May 2, 2020

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

Re: K200417
Device Name: RIST Radial Access Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: QJP, DQY
Dated: February 19, 2020
Received: February 20, 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,

Xiaolin Zheng, Ph.D., M.S.
Director
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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)*
K200417

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.

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.

510(k) Summary

Date Summary Prepared: April 23, 2020

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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: Cardiovascular

Product Code: QJP, DQY

Predicate Device: Penumbra, Inc. Benchmark Intracranial Access System (5F Select Catheter), #K142321

Reference Predicate: RIST Cath Radial Access Long Sheath, #K191551

1. 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 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.

2. Indications for Use

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

The indication for use for the RIST Radial Access Catheter is identical to the indication for use of the predicate device.

3. 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 device, the Penumbra, Inc. 5F Select Catheter that was cleared as part of the Benchmark Intracranial Access System, and the reference predicate device, the RIST Cath Radial Access Long Sheath.

A comparison of the technological characteristics of the subject device, the predicate, and the reference predicate devices, is summarized in **Table 1**.

Table 1 – Comparison Between the RIST Radial Access Catheter and Predicate Device

Parameter	Subject Device RIST Radial Access Catheter	Predicate Device Penumbra Benchmark Access System (5F Select Catheter) 510(k) # K142321	Reference Predicate Device RIST Cath Radial Access Long Sheath 510(k) #K191551
Indications for Use	The RIST Radial Access Catheter is indicated for the introduction of interventional devices into the peripheral, coronary, and neuro vasculature.	The Benchmark Intracranial Access System is indicated for the introduction of interventional devices into the peripheral, coronary, and neuro vasculature.	The RIST Cath Radial Access Long Sheath is indicated for the introduction of interventional devices into the peripheral, coronary, and neuro vasculature.
Product Code	QJP, DQY	DQY	DQY
Regulation No.	21 CFR 870.1250	21 CFR 870.1250	21 CFR 870.1250
Classification	Class II	Class II	Class II
Catheter Material	Polyether Block Amide (PEBAX) with $BaSO_4$	Commonly used medical grade plastics	Chronoflex/Polyblend (distal most section) Chronoflex Polyether Block Amide (PEBAX) Vestamid (proximal most section)
Hub Material	Polycarbonate (Makrolon)	Not Available	Polycarbonate (Makrolon)
Catheter Shaft Reinforcement	Stainless Steel	Stainless Steel	Stainless Steel Coil (proximal) Nitinol Wire Coil (distal)
Working Length	120, 130 cm	123, 131.5 cm	95, 100 cm
Inner Diameter	0.040 inches Minimum	0.043 inches Maximum	0.079 inches
Outer Diameter	0.070 inches Maximum	0.069 inches Maximum	0.093 inches
Tip Shapes	Simmons 2 Berenstein	Simmons Berenstein H1	N/A
Packaging	Tyvek/Nylon pouch, polyethylene support tube, packaging card, SBS carton	Commonly used medical device packaging materials	Tyvek/Nylon pouch, polyethylene support tube, packaging card, SBS carton
Sterilization	Ethylene Oxide	Ethylene Oxide	Ethylene Oxide
Pyrogenicity	Nonpyrogenic	Nonpyrogenic	Nonpyrogenic
Number of Uses	Single Use	Single Use	Single Use

4. 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 device. There are no known performance standards for this device. A list of the performance testing conducted on the RIST Radial Access Catheter is presented in **Table 2**. Some of the tests were also conducted on the predicate device to help establish substantial equivalence. All pre-determined acceptance criteria were met.

In some cases, verification test data were leveraged from data that had been generated from testing done on previously cleared devices. These tests are included in **Table 3**.

The data demonstrates that the RIST Radial Access Catheter is substantially equivalent to the predicate device.

Table 2 – Summary of Performance Testing Conducted on RIST Radial Access Catheter

Test Performed	Test Method	Results	Discussion of How This Test Supports a Finding of Substantial Equivalence
Design Verification Testing			
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.	This test demonstrates that the RIST Radial Access Catheter is structurally sound after passing it through a model which simulates actual anatomy. Simulating actual use supports the indications for use which are the same in the RIST Radial Access Catheter and in the predicate device.
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.	This test demonstrates the ability of the unit to function in a clinical setting and therefore supports the indications for use which is the same in the RIST Radial Access Catheter and in the predicate device.
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.	This test quantifies the number of particles generated during simulated use and demonstrate that the particle quantities are within expected parameters which do not raise any new questions

Test Performed	Test Method	Results	Discussion of How This Test Supports a Finding of Substantial Equivalence
			of safety and efficacy. The test supports the indications for use which are the same in the RIST Radial Access Catheter and in the predicate device.
Dimensional Verification – ID	The ID was measured to ensure the acceptance criteria was met.	The acceptance criteria for ID Dimensional Verification was met.	This test verifies functional characteristics of the RIST Radial Access Catheter. The internal diameter of the RIST Radial Access Catheter and the predicate are minimally different, but this does not affect safety or efficacy. The test supports the indications for use which are the same in the RIST Radial Access Catheter and in the predicate device.
Dimensional Verification –OD	The OD was measured to ensure the acceptance criteria was met.	The acceptance criteria for OD Dimensional Verification was met.	This test verifies functional characteristics of the RIST Radial Access Catheter. The outer diameter of the RIST Radial Access Catheter and the predicate are minimally different, but this does not affect safety or efficacy. The test supports the indications for use which are the same in the RIST Radial Access Catheter and in the predicate device.
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.	This test verifies the functional characteristics of working length. The RIST Radial Access Catheter is offered in similar working lengths as the predicate device. The working length of the RIST Radial Access Catheter and the

Test Performed	Test Method	Results	Discussion of How This Test Supports a Finding of Substantial Equivalence
			predicate are minimally different, but this does not affect safety or efficacy. The test supports the indications for use which are the same in the RIST Radial Access Catheter and in the predicate device.
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.	Both the RIST Radial Access Catheter and the predicate device have similar functional characteristics. This test demonstrates the integrity of the RIST Radial Access Catheter under predetermined conditions. The test supports the indications for use which are the same in the RIST Radial Access Catheter and in the predicate device.
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.	This test demonstrates the ability of the unit to maintain structural integrity and therefore supports the indications for use which is the same in the RIST Radial Access Catheter and in the predicate device.
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	Both the RIST Radial Access Catheter and the predicate device have similar functional characteristics. This test demonstrates the integrity of the RIST Radial Access Catheter under predetermined conditions. The test supports the indications for use which are the same in the RIST Radial Access Catheter and in the predicate device.

Test Performed	Test Method	Results	Discussion of How This Test Supports a Finding of Substantial Equivalence
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.	Both the RIST and the predicate device have similar functional characteristics. This test demonstrates the RIST Radial Access Catheter tip will retain its shape. The test supports the indications for use which are the same in the RIST Radial Access Catheter and in the predicate device.
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.	Both the RIST Radial Access Catheter and the predicate device have similar functional characteristics. This test demonstrates the integrity of the RIST Radial Access Catheter under predetermined conditions. The test supports the indications for use which are the same in the RIST Radial Access Catheter and in the predicate device.
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.	Both the RIST Radial Access Catheter and the predicate device have similar functional characteristics. This test demonstrates the functional integrity of the RIST Radial Access Catheter under predetermined conditions. The test supports the indications for use which are the same in the RIST Radial Access Catheter and in the predicate device.
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.	Both the RIST Radial Access Catheter and the predicate device have similar functional characteristics. This test

Test Performed	Test Method	Results	Discussion of How This Test Supports a Finding of Substantial Equivalence
			demonstrates the functional integrity of the RIST Radial Access Catheter under predetermined conditions. The test supports the indications for use which are the same in the RIST Radial Access Catheter and in the predicate device.
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.	The materials of the predicate are mostly the same as those of the RIST Radial Access Catheter. This test confirms that the materials of the RIST Radial Access Catheter can be used with chemicals typically used in a clinical setting. The test supports the indications for use which are the same in the RIST Radial Access Catheter and in the predicate device.
Corrosion	Testing was conducted per ISO 10555-1 Annex A.	All units met the Corrosion acceptance criteria.	This test demonstrates the ability of the stainless-steel reinforcement to resist deterioration. This test supports substantial equivalence because the RIST Radial Access Catheter and the predicate device have the same stainless steel reinforcement.
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.	The packaging of the RIST Radial Access Catheter is identical to the reference predicate device. This test verifies the integrity of the pouched unit which helps support the packaging comparison. The test supports the indications for use

Test Performed	Test Method	Results	Discussion of How This Test Supports a Finding of Substantial Equivalence
			which are the same in the RIST Radial Access Catheter and in the predicate device.
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	The packaging of the RIST Radial Access Catheter is identical to the reference predicate device. This test demonstrates that the seals have no channels which would inhibit sterilization which helps support the packaging comparison. The test supports the indications for use which are the same in the RIST Radial Access Catheter and in the predicate device.
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.	The packaging of the RIST Radial Access Catheter is identical to the reference predicate device. This test verifies the integrity of the pouch seal which helps support the packaging comparison. The test supports the indications for use which are the same in the RIST Radial Access Catheter and in the predicate device.
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.	The packaging of the RIST Radial Access Catheter is identical to the reference predicate device. This test verifies the integrity of the sealed pouch unit which helps support the packaging comparison. The test supports the indications for use which are the same in the RIST Radial Access Catheter and in the predicate device.

Test Performed	Test Method	Results	Discussion of How This Test Supports a Finding of Substantial Equivalence
Comparative Testing			
Friction Force	The frictional forces of the RIST Radial Access Catheter and the predicate Penumbra catheter were measured when deployed and retracted in a simulated-use anatomical model.	The RIST Radial Access Catheter and predicate device had comparable friction forces.	Both the RIST Radial Access Catheter and the predicate device have comparable friction forces. The test supports the indications for use which are the same in the RIST Radial Access Catheter and in the predicate device.
Design Validation Testing			
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. (Note – the competitive device used for this evaluation was Penumbra Neuron Select 5Fr (K082290). This device is identical to the predicate 5Fr Select catheter, cleared as part of the Benchmark Intracranial Access System (K142321).	All acceptance criteria were met.	The performance of the RIST Radial Access Catheter was found to be substantially equivalent to the predicate device. The test supports the indications for use which are the same in the RIST Radial Access Catheter and in the predicate device.

Test Performed	Test Method	Results	Discussion of How This Test Supports a Finding of Substantial Equivalence
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.	The performance of the RIST Radial Access Catheter was found to be substantially equivalent to the predicate device. The test supports the indications for use which are the same in the RIST Radial Access Catheter and in the predicate device.
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.	The usability of the RIST Radial Access Catheter was able to be used as per the Instruction for Use. The test supports the indications for use which are the same in the RIST Radial Access Catheter and in the predicate device.

Table 3 – Summary of Testing Leveraged from Previous Submissions

Test Leveraged	Test Method	Results	Discussion of How This Test Supports a Finding of Substantial Equivalence
Testing Leveraged from SYPHONTRAK IC (formerly known as the InNeuroCo Intermediate Catheter or IC), 510(k) #K152202			
Hub Compatibility	Catheter luers were tested per ISO 594.	All units met the Hub Compatibility acceptance criteria	This test demonstrates compatibility of the RIST Radial Access Catheter luer with mating luer surfaces. Both the predicate device and the RIST Radial Access Catheter have luer tapered hubs. The test supports the indications for use which are the same in the RIST Radial Access Catheter and in the predicate device.
Testing Leveraged from SYPHONTRAK SDA, 510(k) #K161262			
Labeling Legibility - Label	Labeling was inspected to ensure test remained legible after transportation and environmental conditioning.	The acceptance criteria for Labeling Legibility was met.	Both the RIST Radial Access Catheter and the predicate device have similar information contained in the product label. This test verifies that the text of the label is legible. The test supports the indications for use which are the same in the RIST Radial Access Catheter and in the predicate device.
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.	Both the RIST Radial Access Catheter and the predicate device have similar information contained in the product barcode. This test verifies that the barcode is scannable and the information within is appropriate. The test supports the indications for use which are the same in the RIST Radial Access Catheter and in the predicate device.

Test Leveraged	Test Method	Results	Discussion of How This Test Supports a Finding of Substantial Equivalence
Testing Leveraged from SYPHONTRAK SDA, 510(k) #K161262, and SYPHONTRAK IC (formerly known as the InNeuroCo Intermediate Catheter or IC), 510(k) #K152202			
Labeling Legibility - IFU	Labeling was inspected to ensure test remained legible after transportation and environmental conditioning.	The acceptance criteria for IFU Legibility was met.	Both the RIST Radial Access Catheter and the predicate device have similar information contained in the product IFU. This test verifies that the text of the IFU is legible. The test supports the indications for use which are the same in the RIST Radial Access Catheter and in the predicate device.
Testing Leveraged from AXS Infinity LS, 510(k) #K152876			
Sterilization	Testing was performed per ANSI/AAMI/ISO 11135:2014 and AAMI TIR 28:2016	Product was sterile.	The adoption assessment documented evidence that the RIST Radial Access Catheter does not present a greater challenge to the sterilization process. Therefore, the sterilization process will deliver a sterility assurance level (SAL) of at least 10^{-6} to the product, which is the same as the predicate device.

5. Biocompatibility Testing

The RIST Radial Access Catheter was assessed for biocompatibility in accordance with EN ISO 10993-1, "Biological evaluation of Medical Devices – Part 1: Evaluation and Testing within a Risk Management Process." The subject device is considered an externally communicating medical device with circulating blood contact for less than 24 hours. The biological effects tests performed are summarized in **Table 4** .

Table 4 – Summary of Biocompatibility Testing

Biological Effect	Test	Results	Conclusion
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.	The RIST Radial Access Catheter is non-cytotoxic.
Sensitization	ISO Guinea Pig Maximization Sensitization	Under the conditions of this protocol, the test article did not elicit a sensitization response.	The RIST Radial Access Catheter is classified as a non-sensitizer.
Irritation	ISO Intracutaneous Irritation	No significant dermal reactions were observed at the injected test and control sites in any of the test subjects.	The RIST Radial Access Catheter is non-irritant.
Systemic Toxicity	ISO Acute Systemic Injection	None of the study subjects were observed with abnormal clinical signs indicative of toxicity during the test period.	The RIST Radial Access Catheter is non-cytotoxic.
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.	The compliment activation of the SC5b assays were similar for test and comparison articles.
	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%.	The RIST Radial Access Catheter is non-hemolytic.
	In Vivo Thromboresistance Evaluation	Implantation of the test and control devices resulted in no adverse effects or clinical signs.	The RIST Radial Access Catheter is considered to be non-activator.
Pyrogenicity	Materials Mediated Rabbit Pyrogen	The test article extracts did not cause a pyrogenic response and all validity criteria were met during the assay.	The RIST Radial Access Catheter is non-pyrogenic.

The results of the testing demonstrate the biocompatibility of the RIST Radial Access Catheter for its indicated use.

6. Conclusion

Review of the verification and validation 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 predicate Penumbra 5F Select Catheter which was cleared as part of the Benchmark Intracranial Access System, K142321, on January 26, 2015. Any differences between the subject and the predicate devices do not raise any issues of safety and effectiveness.