December 23, 2019

RIST Neurovascular, Inc.
% Elena Jugo
Regulatory Consultant
Caraballo Consulting
11037 Bitternut Hickory Lane
Boynton Beach, Florida 33437

Re: K191551
Device Name: RIST Cath Radial Access Long Sheath
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: DQY
Dated: November 27, 2019
Received: November 29, 2019

Dear Elena Jugo:

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, PhD, MS
Director
DHT5A: Division of Neurosurgical,
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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)*
K191551

Device Name
RIST Cath Radial Access Long Sheath

Indications for Use *(Describe)*
The RIST Cath Radial Access Long Sheath 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

Date Summary Prepared: November 22, 2019

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Trade Name: RIST Cath Radial Access Long Sheath

Regulation Number: 21 CFR 870.1250

Device Common or Classificaiton Name: Percutaneous Catheter

Product Class: Class II

Product Panel: Cardiovascular

Product Code: DQY

Predicate Device: Stryker AXS Infinity # K 152876
Reference Predicate: Terumo Glidesheath Slender # K173831

1. Device Description

The RIST Cath Radial Access Long Sheath (RIST Cath) is a single lumen, variable stiffness catheter with a stainless steel and nitinol reinforced shaft and has a radiopaque marker band on the distal end to aid in visualization. The catheter has a nominal outer diameter of 0.093 inches and a nominal inner diameter of 0.079 inches. It is available in two working lengths: 95 cm and 100 cm. The RIST Cath is intended to provide access to the target site via transradial access and once in place, provides a reinforcing conduit for other intravascular devices. The RIST Cath Radial Access Long Sheath has a PTFE-lined lumen to facilitate movement of other devices passing through its lumen. Accessories included with the device are a radial access dilator and a hemostasis valve. The RIST Cath is supplied sterile, non-pyrogenic, and intended for single use only.

2. 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.

3. Technological Characteristics and Basis for Substantial Equivalence

The RIST Cath, 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 Stryker AXS Infinity LS. The inner and outer diameters of the RIST Cath are within the cleared range of diameters for the predicate reference device, the Terumo Glidesheath Slender.

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 Cath Radial Access Long Sheath and Predicate Device

Parameter	Subject Device RIST Cath Radial Access Long Sheath	Predicate Device Stryker AXS Infinity LS 510(k) # K152876	Reference Predicate Device Terumo Glidesheath Slender 510(k) # K173831
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 Long Sheath is indicated for the introduction of interventional devices into the peripheral, coronary, and neuro vasculature.	The Glidesheath Slender is indicated to facilitate placing a catheter through the skin into the radial artery.
Product Code	DQY	DQY	DYB
Regulation No.	21CFR870.1250	21CFR870.1250	21 CFR 870.1340
Classification	Class II	Class II	Class II
Components Supplied	Sheath, Vessel Dilator, Hemostasis Valve	Sheath, Vessel Dilator, Hemostasis Valve	Sheath, Vessel dilator, Entry Needle, Miniguide Wire, Guidewire Inserter
Catheter Shaft Material	Chronoflex/Polyblend (distal most section) Chronoflex Polyether Block Amide (PEBAX) Vestamid (proximal most section)	Chronoflex Polyether Block Amide (PEBAX) Vestamid	Ethylene-Tetrafluoroethylene (ETFE) copolymer Colorant Barium sulfate Dispersant Silicone oil Polypropylene Stainless Steel Sorbitan fatty acid ester Polycarbonate Polystyrene Polyester-Chlorinated polyvinyl chloride
Inner Liner	PTFE	PTFE	
Hub Material	Polycarbonate (Makrolon)	Polycarbonate	
Strain Relief	Polyolefin	Polyolefin	
Catheter Shaft Reinforcement	Stainless Steel Coil (proximal) Nitinol Wire Coil (distal)	Stainless Steel Braid	
Lubricious Coating	Hydrophilic Coating	Hydrophilic Coating	Hydrophilic Coating
Radiopaque Marker Band	Platinum/Iridium	Platinum/Iridium	Information not available
Working Length	95, 100cm	70, 80, 90 cm	10, 16 cm
Inner Diameter	0.079 inches	0.088 inches	Body: 0.074, 0.087, 0.100 inches Tip: 0.070, 0.083, 0.096 inches
Outer Diameter	0.093 inches	0.109 inches	0.084, 0.097, 0.110 inches
Packaging	Tyvek/Nylon pouch, polyethylene support tube, packaging card, SBS carton	Tyvek/Nylon pouch, polyethylene support tube, packaging card, SBS carton	Tyvek, Polyester-polyethylene laminated film, high impact Polystyrene

Table 1 – Comparison Between the RIST Cath Radial Access Long Sheath and Predicate Device

Parameter	Subject Device RIST Cath Radial Access Long Sheath	Predicate Device Stryker AXS Infinity LS 510(k) # K152876	Reference Predicate Device Terumo Glidesheath Slender 510(k) # K173831
Sterilization	Ethylene Oxide	Ethylene Oxide	Ethylene Oxide
Pyrogenicity	Nonpyrogenic	Nonpyrogenic	Information not available
Number of Uses	Single Use	Single Use	Single Use

The minor differences between the subject and predicate devices are listed in **Table 2**, along with an explanation as to why these differences are not critical to the intended use of the device and do not impact the substantial equivalence of the subject device with the predicate device.

Table 2 – Differences Between the RIST Cath Radial Access Long Sheath and Predicate Devices

Feature of the Device	Subject Device RIST Cath Radial Access Long Sheath	Predicate Device Stryker AXS Infinity LS 510(k) # K152876	Reference Predicate Device Terumo Glidesheath Slender 510(k) # K173831	Discussion / Comment
Catheter Shaft Reinforcement	Stainless Steel Coil (proximal) Nitinol Wire Coil (distal)	Stainless Steel Braid	Information not available	The purpose of the reinforcement feature of the catheter device is to provide structural support along the length. This support is provided using various metals and patterns. This reinforcement layer is encapsulated between the inner and outer polymer layers. This slight difference in the pattern and metal used does not impact safety or efficacy, as demonstrated by test results.
Working Length	95, 100 cm	70, 80, 90 cm	10, 16 cm	Functional testing demonstrated the slight difference in length does not impact safety or efficacy.

4. Performance Data

Design verification and validation were performed to ensure that the RIST Cath 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 Cath Radial Access Long Sheath is presented in Table 3. 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 Cath is substantially equivalent to the predicate device.

Table 3 – Summary of Performance Testing Conducted on RIST Cath

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 Cath 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 Cath and in the predicate device.
PTFE Delamination	The liner was inspected for signs of damage.	All units met the PTFE Delamination acceptance criteria.	This test demonstrates that the inner liner will remain adhered to the outer jacket. This test supports substantial equivalence because both the RIST Cath and the predicate device have a PTFE liner.
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 Cath and in the predicate device.
Hydrophilic Coating	The integrity of the hydrophilic coating was inspected before and after	All units met the Hydrophilic Coating acceptance criteria.	Both the RIST Cath and the predicate device have a hydrophilic

Table 3 – Summary of Performance Testing Conducted on RIST Cath

Test Performed	Test Method	Results	Discussion of How This Test Supports a Finding of Substantial Equivalence
	simulation, and the length of the coating was measured.		coating which aids in tracking. This test demonstrates that the hydrophilic coating is present after simulated use. In simulating actual use, the test supports the indications for use which are the same in the RIST Cath and in the predicate device and helps support the presence of the hydrophilic coating.
Particulates	Particulate testing was performed in a tortuous model.	The acceptance criteria for Particulate testing was met.	Both the RIST Cath and the predicate device have a hydrophilic coating. 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 of safety and efficacy. The test supports the indications for use which are the same in the RIST Cath 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 Cath. The internal diameter of the RIST Cath 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 Cath and in the predicate device.

Table 3 – Summary of Performance Testing Conducted on RIST Cath

Test Performed	Test Method	Results	Discussion of How This Test Supports a Finding of Substantial Equivalence
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 Cath. The outer diameter of the RIST Cath 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 Cath and in the predicate device.
Dimensional Verification – Working Length	The working length was measured to ensure the acceptance criteria was met.	The acceptance criteria for Working Length Dimensional Verification was met.	This test verifies the functional characteristics of working length. The RIST Cath is offered in similar working lengths as the predicate device. The test supports the indications for use which are the same in the RIST Cath 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 Cath and in the predicate device.
Visual Inspection (Transitions & Tip)	Samples were visually inspected to ensure the acceptance criteria were met.	All units met the Transition and Tip Visual Inspection acceptance criteria	Both the RIST Cath and the predicate device have similar functional characteristics. This test demonstrates the integrity of the RIST Cath under predetermined conditions. The test supports the indications for use which are the same in the RIST Cath and in the predicate device.
Catheter Burst	Testing was completed per ISO 10555-1 by clamping the distal end and pressurizing	All units met the Catheter Burst acceptance criteria.	Both the RIST and the predicate device have similar functional

Table 3 – Summary of Performance Testing Conducted on RIST Cath

Test Performed	Test Method	Results	Discussion of How This Test Supports a Finding of Substantial Equivalence
	the assembly was pressurized and peak pressure was recorded.		characteristics. This test demonstrates the integrity of the RIST Cath under predetermined conditions. The test supports the indications for use which are the same in the RIST Cath 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 Cath and the predicate device have similar functional characteristics. This test demonstrates the functional integrity of the RIST Cath under predetermined conditions. The test supports the indications for use which are the same in the RIST Cath 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 Cath and the predicate device have similar functional characteristics. This test demonstrates the functional integrity of the RIST Cath under predetermined conditions. The test supports the indications for use which are the same in the RIST Cath 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 Cath is identical to the 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 Cath and in the predicate device.
Packaging – Pouch Leak	Testing was conducted per ASTM F-1929-12. The	All units met the Pouch Leak test	The packaging of the RIST Cath is identical to

Table 3 – Summary of Performance Testing Conducted on RIST Cath

Test Performed	Test Method	Results	Discussion of How This Test Supports a Finding of Substantial Equivalence
	pouch was dipped into a dyed solution and visually inspected for dye penetration through the seal.		the 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 Cath and in the predicate device
Packaging – Visual Inspection	Packaging was visually inspected to verify the integrity of the pouch and of the seals.	All units met the Packaging Visual Inspection.	The packaging of the RIST Cath is identical to the predicate device. This test verifies the integrity of the pouched unit which helps support the packaging comparison. The test supports the indications for use which are the same in the RIST Cath 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 Cath is identical to the 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 Cath and in the predicate device.
Design Validation Testing			
In vitro Simulated Use Study - Bench	The RIST Cath was prepared per the IFU with all the product accessories including the dilator and hemostasis valve. A simulated interventional procedure was performed by physicians in order to verify the product's performance.	All acceptance criteria were met.	The performance of the RIST Cath was found to be substantially equivalent to the predicate device. The test supports the indications for use which are the same in the RIST Cath

Table 3 – Summary of Performance Testing Conducted on RIST Cath

Test Performed	Test Method	Results	Discussion of How This Test Supports a Finding of Substantial Equivalence
	Competitive devices were evaluated in order to establish a baseline for trackability and support ratings.		and in the predicate device.
In vitro Simulated Use Study - Usability	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.	The usability of the RIST Cath 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 Cath and in the predicate device.

Table 4 – Summary of Completed Testing from Previous Submissions used to Support the Subject Device			
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, and Zenith, 510(k) #K171672			
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 device and accessories are mostly the same as those of the RIST Cath and accessories. This test confirms that the materials of the RIST Cath and accessories 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 Cath and in the predicate device.
Hub Compatibility	Catheter luers were tested per ISO 80369.	All units met the Hub Compatibility acceptance criteria	This test demonstrates compatibility of the RIST Cath luer and accessory luers with mating luer surfaces. Both the predicate device (along with accessory luers) and the RIST Cath (along with accessory luers) have luer

Table 4 – Summary of Completed Testing from Previous Submissions used to Support the Subject Device			
Test Leveraged	**Test Method**	**Results**	**Discussion of How This Test Supports a Finding of Substantial Equivalence**
			tapered hubs. The test supports the indications for use which are the same in the RIST Cath 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 Cath and the predicate device have the same stainless steel reinforcement.
Testing Leveraged from SYPHONTRAK SDA, 510(k) #K161262, and SYPHONTRAK IC (formerly known as the InNeuroCo Intermediate Catheter or IC), 510(k) #K15220			
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 Cath 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 Cath and in the predicate device.
Labeling Legibility - IFU	Labeling was inspected to ensure test remained legible after transportation and environmental conditioning.	The acceptance criteria for IFU Legebility was met.	Both the RIST Cath 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 Cath 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 Cath and the predicate device have similar information contained in the product barcode. This test verifies that the barcode is scannable and the

Table 4 – Summary of Completed Testing from Previous Submissions used to Support the Subject Device			
Test Leveraged	**Test Method**	**Results**	**Discussion of How This Test Supports a Finding of Substantial Equivalence**
			information within is appropriate. The test supports the indications for use which are the same in the RIST Cath 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 Cath 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 Cath 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 5**.

Table 5 – Summary of Biocompatibility Testing

Test	Results	Conclusion
Cytotoxicity	All test method acceptance criteria were met.	The RIST Cath is non-cytotoxic.
Sensitization	The USP 0.9% Sodium Chloride for Injection and Cottonseed Oil extracts of the test article elicited no reaction at the challenge, following an induction phase.	The RIST Cath is classified as a non-sensitizer.
Irritation	The test article sites did not show a significantly greater biological	The RIST Cath is non-irritant.

Table 5 – Summary of Biocompatibility Testing

Test	Results	Conclusion
	reaction than the sites injected with the control article.	
Material Mediated Pyrogenicity	The test article extracts did not cause a pyrogenic response and all validity criteria were met during the assay.	The RIST Cath is non-pyrogenic.
Systemic Toxicity	The test article extracts did not cause acute adverse effects under the conditions of this assay.	The RIST Cath is non-cytotoxic.
Hemolysis, ASTM Method, indirect contact (human blood)	The difference between the hemolytic indexes of the test article and the negative control is 0.00 percent; this places the test article in the non-hemolytic range.	The RIST Cath is non-hemolytic.
Hemolysis, ASTM Method, direct contact (human blood)		
Complement Activation, C3a and SC5b-9	SC5b-9 curve has a correlation coefficient above 0.95, which indicates that the results are acceptable.	The compliment activation of the C3a and SC5b assays were similar for test and comparison articles.
Partial Thromboplastin Time (PTT), Human Plasma	P values of clotting time for the test article and predicate were "Similar", hence results are acceptable.	The RIST Cath is considered to be non-activator.
Dog Thrombogenicity	The test article had an acceptable interaction with blood under the conditions tested.	The RIST Cath is non thrombogenic.

The results of the testing demonstrate the biocompatibility of the RIST Cath 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 Cath Radial Access Long Sheath, is substantially equivalent to the predicate Stryker, AXS Infinity LS, K152876, cleared on January 8, 2016. Any differences between the subject and the predicate devices do not raise any issues of safety and effectiveness.