAL ACCESS Catheter (K200417)		
Burst Test	Testing was completed per ISO 10555-1 by clamping the distal end and pressurizing the assembly was pressurized and peak pressure was recorded.	All units met the Catheter Burst acceptance criteria.
Liquid Leak Test	Testing was completed per ISO 10555-1 by connecting the catheter to test equipment, sealing the distal end of the catheter, pressurizing the catheter, holding the pressure, and ensuring there was no leakage.	All units met the Liquid Leak acceptance criteria.
Air Leak Test	Testing was conducted per ISO 80369-7 to ensure no air leaks into the product assembly.	All units met the Air Leak Test acceptance criteria.
Hub Compatibility	Catheter luers were tested per ISO 594.	All units met the Hub Compatibility 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.
Corrosion	Testing was conducted per ISO 10555-1 Annex A.	All units met the Corrosion acceptance criteria.
Packaging – Visual Inspection	Packaging was visually inspected to verify the integrity of the pouch and verify the product was free from damage prior to, and when removed from the packaging.	All units met the Packaging Visual Inspection.
Packaging – Pouch Leak	Testing was conducted per ASTM F-1929-15. The pouch was dipped into a dyed solution and visually inspected for dye penetration through the seal.	All units met the Pouch Leak test
Packaging – Pouch Peel	Testing was conducted per ASTM F-88/F88M-15. A Sample from the chevron seal and in-house seal were cut and pulled using a force gauge until the two pieces of pouch material separate.	All units met the Pouch Peel test.
Packaging – Seal Width	The in-house pouch seal width was measured to ensure the acceptance criteria were met.	All seals met the acceptance criteria for Seal Width.
Labeling Legibility - Label	Labeling was inspected to ensure test remained legible after transportation and environmental conditioning.	The acceptance criteria for Labeling Legibility was met.
Barcode	Barcode was scanned on randomly selected carton and pouch to ensure the scan matches the appropriate information.	The acceptance criteria for Barcode was met.
Labeling Legibility - IFU	Labeling was inspected to ensure test remained legible after transportation and environmental conditioning.	The acceptance criteria for IFU Legibility was met.
Sterilization	Testing was performed per ANSI/AAMI/ISO 11135:2014 and AAMI TIR 28:2016	Product was sterile.
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 Guinea Pig Maximization Sensitization)	Under the conditions of this protocol, the test article did not elicit a sensitization response.

Test Performed	Test Method / Applicable Standard	Results
Testing Leveraged from RIST RADIAL ACCESS Catheter (K200417)		
	Irritation (ISO Intracutaneous Irritation)	No significant dermal reactions were observed at the injected test and control sites in any of the test subjects.
	Systemic Toxicity ISO Acute Systemic Injection	None of the study subjects were observed with abnormal clinical signs indicative of toxicity during the test period.
	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 Extract Method	For Direct Contact method and Extract method, the test article returned a blank corrected percent hemolysis above the negative control of 0.0%.
	Hemocompatibility In Vivo Thromboresistance Evaluation	Implantation of the test and control devices resulted in no adverse effects or clinical signs.
	Pyrogenicity Materials Mediated Rabbit Pyrogen	The test article extracts did not cause a pyrogenic response and all validity criteria were met during the assay.
Friction Force	The frictional forces of the RIST Radial Access Catheter and the predicate device were measured when deployed and retracted in a simulated-use anatomical model.	The RIST Radial Access Catheter had comparable friction forces to it's predicate devices.
In vitro Simulated Use Study - Bench	The Berenstein (BER) and Simmons 2 (SIM2) shapes of the RIST Radial Access Catheter were prepared per the IFU. A simulated interventional procedure was performed by physicians in order to verify the product's performance. Competitive devices were evaluated in order to establish a baseline for trackability and support ratings.	All acceptance criteria were met.
In vitro Simulated Use Study - Usability	Evaluators representative of the intended user population evaluated the RIST Radial Access Catheter as per the Instructions for Use.	All acceptance criteria were met.

E) Shelf Life Testing

The labeled shelf life for the RIST Radial Access Catheter is 6months. Shelf life testing (product and packaging) and Distribution Shipping Challenge Conditioning and testing results were leveraged from data generated to support the previously cleared predicate device RIST Radial Access Catheter (K200417). All results met established criteria.

F) Conclusion

Review of the test data, as well as comparison of the device classification, indications for use, operating principle, technological characteristics, sterility, and biocompatibility, demonstrate that the subject device,

the RIST Radial Access Catheter, is substantially equivalent to the predicates SOFIA 6F Plus/Distal Access Catheter (K150366) and RIST Radial Access Catheter (K200417). Any differences between the subject and the predicate devices do not raise new issues of safety and effectiveness.