



Food and Drug Administration  
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November 13, 2015

Stryker Neurovascular  
Ms. Rhoda M. Santos  
Principal Regulatory Affairs Specialist  
47900 Bayside Parkway  
Fremont, California 94538

Re: K151667

Trade/Device Name: AXS Catalyst™ Distal Access Catheter  
Regulation Number: 21 CFR 870.1250  
Regulation Name: Percutaneous Catheter  
Regulatory Class: Class II  
Product Code: DQY  
Dated: October 9, 2015  
Received: October 13, 2015

Dear Ms. Santos:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

Carlos L. Pena 

Carlos L. Peña, PhD, MS  
Director  
Division of Neurological  
and Physical Medicine Devices  
Office of Device Evaluation  
Center for Devices and Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known)

K151667

Device Name

AXS Catalyst™ Distal Access Catheter

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** K151667

**Date Prepared:** July 27, 2015

**Trade Name:** AXS Catalyst™ Distal Access Catheter  
**Common Name:** Percutaneous Catheter  
**Classification Name:** Percutaneous Catheter, 21CFR 870.1250 – Class II  
**Product Code:** DQY

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

**Contact:** Rhoda M. Santos  
 Principal Regulatory Affairs Specialist  
 Phone: 510-413-2269  
 Fax: 510-413-2588  
 Email: [rhoda.santos@stryker.com](mailto:rhoda.santos@stryker.com)

**Legally Marketed Predicate Device(s):**

Reference (Clearance Date)	Device
K090335 (May 6, 2009)	Concentric HD Guide Catheter
K110483 (April 4, 2011)	Modified HD Guide Catheter
K133177 (February 25, 2014)	Modified HD Guide 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 the peripheral and neuro vascular system. 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 Hemostatic Valve (RHV) and Tuohy Borst valve with sideport 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 believes the AXS Catalyst Distal Access Catheters are substantially equivalent to the predicate devices (K133177, K110483, K090335) based on similar intended use / indications for use, same or similar materials, same fundamental design, and the same fundamental operating principles. A comparison of the subject device with the predicate device is summarized in the table below.

**Product Feature Comparison of Subject Device to Primary Predicate Device and Reference Predicate Devices**

<b>Feature</b>	<b><u>Reference Predicate Device</u> HD Guide Catheter (DAC®) (K090335)</b>	<b><u>Reference Predicate Device</u> Modified HD Guide Catheter (DAC®) (K110483)</b>	<b><u>Primary Predicate Device</u> Modified HD Guide Catheter (DAC®) (K133177)</b>	<b><u>Subject Device</u> AXS Catalyst Distal Access Catheter</b>	<b><u>Rationale for difference (if applicable)</u></b>
Intended Use / Indications for Use	Indicated for use in facilitating the insertion and guidance of an occlusion catheter, infusion catheter or other appropriate microcatheter into a selected blood vessel in the peripheral, coronary or neuro vascular systems. It may also be used as a diagnostic angiographic catheter.	Same	The Modified HD Guide Catheter is indicated for use in facilitating the insertion and guidance of an occlusion catheter, infusion catheter or other appropriate microcatheter into a selected blood vessel in the peripheral, coronary and neuro vascular systems. It may also be used as a diagnostic angiographic catheter and as a conduit for retrieval devices.	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.	Intended Use / Indications for Use reflect user preferences. AXS Catalyst Catheter is not intended to be marketed for use in coronary systems nor is it intended to be used as a diagnostic catheter.  Bench testing and animal testing has demonstrated that the proposed intended use / indications for use do not affect the safety and effectiveness of the device.
Device Description	The HD Guide Catheter is a single-lumen, braided shaft, variable	Same	The Modified HD Guide Catheter is a single-lumen, braided shaft,	The AXS Catalyst™ Distal Access Catheter is a single lumen, variable	Additional accessories included for ease of use

Feature	Reference Predicate Device HD Guide Catheter (DAC®) (K090335)	Reference Predicate Device Modified HD Guide Catheter (DAC®) (K110483)	Primary Predicate Device Modified HD Guide Catheter (DAC®) (K133177)	Subject Device AXS Catalyst Distal Access Catheter	Rationale for difference (if applicable)
	<p>stiffness catheter with a radiopaque marker on the distal end and a luer hub on the proximal end. The catheter shaft has a hydrophilic coating to reduce friction during use. A rotation hemostatic side arm adapter is provided with each catheter.</p>		<p>variable stiffness catheter with radiopaque marker on the distal end and a luer hub on the proximal end. The catheter shaft has a hydrophilic coating to reduce friction during use. Device dimensions and configuration are shown on the product label. A rotating hemostasis valve with side-arm adapter is provided with each catheter. The rotating hemostasis valve is typically “y” shaped with a female luer lock and a manual hemostasis valve. The female port allows for aspiration and contrast injections while the hemostasis valve allows direct arterial access when using other devices such as guidewires and/or interventional devices.</p>	<p>stiffness catheter designed for use in facilitating the insertion and guidance of appropriately sized interventional devices into the peripheral and neuro vascular system. 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 Hemostatic Valve (RHV) and Tuohy Borst valve with sideport 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.</p>	<p>Bench testing and animal testing has demonstrated that the proposed intended use / indications for use do not affect the safety and effectiveness of the device.</p>

<b>Feature</b>	<b>Reference Predicate Device HD Guide Catheter (DAC®) (K090335)</b>	<b>Reference Predicate Device Modified HD Guide Catheter (DAC®) (K110483)</b>	<b>Primary Predicate Device Modified HD Guide Catheter (DAC®) (K133177)</b>	<b>Subject Device AXS Catalyst Distal Access Catheter</b>	<b>Rationale for difference (if applicable)</b>
Accessory Devices Provided (not in direct contact with patient)	RHV	Same	Same	RHV Tuohy Borst Valve with Sideport (2) Peel Away Sheaths	Additional accessories included for ease of use.  Bench testing and animal testing has demonstrated that the additional accessories do not affect the safety and effectiveness of the device.
Regulation Number	21CFR 870.1250	Same	Same	Same	NA
Regulation Name	Percutaneous Catheter	Same	Same	Same	NA
Regulatory Class	II	Same	Same	Same	NA
Product Code	DQY, DQO	Same	Same	DQY	Product code reflects intended use / indications for use
<b>Materials</b>					
Outer Jacket	Pebax	Same	Same	Same with Nylon	Nylon material added to meet performance needs of user. Bench testing and animal testing has demonstrated that the additional nylon material does not affect the safety and effectiveness of the device.

Feature	Reference Predicate Device HD Guide Catheter (DAC®) (K090335)	Reference Predicate Device Modified HD Guide Catheter (DAC®) (K110483)	Primary Predicate Device Modified HD Guide Catheter (DAC®) (K133177)	Subject Device AXS Catalyst Distal Access Catheter	Rationale for difference (if applicable)
Reinforcement	Stainless Steel	Same	Same	Same with Nitinol and Polymer fiber	Nitinol wire and polymer fiber added to meet performance needs of user. Bench testing and animal testing has demonstrated that the additional nitinol and polymer fiber materials do not affect the safety and effectiveness of the device.
Strain Relief	Polyolefin	Same	Same	Thermoplastic rubber	Use of thermoplastic rubber material is consistent with other commercially available Stryker Neurovascular products. Bench testing has demonstrated that the thermoplastic rubber material does not affect the safety and effectiveness of the device.
Inner layer	PTFE	Same	Same	Same	NA
Catheter Hub	Pebax	Same	Same	Nylon	Use of nylon material is consistent with other commercially available Stryker Neurovascular products. Bench testing has demonstrated that the nylon material does not affect the safety and effectiveness of the device.

Feature	Reference Predicate Device HD Guide Catheter (DAC®) (K090335)	Reference Predicate Device Modified HD Guide Catheter (DAC®) (K110483)	Primary Predicate Device Modified HD Guide Catheter (DAC®) (K133177)	Subject Device AXS Catalyst Distal Access Catheter	Rationale for difference (if applicable)
Marker Band	Platinum/Iridium	Same	Same	Same	NA
Adhesive	Acrylic (Acrylated Urethane)	Same	Same	Cyanoacrylate	Use of cyanoacrylate adhesive is consistent with other commercially available Stryker Neurovascular products. Bench testing has demonstrated that the cyanoacrylate adhesive does not affect the safety and effectiveness of the device.
Outer jacket coating	hydrophilic coating	Same	Same	Same	NA
Labeled Shaft Outer Diameter	OD of effective length: 3.9F, 5.2F	OD of effective length: 6.3F	Same as predicate devices, K090335 and K114083	Distal OD: 5.3F, 5.4F Proximal OD: 5.6F, 6.0F	NA
Effective Lengths	115 cm, 125 cm, 136 cm	105 cm, 120 cm	Same as predicate devices, K090335 and K114083	115 cm, 132 cm	NA
Packaging Materials and Configuration	Polyethylene Tube and HDPE Packaging Card	Same	Same	Same	NA
Sterilization Method	EO Sterilization	Same	Same	Same	NA
How Supplied	Pebax	Same	Same	Same	NA

**Risk Assessment**

Risk assessment of the AXS Catalyst Distal Access Catheter has been conducted in accordance with EN ISO 14971. Stryker Neurovascular has determined that the AXS Catalyst Distal Access Catheter raises no new questions of safety or effectiveness. Results of verification and validation testing are appropriate for use in determining that the AXS Catalyst™ Distal Access Catheter is substantially equivalent to the legally marketed predicate devices.

**Testing Summary**

**Performance Data – Bench**

The results of design verification testing conducted on the AXS Catalyst Distal Access Catheter demonstrate that it performs as designed, is suitable for its intended use and is substantially equivalent to the legally marketed predicate device. Testing was conducted in accordance with EN ISO 10555-1 and EN 1707. Specifically, the following tests were performed on the subject device:

Test	Test Method Summary	Conclusions
Dimensional Verification	<p><u>Purpose:</u> To describe the procedure and technique of making dimensional measurements using various measurement equipment.</p> <p><u>Method:</u> Verify dimensions using specified measurement tool. Record measurements.</p>	Dimensional verification meets acceptance criteria.
Tip Configuration	<p><u>Purpose:</u> 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.</p> <p><u>Method:</u> Visually inspect distal tip at 10X magnification to verify distal tip end is smooth, rounded, tapered or similarly finished. Record results.</p>	Tip configuration meets acceptance criteria.
Surface Integrity	<p><u>Purpose:</u> 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.</p> <p><u>Method:</u> Visually inspect external surface of catheter for extraneous matter, process and surface defects, and drops of lubricant fluids. Record results.</p>	Surface integrity meets acceptance criteria.
Tip Buckling	<p><u>Purpose:</u> To measure the maximum force required to cause a test sample to buckle.</p> <p><u>Method:</u> Prepare sample for test. Use buckling tester to measure the maximum force required to cause a test sample to buckle. Record results.</p>	Tip buckling meets acceptance criteria.

Test	Test Method Summary	Conclusions
Catheter lubricity and durability	<p><u>Purpose:</u> To determine the lubricity and durability of the coating on the catheter outer shaft.</p> <p><u>Method:</u> 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 after 5 cycles.</p>	Coating lubricity and durability meets acceptance criteria.
Trackability	<p><u>Purpose:</u> To measure track advance force of catheter over microcatheter.</p> <p><u>Method:</u> A neurovascular model is placed in a re-circulating water bath at 37°C to simulate human arterial circulation. The sample is inserted through model over a microcatheter and attached to a tensile tester. Advance catheter through model and determine peak tracking force. Record results.</p>	Track advance force meets acceptance criteria.
Tensile Strength	<p><u>Purpose:</u> 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.</p> <p><u>Method:</u> Identify joint and prepare sample for test. Use tensile tester to determine applied peak tensile force. Record results.</p>	Tensile strength meets acceptance criteria.
Liquid Leak Resistance	<p><u>Purpose:</u></p> <ol style="list-style-type: none"> <li>1) To determine whether catheter meets the freedom from leakage-liquid leak requirement 4.7.1 of EN ISO 10555-1.</li> <li>2) To determine if catheter hub meets the liquid leakage requirement 4.2.1 of EN 1707.</li> </ol> <p><u>Method:</u> 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.</p>	Liquid leak resistance of catheter meets acceptance criteria.

Test	Test Method Summary	Conclusions
Air Leak Resistance	<p><u>Purpose:</u></p> <p>1) To determine whether catheter meets the freedom from leakage-air aspiration requirement of 4.7.2 of EN ISO 10555-1.</p> <p>2) To determine if catheter hub meets the air leakage requirement 4.2.2 of EN 1707.</p> <p><u>Method:</u> 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.</p>	Air leak resistance of catheter meets acceptance criteria.
Catheter Torsional Bond Strength	<p><u>Purpose:</u> To measure the strength of a catheter shaft when torque is applied. Torque strength is defined as number of rotations before failure occurs.</p> <p><u>Method:</u> 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.</p>	Catheter torsional bond strength meets acceptance criteria.
Flexural Fatigue	<p><u>Purpose:</u> To determine the flexural fatigue on the catheter shaft.</p> <p><u>Method:</u> 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 pack 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 for kink or damage. Record results.</p>	Flexural fatigue meets acceptance criteria.

Test	Test Method Summary	Conclusions
Catheter Kink Radius	<p><u>Purpose:</u> To measure the kink radius of a catheter at its distal and specific mid-shaft joint section.</p> <p><u>Method:</u> 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 2<sup>nd</sup> to final loop OD and sample OD. Record results.</p>	Catheter kink radius meets acceptance criteria.
Catheter Tip and Lumen Patency (Adjunctive Aspiration)	<p><u>Purpose:</u> To test resistance to tip and lumen collapse during adjunctive aspiration and test tip integrity to tears and missing material.</p> <p><u>Method:</u> 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. Aspirate test sample using 60cc syringe. Visually inspect test sample to verify indication of no tip or lumen collapsed. Record results.</p>	Catheter tip and lumen patency during adjunctive aspiration meets acceptance criteria.
Catheter Tip and Lumen Patency (with retrieval device)	<p><u>Purpose:</u> To determine ability of catheter to deliver and withdraw retrieval device 3 times when located in a simulated use tortuous path without functional impact and integrity to the tip.</p> <p><u>Method:</u> 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. Aspirate test sample using 60cc syringe. Visually inspect test sample to verify indication of no tip or lumen collapsed. Record results.</p>	Catheter tip and lumen patency meets acceptance criteria.

Test	Test Method Summary	Conclusions
Chemical Compatibility	<p><u>Purpose:</u> To determine visual and dimensional integrity of catheter following exposure to saline, non-ionic and ionic contrast liquids.</p> <p><u>Method:</u> 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.</p>	Chemical compatibility meets acceptance criteria.
Hub Gauging	<p><u>Purpose:</u> To determine if catheter hub meets gauging requirement 4.1 of EN 1707.</p> <p><u>Method:</u> Using the appropriate gauge, the gauge was applied to the conical fitting with a total axial force of 5N without the use of torque. The axial load was then removed and the sample inspected.</p>	Hub gauging meets acceptance criteria.
Simulated Use	<p><u>Purpose:</u> To evaluate performance design attributes through user evaluation in an <i>in vitro</i> flow model.</p> <p><u>Method:</u> Simulated use testing uses a neurovascular model that replicates the tortuosity, diameter and location of the arteries in the neurovasculature. The model incorporates a re-circulating water bath at approximately 37°C to simulate the human arterial circulation and interior core body temperature. All testing follows the procedural instructions outlined in the Instructions for Use.</p>	Simulated use meets acceptance criteria.

**Performance Data – Animal**

An animal study was conducted in compliance with applicable requirements in the GLP regulation (21 CFR Part 58) to evaluate performance design attributes of the AXS Catalyst™ Distal Access Catheter through user evaluation in an acute animal model.

**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 Distal Access Catheter is 6 months. 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 Distal Access Catheter and all system components are sterilized with 100% Ethylene Oxide. The AXS Catalyst Distal Access Catheter is provided sterile to a sterility assurance level (SAL) of  $10^{-6}$ , and is for single use only.

Ethylene oxide (EO) residuals on a sample representative of the AXS Catalyst Distal Access Catheter are less than the maximum allowed for EO residuals per EN ISO 10993-7 for a limited contact delivery system –externally communicating.

Results are:

- Ethylene Oxide Results: 2.29 mg/device extracted residuals (EN ISO 10993-7 requirement is average daily dose  $\leq 4$  mg)
- Ethylene Chlorohydrin Results: 0.07 mg/device extracted residuals (EN ISO 10993-7 requirement is average daily dose  $\leq 9$  mg)

**Biocompatibility**

The AXS Catalyst™ 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.

Based on this classification, tests relevant to the device were selected and conducted in accordance with EN ISO 10993-1 and its applicable sub-parts.

The AXS Catalyst Distal Access Catheter, including its packaging, passed all required biocompatibility testing. The results of the biocompatibility testing are summarized in the table below.

**Overview of Biocompatibility Studies Performed on the Subject Device**

<b>Test Performed / Applicable ISO 10993 Part No.</b>	<b>Results</b>	<b>Conclusion</b>
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 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
Guinea Pig Maximization Sensitization/Part 10	The USP 0.9% Sodium Chloride for Injection (NaCl) and Cottonseed Oil (CSO) extracts of the test article elicited no reaction at the challenge (0% sensitization), following an induction phase.	PASS No evidence of sensitization
Intracutaneous Reactivity/Part 10	The test article sites did not show a significantly greater biological reaction than the sites injected with the control article. The difference of the overall mean score between the test article and the control article was 0.0.	PASS Non-irritant
Acute Systemic Injection/Part 11	The 0.9% Sodium Chloride for Injection (NaCl) and Cottonseed Oil (CSO) extracts of the test article did not induce a significantly greater biological reaction than the control extracts, when tested in Swiss Albino mice.	PASS No mortality or evidence of systemic toxicity
Rabbit Pyrogen / Part 11	No rabbit injected with the test article extract showed an individual rise in temperature of 0.5°C or more.	PASS Non-pyrogenic

Test Performed / Applicable ISO 10993 Part No.	Results	Conclusion
Hemolysis Extract/Direct Contact Method/Part 4	The test article exhibited 0.17% hemolysis above the level of hemolysis exhibited by the negative control via the direct method and 0.12% hemolysis above the level of hemolysis exhibited by the negative control via the indirect method.	PASS Non-hemolytic
In Vitro Hemocompatibility/Part 4	Results comparable to the Negative Control.  The test article results for WBC, RBC, platelets, hematocrit and hemoglobin were:  Group 1 89% - 98% Group 2 97% - 103% Group 3 100% - 105% Group 4 98% - 105%	PASS
Complement Activation (SC5b-9) /Part 4	Concentration of SC5b-9 in the test articles was not statistically higher than the negative control. The test articles are not considered to be potential activators of the complement system.	PASS
Complement Activation (C3a) /Part 4	Concentration of C3a in the test articles was not statistically higher than the negative control. The test articles are not considered to be a potential activator of the complement system.	PASS
Partial Thromboplastin (PTT) /Part 4	The test sample and the predicate sample demonstrated a shortened clotting time when compared to the negative control. However, the test sample demonstrated a similar clotting time when compared to the predicate sample.	PASS  Results were comparable to the Negative Control. Test articles are considered minimal activators with clotting time being 90.0% (catheter) and 92.1% (tubing) of the Negative Control and therefore met the requirements of the test.

**Summary of Substantial Equivalence**

Stryker Neurovascular believes the AXS Catalyst Distal Access Catheters are substantially equivalent to the predicate device (**K133177, K110483, K090335**) based on similar intended use / indications for use, same or similar materials, same fundamental design, and the same fundamental operating principles. The conclusions drawn from risk assessments and the bench testing conducted using the subject device demonstrate that the device performs as designed, is suitable for its intended use, and that the benefits of the device outweigh any residual risks when used in accordance with device Instructions for Use.