March 13, 2019

Stryker Neurovascular
Germaine Fu, PhD
Associate Project Manager, Regulatory Affairs
47900 Bayside Parkway
Fremont, California 94538

Re: K183463
Trade/Device Name: AXS Catalyst Distal Access Catheter (AXS Catalyst 7)
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: DQY
Dated: December 13, 2018
Received: December 14, 2018

Dear Germaine Fu, PhD:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Lin Zheng
Digitally signed by Xiaolin Zheng -S
Date: 2019.03.13 11:43:51 -04'00'

for Carlos L. Peña, PhD, MS
Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
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)*
K183463

Device Name
AXS Catalyst Distal Access Catheter (AXS Catalyst 7)

Indications for Use *(Describe)*
The AXS Catalyst Distal Access Catheter is indicated for use in facilitating the insertion and guidance of appropriately sized interventional devices into a selected blood vessel in the peripheral and neurovascular systems. The AXS Catalyst Distal Access Catheter is also indicated for use as a conduit for retrieval devices.

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
K183463

Introduction:

According to the requirements of 21 CFR 807.92, the following information provides sufficient details to understand the basis for a determination of substantial equivalence.

Submitter Name, Address and Content:

Submitter: Stryker Neurovascular
47900 Bayside Parkway
Fremont, CA 94538-6515
(FDA Registration Number: 3008853977)

Contact: **Germaine Fu**
Associate Project Manager, Regulatory Affairs
Phone: 510-413-2862
Fax: 510-413-2588
Email: germaine.fu@stryker.com

Date Prepared: December 13, 2018

Device Name and Classification:

Trade/Proprietary Name: AXS Catalyst Distal Access Catheter (AXS Catalyst 7)

Common Name: Percutaneous Catheter

Classification Name: Percutaneous Catheter, 21CFR 870.1250 – Class II

Product Code: DQY

Legally Marketed Predicate Device(s):	**Primary Predicate Device**	**Additional Predicate Device**
	AXS Catalyst Distal Access Catheter (K151667)	React™ 68 Catheter (K180715)

Device Description

The AXS Catalyst® 7 Distal Access Catheter is a sterile, single lumen, variable stiffness catheter designed for use in facilitating the insertion and guidance of appropriately sized interventional devices into a selected blood vessel in the peripheral and neurovascular systems. The catheter shaft has a hydrophilic coating to reduce friction during use. The catheter includes a radiopaque marker on the distal end for angiographic visualization and a luer hub on the proximal end allowing attachments for flushing and aspiration. It is packaged with a Rotating Hemostasis Valve (RHV), Tuohy Borst Valve with Sideport, and two peel away introducer sheaths. The RHV and Tuohy Borst valve with sideport are used for flushing, insertion of catheters, and aspiration. The peel away introducer sheaths are designed to protect the distal tip of the catheter during insertion into the RHV or Tuohy Borst.

Indications for Use

The AXS Catalyst Distal Access Catheter is indicated for use in facilitating the insertion and guidance of appropriately sized interventional devices into a selected blood vessel in the peripheral and neurovascular systems. The AXS Catalyst Distal Access Catheter is also indicated for use as a conduit for retrieval devices.

Technological Characteristics and Product Feature Comparison

Stryker Neurovascular has demonstrated the AXS Catalyst 7 Distal Access Catheter is substantially equivalent to the Primary Predicate device (K151667) and Additional Predicate Device (K180715) based on the same or similar materials, similar design, and the same fundamental operating principles. A comparison of the Subject device with the Predicate devices is summarized in **Table 1** below.

Table 1: Product Feature Comparison of Subject Device to Predicate Devices			
Detail	**Submission Subject Device** AXS Catalyst 7 Distal Access Catheter	**Primary Predicate Device** AXS Catalyst 5 and 6 Distal Access Catheter	**Additional Predicate Device** React 68 Catheter
Manufacturer	Stryker Neurovascular	Stryker Neurovascular	Micro Therapeutics, Inc. d/b/a ev3 Neurovascular
510(k) Number	**K183463**	**K151667**	**K180715**
Device Trade Name	**AXS Catalyst® 7 Distal Access Catheter**	**AXS Catalyst® 5 and 6 Distal Access Catheter**	**React™ 68 Catheter**
Regulation Number	21 CFR 870.1250	Same	Same
Regulation Name	Percutaneous Catheter	Same	Same
Classification	II	Same	Same
Product Code	DQY	Same	Same
Intended Use/Indication for Use	The AXS Catalyst Distal Access Catheter is indicated for use in facilitating the insertion and guidance of appropriately sized interventional devices into a selected blood vessel in the peripheral and neurovascular systems. The AXS Catalyst Distal Access Catheter is also indicated for use as a conduit for retrieval devices.	Same	The React™ 68 Catheter is indicated for the introduction of interventional devices into the peripheral and neuro vasculature.

Table 1: Product Feature Comparison of Subject Device to Predicate Devices			
Detail	**Submission Subject Device** AXS Catalyst 7 Distal Access Catheter	**Primary Predicate Device** AXS Catalyst 5 and 6 Distal Access Catheter	**Additional Predicate Device** React 68 Catheter
Device Description	The AXS Catalyst™ Distal Access Catheter is a sterile, single lumen, variable stiffness catheter designed for use in facilitating the insertion and guidance of appropriately sized interventional devices into a selected blood vessel in the peripheral and neurovascular systems. The catheter shaft has a hydrophilic coating to reduce friction during use. The catheter includes a radiopaque marker on the distal end for angiographic visualization and a luer hub on the proximal end allowing attachments for flushing and aspiration.	Same	The React™ 68 Catheter is a single lumen, flexible, variable stiffness composite catheter with a nitinol structure that is jacketed with a durable polymer outer layer. A lubricous, polytetrafluoroethylene liner is used to create a structure that has both proximal stiffness and distal flexibility, and an encapsulated radiopaque distal platinum-iridium markerband which is used for visualization under fluoroscopy. The React™ 68 Catheter is introduced into the vasculature through the split y-introducer sheath. The proximal end of the React™ 68 Catheter is designed with a thermoplastic elastomer strain relief and a clear hub. The distal end of the React™ 68 Catheter is

Table 1: Product Feature Comparison of Subject Device to Predicate Devices			
Detail	**Submission Subject Device** AXS Catalyst 7 Distal Access Catheter	**Primary Predicate Device** AXS Catalyst 5 and 6 Distal Access Catheter	**Additional Predicate Device** React 68 Catheter
			designed with a hydrophilic coating.
Accessory Devices Provided (not in direct contact with patient)	Rotating Hemostasis Valve, Tuohy Borst Valve with Sideport, (2) Peel-Away Introducer Sheaths	Same	Peelable Sheath, Rotating Hemostasis Valve
Outer Jacket	Pebax with Nylon, Tecoflex	Same	Grilamid, Pebax
Reinforcement	Nitinol wire and polymer fiber	Stainless steel, Nitinol wire, and polymer fiber	Nitinol
Strain Relief	Thermoplastic rubber (Polyolefin)	Thermoplastic rubber (Santoprene)	DynaFlex
Inner Layer	PTFE	Same	Same
Catheter Hub	Nylon	Same	Trogamid
Marker Band	Platinum/Iridium	Same	Same
Adhesive	Cyanoacrylate	Same	Same
Outer Jacket Coating	Hydrophilic Coating	Same	Same
Labeled Shaft Outer Diameter	Distal OD: 6.2F (0.082 in.) Proximal OD: 6.3F (0.0825 in.)	Distal OD: CAT 5: 5.3F (0.0696 in.) CAT 6: 5.4F (0.0709 in.) Proximal OD:	Distal OD: 0.083 in Proximal OD: 0.083 in

Table 1: Product Feature Comparison of Subject Device to Predicate Devices			
Detail	**Submission Subject Device** AXS Catalyst 7 Distal Access Catheter	**Primary Predicate Device** AXS Catalyst 5 and 6 Distal Access Catheter	**Additional Predicate Device** React 68 Catheter
		CAT 5: 5.6F (0.0735 in.) CAT 6: 6.0F (0.0787 in.)	
Effective Lengths	115cm 125cm 132cm	CAT 5: 115cm,132cm CAT 6: 132cm	132cm
Distal ID	0.068 in.	CAT 5: 0.058 in. CAT 6: 0.060 in.	Same
Proximal ID	0.068 in.	CAT 5: 0.058 in. CAT 6: 0.060 in.	Same
Packaging Materials and Configuration	Polyethylene Tube and HDPE Packaging Card	Same	Polyethylene Packaging Card and Hoop
Sterilization Method	EO Sterilization	Same	Same
How Supplied	Single Use/Sterile	Same	Same
Principles of Operation	The AXS Catalyst Distal Access Catheter is advanced into the neuro vasculature by a physician trained in interventional endovascular procedures using a compatible sheath or guide catheter, and over an appropriately sized guide wire. A peel away sheath is provided in the package to provide	Same	The catheter is introduced through a guide catheter or femoral sheath and into the intracranial vasculature and guided over a neurovascular guidewire and/or microcatheter. The proximal end of the catheter has a luer fitting to allow attachment of

Table 1: Product Feature Comparison of Subject Device to Predicate Devices			
Detail	**Submission Subject Device** AXS Catalyst 7 Distal Access Catheter	**Primary Predicate Device** AXS Catalyst 5 and 6 Distal Access Catheter	**Additional Predicate Device** React 68 Catheter
	support and facilitate the introduction of the AXS Catalyst Catheter tip into the sheath/guide catheter valve. Once the catheter is inserted, the peel away sheath can be removed. Under fluoroscopic guidance, the catheter can be advanced through the vasculature to the desired location. Once the catheter is at the desired location, appropriately sized interventional devices may be inserted into the selected blood vessel. If used with a retriever, aspiration may be applied to the catheter using a 60mL syringe during withdrawal of the retrieval device, until the retriever and microcatheter are withdrawn from the catheter.		accessories and infusion of liquids through the system.

The differences between the devices are not critical as demonstrated above and through the testing referenced below.

Risk Assessment

Risk assessment of the AXS Catalyst 7 Distal Access Catheter has been conducted in accordance with EN ISO 14971. Stryker Neurovascular has determined that the AXS Catalyst 7 Distal Access Catheter raises no new questions of safety or effectiveness. Results of testing are appropriate for determining that the AXS Catalyst 7 Distal Access Catheter is substantially equivalent to the legally marketed Primary Predicate device.

Testing Summary

Performance Data – Bench Testing

The results of design verification and design validation testing conducted on the AXS Catalyst 7 Distal Access Catheter demonstrates that it performs as designed, is suitable for the indication for use, and is substantially equivalent to the legally marketed Primary Predicate device. Testing was conducted in accordance with EN ISO 10555-1 and EN 1707. The design verification and design validation bench testing are summarized in **Table 2** below.

Table 2: Performance Data - Bench Testing

Test	Test Method Summary	Conclusions
Design Verification Testing		
Dimensional Verification	Purpose: To describe the procedure and technique of making dimensional measurements using various measurement equipment. Method: Verify dimensions using specified measurement tool. Record measurements.	Dimensional verification meets acceptance criteria.
Tip Configuration	Purpose: To verify that the catheter tip is smooth, rounded, tapered or similarly finished in order to minimize trauma to vessels during use per EN ISO 10555-1. Method: Visually inspect distal tip at 10X magnification to verify distal tip end is smooth, rounded, tapered or similarly finished. Record results.	Tip configuration meets acceptance criteria.

Table 2: Performance Data - Bench Testing		
Test	**Test Method Summary**	**Conclusions**
Surface Integrity	Purpose: To determine if external surface of the catheter is free from extraneous matter, process and surface defects, and does not have drops of lubricant fluids. Method: Visually inspect external surface of catheter for extraneous matter, process and surface defects, and drops of lubricant fluids. Record results.	Surface integrity meets acceptance criteria.
Tip Buckling	Purpose: To measure the maximum force required to cause a test sample to buckle. Method: Prepare sample for test. Use buckling tester to measure the maximum force required to cause a test sample to buckle. Record results.	Tip buckling meets acceptance criteria.
Catheter lubricity and durability	Purpose: To determine the lubricity and durability of the coating on the catheter outer shaft. Method: Prepare sample for test. Use friction tester to measure the frictional force of the device sample when pulled between two clamped pads. Record the peak frictional force over 5 cycles.	Coating lubricity and durability meets acceptance criteria.
Particulate characterization	Purpose: To evaluate particulates per the FDA Guidance Document: Class II Special Controls for Certain Percutaneous Transluminal Coronary Angioplasty (PTCA) Catheters. Method: Use light obscuration particle counting to measure the total number of particulates generated during simulated use in each of three size ranges: ≥ 10 µm, ≥ 25 µm, and ≥ 50 µm.	Particulate generation was acceptable.

Table 2: Performance Data - Bench Testing		
Test	**Test Method Summary**	**Conclusions**
Coating integrity	Purpose: To evaluate coating consistency pre and post simulated use. Method: Visually inspect for coating anomalies, defects or artifacts pre and post simulated use using a simulated in vitro test model.	Coating integrity was acceptable.
Trackability	Purpose: To measure track advance force of catheter over microcatheter. Method: Place neurovascular model in a re-circulating water bath at 37°C to simulate human arterial circulation. Insert sample, attached to a motor drive assembly, through model over a microcatheter. Advance catheter through model and determine peak tracking force. Record results.	Track advance force meets acceptance criteria.
Tensile Strength	Purpose: To determine tensile force tensile force required to induce failure of fused joints, shaft junctions, and marker band for non-hydratable catheters based on EN ISO 10555-1. Method: Identify joint and prepare sample for test. Use tensile tester to determine applied peak tensile force. Record results.	Tensile strength meets acceptance criteria.
Liquid Leak Resistance	Purpose: 1) To determine whether catheter meets the freedom from leakage-liquid leak requirement 4.7.1 of EN ISO 10555-1. 2) To determine if catheter hub meets the liquid leakage requirement 4.2.1 of EN 1707. Method: Connect test hub sample to fixture and flush with water to expel air. Occlude distal tip. Apply pressure of 300kPa minimum and maintain pressure for 30s. Visually inspect catheter/hub joint and catheter shaft for leaks. Record results.	Liquid leak resistance of catheter meets acceptance criteria.

Table 2: Performance Data - Bench Testing		
Test	**Test Method Summary**	**Conclusions**
Air Leak Resistance	Purpose: 1) To determine whether catheter meets the freedom from leakage-air aspiration requirement of 4.7.2 of EN ISO 10555-1. 2) To determine if catheter hub meets the air leakage requirement 4.2.2 of EN 1707. Method: Connect test hub sample to a partially filled syringe. With the nozzle of the syringe pointing down towards the ground, withdraw the plunger to the 10cc mark. Hold for 15 seconds and examine the water in the syringe for the formation of air bubbles. Record results.	Air leak resistance of catheter meets acceptance criteria.
Catheter Torsional Bond Strength	Purpose: To measure the strength of a catheter shaft when torque is applied. Torque strength is defined as number of rotations before failure occurs. Method: Prepare test sample and insert into torsional bond strength test fixture with tortuous path model. Apply torque to catheter shaft and observe number of 360-degree rotations before failure occurs. Record results.	Catheter torsional bond strength meets acceptance criteria.
Flexural Fatigue	Purpose: To determine the flexural fatigue on the catheter shaft. Method: Prepare test sample. Advance entire assembly of guide wire, microcatheter, and test sample into test model and track it through test model. While holding the guide wire, microcatheter, and test sample, pull the whole assembly back proximally until it exits the models. Repeat for nine more runs. After run number ten, remove guide wire and microcatheter out of test sample and inspect sample for kink or damage. Record results.	Flexural fatigue meets acceptance criteria.

Table 2: Performance Data - Bench Testing		
Test	**Test Method Summary**	**Conclusions**
Catheter Kink Radius	Purpose: To measure the kink radius of a catheter at its distal and specific mid-shaft joint section. Method: Prepare test sample. Thread test sample through fixture loop and lock down test sample. Pull both ends of test sample until test sample kinks. Calculate kink radius using measurement of 2nd to final loop OD and sample OD. Record results.	Catheter kink radius meets acceptance criteria.
Catheter Tip and Lumen Integrity (Adjunctive Aspiration)	Purpose: To determine ability of catheter to deliver and withdraw retrieval device 3 times when located in a simulated use tortuous path without negative impact to function and integrity to the tip. Method: Prepare test sample and simulated use model. Place test sample in the model to a specified location following procedural instructions outlined in the Instructions for Use. Deliver retrieval device. Aspirate test sample using 60cc syringe during retrieval device withdrawal. Visually inspect test sample to verify absence of no tip or lumen collapse. Record results.	Catheter tip and lumen integrity during adjunctive aspiration meets acceptance criteria.
Chemical Compatibility	Purpose: To determine visual and dimensional integrity of catheter following exposure to saline and non-ionic contrast liquids. Method: Prepare sample for test. Flush sample with appropriate chemical. Measure ID and OD using RAM optical measurement system. Insert mandrel through sample to verify inner lumen integrity. Repeat with second mandrel and record results. Visually inspect distal end of sample for any chemical effects on the shaft, inner lumen and cross-sectional areas. Record results.	Chemical compatibility meets acceptance criteria.

Table 2: Performance Data - Bench Testing		
Test	**Test Method Summary**	**Conclusions**
Hub Gauging	Purpose: To determine if catheter hub meets gauging requirement 4.1 of EN 1707. Method: Using the appropriate gauge, apply gauge to the conical fitting with a total axial force of 5N without use of torque. Remove axial load and inspect sample.	Hub gauging meets acceptance criteria.
Design Validation Testing		
In-vitro Simulated Use Study	Purpose: To evaluate interventional device delivery, and the durability and kink resistance of the Subject and Primary Predicate devices in a tortuous anatomical model with multiple physician users. Method: Perform a simulated interventional procedure and track the devices to the target site for interventional device delivery using a neurovascular model that replicates the tortuosity, diameter and location of the arteries in the neurovasculature.	All test samples meet acceptance criteria.

Performance Data – Animal Study

An animal study was conducted in compliance with applicable requirements in the GLP regulation (21 CFR Part 58) to evaluate navigation safety of the AXS Catalyst 7 Distal Access Catheter in clinically relevant vessel sizes.

Performance Data – Clinical

No clinical study was conducted as bench and animal testing was determined sufficient for verification and validation purposes.

Shelf Life Testing

The labeled shelf life for the AXS Catalyst 7 Distal Access Catheter is one year. Shelf life testing (product and packaging) and Distribution Shipping Challenge Conditioning and testing were performed on the Subject device, and the results met established criteria.

Sterilization

The AXS Catalyst 7 Distal Access Catheter and all system components (including the Rotating Hemostasis Valve, the Tuohy Borst Valve and the Peel-Away Introducer Sheath) are sterilized with 100% Ethylene Oxide. The AXS Catalyst 7 Distal Access Catheter and the accessories packaged with the Catheter (RHV, Tuohy Borst Valve, and the Peel-Away Introducer Sheath) are provided sterile. A sterility assurance level (SAL) of 10^{-6} has been demonstrated. The AXS Catalyst 7 Distal Access Catheter and all system components meets EO residuals per EN ISO 10993-7 for a limited contact delivery system – externally communicating. The AXS Catalyst 7 Distal Access Catheter and all system components are for single use only.

Biocompatibility

The AXS Catalyst™ 7 Distal 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.

Biocompatibility testing previously conducted for AXS Catalyst 5 & 6 Distal Access Catheter product is representative of the AXS Catalyst 7 Distal Access Catheter product due to similarity of materials, manufacturing processes and design. While there are minor differences, the biocompatibility assessment determined that these differences are low risk and do not impact product biocompatibility. Therefore, the AXS Catalyst 7 Distal Access Catheter will have the same or similar toxicological profile as the AXS Catalyst 5 and 6 Distal Access Catheter. This conclusion was confirmed by conducting selected tests in accordance with EN ISO 10993-1 and its applicable sub-parts. The AXS Catalyst 7 Distal Access Catheter, passed all required biocompatibility testing.

The results of the biocompatibility testing are summarized in **Table 3** below.

Table 3: Overview of Biocompatibility Studies Performed on the Subject Device

Test Performed / Applicable ISO 10993 Part No.	Results	Conclusion
MEM Elution Cytotoxicity/Part 5	No biological activity (Grade 0) was observed in the L929 mammalian cells at 48 hours post exposure to the test article extract. The test article met the requirements of the test since the grade was less than grade 2. The observed cellular response obtained from the positive control article extract (Grade 4) and negative control article extract (Grade 0) confirmed the suitability of the test system.	PASS No cytotoxicity or cell lysis
Hemolysis Extract/Direct Contact Method /Part 4	The test article exhibited 0.0% hemolysis above the level of hemolysis exhibited by the negative control via the direct method and 0.0% hemolysis above the level of hemolysis exhibited by the negative control via the indirect method.	PASS Non-hemolytic
USP Physiochemical <661> / Part 18	Non-volatile residue: 7 mg Residue on ignition: < 1 mg	PASS

Table 3: Overview of Biocompatibility Studies Performed on the Subject Device		
Test Performed / Applicable ISO 10993 Part No.	**Results**	**Conclusion**
	Heavy metal: < 1 ppm Buffering capacity: < 1.0 ml	
Chemistry (Heptane) Analysis	Below level of detection	PASS
FTIR (ISO 10993-18)	Scan was conducted to establish baseline for the AXS Catalyst 7 Distal Access Catheter device.	PASS
Natural Rubber Latex ELISA Inhibition Assay for Antigenic Protein ASTM D6499-12	Below level of detection	PASS

Conclusion

Stryker Neurovascular has demonstrated the AXS Catalyst 7 Distal Access Catheter is substantially equivalent to the Predicate devices (**K151667** and **K180715**) based on same intended use / indications for use, same or similar materials, same fundamental design, and the same operating principles. The conclusions drawn from risk assessments, the bench testing conducted using the Subject device compared to the Primary Predicate device, and an animal safety study demonstrate that the subject device is suitable for the indication for use with the associated DQY Product Code. Additionally, the testing results summarized above along with the risk assessment demonstrate that the benefits of the device outweigh any residual risks when used in accordance with device Instructions for Use.

Stryker Neurovascular has demonstrated that the AXS Catalyst 7 Distal Access Catheter is as safe, as effective, and performs as well as the legally marketed Predicate devices.