March 18, 2018

Stryker Neurovascular
Angelica Beckmann
Director, Regulatory Affairs
47900 Bayside Parkway
Fremont, California 94538

Re: K173841
Trade/Device Name: AXS Catalyst Distal Access Catheter as part of the AXS Universal Aspiration System
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: NRY
Dated: December 14, 2017
Received: December 18, 2017

Dear Angelica Beckmann:

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.

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.

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,

Carlos L. Pena -S

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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K173841

Device Name
AXS Catalyst Distal Access Catheter as part of the AXS Universal Aspiration System

Indications for Use *(Describe)*
The AXS Catalyst Distal Access Catheter as part of the AXS Universal Aspiration System is indicated for use in the revascularization of patients with acute ischemic stroke secondary to intracranial large vessel occlusive disease (in the internal carotid, middle cerebral - M1 and M2 segments, basilar, and vertebral arteries) within 8 hours of symptom onset. Patients who are ineligible for intravenous tissue plasminogen activator (IV t-PA) or who failed IV t-PA are candidates for treatment.

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 of Safety and Effectiveness

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

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:	**Angelica Beckmann** Director, Regulatory Affairs Phone: 510-413-2900 Fax: 510-413-2588 Email: angelica.beckmann@stryker.com

Date Prepared:	March 12, 2018

Device Name and Classification:

Trade/Proprietary Name:	AXS Catalyst™ Distal Access Catheter as part of the AXS Universal Aspiration System
Common Name:	Catheter, Thrombus Retriever
Classification Name:	Percutaneous Catheter, 21CFR 870.1250 – Class II
Product Code:	NRY

Legally Marketed Predicate Device(s):

	Primary Predicate	Reference Predicate
Catheter	Penumbra Reperfusion Catheter (K090752)	AXS Catalyst Distal Access Catheter (K151667)
Aspiration System Components	Penumbra Max Pump Penumbra Hi-Flo Aspiration Tubing Penumbra MAX Canister (K160449)	N/A

Device Description

The AXS Catalyst Distal Access Catheter as part of the AXS Universal Aspiration System is designed to restore blood flow in patients with acute ischemic stroke secondary to intracranial large vessel occlusive disease. The AXS Universal Aspiration System is designed for use within the internal carotid, middle cerebral – M1 and M2 segments, basilar, and vertebral arteries. The AXS Universal Aspiration System is composed of the following components:

- AXS Catalyst™ Distal Access Catheter
- AXS Universal Aspiration Tubing
- Medela Dominant Flex Pump
- AXS Universal Liner Set

The AXS Catalyst™ Distal Access Catheter is a sterile, single lumen, variable stiffness catheter. The catheter shaft has a hydrophilic coating to reduce friction during use, includes a radiopaque marker on the distal end for angiographic visualization, and includes a luer hub on the proximal end allowing attachments for flushing and aspiration. It is packaged with a Rotating Hemostastic Valve (RHV), Tuohy Borst Valve with Sideport, and Peel Away Introducer. The Rotating Hemostastic Valve 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. The AXS Catalyst Distal Access Catheter is the only component of the AXS Universal Aspiration System that is used intravascularly.

The AXS Universal Aspiration Tubing serves as a conduit to supply vacuum from the Medela Dominant Flex Pump to the distal tip of the AXS Catalyst Distal Access Catheter. The AXS Universal Aspiration Tubing provides a connection between the sterile and non-sterile environments. The proximal end of the AXS Universal Aspiration Tubing is connected to the AXS Universal Liner Set (outside of the sterile environment) while the distal end of the AXS Universal Aspiration Tubing is connected to the AXS Catalyst Distal Access Catheter (inside the sterile environment). The AXS Universal Liner Set is connected to the Medela Dominant Flex Pump (also outside of the sterile environment).

The Medela Dominant Flex Pump is designed to generate vacuum for the AXS Universal Aspiration System. When used as part of the AXS Universal Aspiration System, the AXS Catalyst Distal Access Catheter requires a minimum vacuum pressure of -68 kPa [-20.08 in Hg] from the Medela Dominant Flex Pump. The Medela Dominant Flex Pump is reusable, non-sterile, and intended to be utilized outside of the sterile environment.

The AXS Universal Liner Set is provided non-sterile and consists of an individually packaged canister liner and a ClotFinder specimen cup. The AXS Universal Liner Set is offered with and without a desiccant. The AXS Universal Liner Set is single-use and the repository for aspirated material.

Indications for Use

The AXS Catalyst Distal Access Catheter as part of the AXS Universal Aspiration System is indicated for use in the revascularization of patients with acute ischemic stroke secondary to intracranial large vessel occlusive disease (in the internal carotid, middle cerebral - M1 and M2 segments, basilar, and vertebral arteries) within 8 hours of symptom onset. Patients who are ineligible for intravenous tissue plasminogen activator (IV t-PA) or who failed IV t-PA are candidates for treatment.

Technological Characteristics and Product Feature Comparison

Stryker Neurovascular has demonstrated the AXS Catalyst Distal Access Catheters when used as part of the AXS Universal Aspiration System are substantially equivalent to the primary predicate device (**K090752** and **K160449**) and reference predicate device **(K151667)** based on the same or similar materials, similar design, and the same fundamental operating principles. A comparison of the subject device with the primary predicate and reference predicate device is summarized in **Table 1** below.

Table 1: Product Feature Comparison of Subject Device to Predicate Device

Detail	**Submission** **Subject Device** AXS Catalyst Distal Access Catheter	**Primary** **Predicate Device** Penumbra Reperfusion Catheter
Manufacturer	Stryker Neurovascular	Penumbra, Inc.
510(k) Number	**K173841**	**K090752**
Device Trade Name	**AXS Catalyst™ Distal Access Catheter**	**Penumbra Reperfusion Catheter (aka 5MAX ACE or 5MAX or ACE60)**
Regulation Number	21 CFR 870.1250	Same as Subject Device

Table 1: Product Feature Comparison of Subject Device to Predicate Device		
Detail	**Submission** **Subject Device** AXS Catalyst Distal Access Catheter	**Primary** **Predicate Device** Penumbra Reperfusion Catheter
Regulation Name	Percutaneous Catheter	Same as Subject Device
Regulatory Class	II	Same as Subject Device
Product Code	NRY	NRY
Intended Use/ Indications for Use	The AXS Catalyst Distal Access Catheter as part of the AXS Universal Aspiration System is indicated for use in the revascularization of patients with acute ischemic stroke secondary to intracranial large vessel occlusive disease (in the internal carotid, middle cerebral – M1 and M2 segments, basilar, and vertebral arteries) within 8 hours of symptom onset. Patients who are ineligible for intravenous tissue plasminogen activator (IV t-PA) or who failed IV t-PA are candidates for treatment.	The Penumbra System is intended for use in the revascularization of patients with acute ischemic stroke secondary to intracranial large vessel occlusive disease (in the internal carotid, middle cerebral – M1 and M2 segments, basilar, and vertebral arteries) within 8 hours of symptom onset.
Device Description	The AXS Catalyst Distal Access Catheter when used as part of the AXS Universal Aspiration System is designed to restore blood flow in patients with acute ischemic stroke secondary to intracranial large vessel occlusive disease. The AXS Universal Aspiration System is designed for use within the internal carotid, middle cerebral – M1 and M2 segments, basilar, and vertebral arteries. The AXS Universal Aspiration System is composed of the following components:	Per the associated DFU: The Penumbra System consists of three devices that work as a system to remove thrombus including the Penumbra Reperfusion Catheter, Penumbra Separator and Aspiration Tubing. The Penumbra System is used with the Penumbra Aspiration Pump. (Note: The use of the separator may not be needed for catheters of inner diameter of .054” or greater).

Table 1: Product Feature Comparison of Subject Device to Predicate Device		
Detail	**Submission** **Subject Device** AXS Catalyst Distal Access Catheter	**Primary** **Predicate Device** Penumbra Reperfusion Catheter
	• AXS Catalyst™ Distal Access Catheter • AXS Universal Aspiration Tubing • AXS Universal Liner Set • Medela Dominant Flex Pump	
Accessory Devices Provided (not in direct contact with patient)	Rotating Hemostatic Valve, Tuohy Borst Valve with sideport (2) Peel Away Sheaths	Peelable Sheath, Rotating Hemostasis Valve, Shaping Mandrel
Outer Jacket	Pebax with Nylon	Not available
Reinforcement	Stainless Steel with Nitinol wire and polymer fiber	Stainless Steel Flat wire (0.002x0.007")
Strain Relief	Thermoplastic rubber	Stainless Steel, 304
Inner Layer	PTFE	Not available
Catheter Hub	Nylon	Proximal Hub Grilamid (TR55-LX)
Marker Band	Platinum/Iridium	Same as Subject Device
Adhesive	Cyanoacrylate	Not available
Outer Jacket Coating	Hydrophilic Coating	SRDX Harmony (proprietary) coating
Labeled Shaft Outer Diameter	Distal OD: 5.3F, 5.4F Proximal OD: 5.6F, 6.0 F	Distal OD: 5MAX 5F 5MAX ACE 5.4F Proximal OD: 5MAX 6F 5MAX ACE 6F
Effective Lengths	115 cm, 132 cm	125 cm, 127 cm, 132 cm
Distal ID (")	0.058, 0.060	0.054, 0.060
Proximal ID (")	0.058, 0.060	0.064, 0.068
Packaging Materials and Configuration	Polyethylene Tube and HDPE Packaging Card	Polyester / Polyethylene / Tyvek and Polyethylene Packaging Card
Sterilization	EO Sterilization	Same as Subject Device

Table 1: Product Feature Comparison of Subject Device to Predicate Device		
Detail	**Submission** **Subject Device** AXS Catalyst Distal Access Catheter	**Primary** **Predicate Device** Penumbra Reperfusion Catheter
Method		
Non-Reusable Device	Single Use device	Same as Subject Device
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 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. The catheter is designed to remove thrombus from the vasculature using aspiration provided by an external source device, the Medela Dominant Flex Pump. The aspiration system is attached to the catheter via the RHV (or Tuohy Borst), and the vacuum is turned on. The aspiration tubing clamp is opened to apply aspiration. Upon completion of the procedure, the AXS Catalyst Distal Access Catheter, the AXS	Confirm vessel diameter and select an appropriate size Penumbra Reperfusion Catheter. The catheter tip may be shaped using the steam shaping mandrel provided. Attach the rotating hemostatis valve provided to the catheter. Insert the catheter into the rotating hemostasis valve connected to the proximal hub of a guide catheter. If a guide catheter is not used, insert the catheter through the valve of the long femoral sheath using the peelable sheath. After inserting the catheter, remove the peelable sheath from the vascular sheath, and peel from the catheter shaft. Using conventional catheterization techniques under fluoroscopic guidance, advance the catheter into the target vessel over an appropriate neurovascular guidewire. Position the catheter proximal to the thrombus. Remove the guidewire from the catheter.

Table 1: Product Feature Comparison of Subject Device to Predicate Device		
Detail	**Submission** **Subject Device** AXS Catalyst Distal Access Catheter	**Primary** **Predicate Device** Penumbra Reperfusion Catheter
	Universal Aspiration Tubing, and the AXS Universal Liner Set are disposed of per the institution's procedures. The Medela Dominant Flex Pump is cleaned per the instructions provided with the pump.	
How Supplied	Sterile/Single Use	Same as Subject Device
Aspiration Pump	Medela AG Dominant Flex Pump K170329 • Adjustable vacuum pressure dial • Three selectable air flow rates: 40,50,60 L/min • Non-Sterile • Reusable • Cleanable • Minimum Vacuum Pressure for aspiration: -68 kPa [-20.08 inHg]	Penumbra MAX Pump K160449 • Adjustable vacuum pressure dial • Non-adjustable air flow rate Non-Sterile • Reusable • Cleanable • Minimum Vacuum Pressure for aspiration: -68 kPa [-20.08 inHg]
Aspiration Tubing	Medela AG AXS Universal Aspiration Tubing • Class II Exempt • EO Sterilized • Non-reusable • ID: 0.218" • Length: 300cm • Flow clamp	Penumbra Hi-Flo Aspiration Tubing • K160449 • EO Sterilized • Non-reusable • ID: 0.110" • Length: 284.5cm • Flow switch
Aspiration Canister	Medela AG Dominant Flex Pump utilizes a reusable polycarbonate suction jar and a non-reusable liner. The AXS Universal Liner Set consists of 3 individually packaged poly-bags containing one canister liner	Penumbra MAX Canister is a non-reusable polycarbonate jar. • Class I Exempt • Non-Sterile

Table 1: Product Feature Comparison of Subject Device to Predicate Device		
Detail	**Submission** **Subject Device** AXS Catalyst Distal Access Catheter	**Primary** **Predicate Device** Penumbra Reperfusion Catheter
	and one ClotFinder specimen cup. The AXS Universal Liner Set if offered with and without a desiccant. • Class I Exempt • Non-Sterile	

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 Distal Access Catheter when used as part of the AXS Universal Aspiration System has been conducted in accordance with EN ISO 14971. A warning has been added to the instructions for use to instruct users as to appropriate use of aspiration. Results of testing are appropriate for determining that the AXS Catalyst Distal Access Catheter when used as part of the AXS Universal Aspiration System is substantially equivalent to the legally marketed predicate devices.

Testing Summary

Performance Data – Bench Testing

The results of design verification and design validation testing conducted on the AXS Catalyst Distal Access Catheter when used as part of the AXS Universal Aspiration System demonstrate that it performs as designed, is suitable for the indication for use, and is substantially equivalent to the legally marketed Primary Predicate device. The following design validation tests outlined below in **Table 2** were performed on the subject device in support of the indication for use:

Table 2: Overview of Design Validation Testing Results – Clot Aspiration		
Test	**Test Method Summary**	**Conclusions**
In-vitro Simulated Use (Direct Aspiration)	Purpose: To evaluate the performance of the Subject Device to Primary Predicate when aspirating clot in tortuous anatomical model. Method: Simulated use testing uses a physiological neurovascular model where clot is aspirated following the written protocol.	All test samples met acceptance criteria.
In-vitro Usability Study	Purpose: Multiple User evaluation of the clot retrieval, durability and kink resistance of the Subject and Primary Predicate Devices in a tortuous anatomical model. Method: Users performed a direct aspiration of a clot procedure, tracked the devices to the site of the occlusion using a neurovascular model that replicated the tortuosity, diameter and location of the arteries in the neurovasculature.	All test samples met acceptance criteria.

Design Verification testing was performed comparing the flow rates of the subject aspiration system to the primary predicate aspiration system. Tip buckling and track forces (insertion and retraction) for the subject device catheters were also compared to the predicate device catheters. Design Verification testing was also performed to assess catheter tip and lumen patency under direct and adjunctive aspiration using the Medela Dominant Flex Pump.

The design verification bench testing is summarized in **Table 3** below.

Table 3: Performance Data - Bench Testing		
Test	**Test Method Summary**	**Conclusions**
Aspiration Flow Rate	Purpose: To determine the aspiration flow rate and lumen integrity of the system when no occlusion is present. Method: The volume of water an aspiration system (catheter + associated pump and accessories) could aspirate in 20s was measured. This volume in mL was divided by 20 to give the flow rate in mL/s.	All test samples met acceptance criteria.
Tip Buckling	Purpose: To determine the maximum force a catheter tip could withstand before buckling. Method: The test catheter was soaked in 37°C water prior to testing. A mandrel was then inserted into the distal end of the catheter and the catheter with mandrel was placed into the test fixture on a tensile test machine. The test catheter was compressed against a load cell until the distal tip buckled. The compression force was recorded.	All test samples met acceptance criteria.
Track Force	Purpose: To determine the maximum force a test catheter exerts on the tortuous vessel model as it tracks to the M2 for both advancing and retracting. Method: The test catheter was soaked in 37°C water prior to testing. The catheter was tracked to the M2 through the smallest ID compatible guide in the neurovascular challenge path model and the force was recorded. The catheter was then retracted through the same model path and the force was recorded.	All test samples met acceptance criteria.

Table 3: Performance Data - Bench Testing		
Test	**Test Method Summary**	**Conclusions**
Catheter Tip and Lumen Patency (Direct Aspiration)	Purpose: To test resistance to tip and lumen collapse during direct aspiration and test tip integrity to tears and missing material. Method: Prepare test sample and simulated use model. Insert plug in catheter tip. 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 and aspiration pump. Visually inspect test sample to verify indication of no tip or lumen collapse.	All test samples met acceptance criteria.

The following bench tests were submitted and cleared as part of K151667 for the AXS Catalyst Distal Access Catheter and remain in effect. The results are provided below in **Table 4** for reference purposes.

Table 4: Performance Data - Bench Testing Previously Cleared		
Test	**Test Method Summary**	**Conclusions**
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 met acceptance criteria and was cleared as part of K151667.
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 met acceptance criteria and was cleared as part of K151667.

Table 4: Performance Data - Bench Testing Previously Cleared		
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 met acceptance criteria and was cleared as part of K151667.
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 met acceptance criteria and was cleared as part of K151667.
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 after 5 cycles.	Coating lubricity and durability met acceptance criteria and was cleared as part of K151667.
Trackability	Purpose: To measure track advance force of catheter over microcatheter. Method: 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.	Track advance force met acceptance criteria and was cleared as part of K151667.

Table 4: Performance Data - Bench Testing Previously Cleared		
Test	**Test Method Summary**	**Conclusions**
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 met acceptance criteria and was cleared as part of K151667.
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 met acceptance criteria and was cleared as part of K151667.

Table 4: Performance Data - Bench Testing Previously Cleared		
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 met acceptance criteria and was cleared as part of K151667.
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 met acceptance criteria and was cleared as part of K151667.

Table 4: Performance Data - Bench Testing Previously Cleared		
Test	**Test Method Summary**	**Conclusions**
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 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.	Flexural fatigue met acceptance criteria and was cleared as part of K151667.
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 met acceptance criteria and was cleared as part of K151667.

Table 4: Performance Data - Bench Testing Previously Cleared		
Test	**Test Method Summary**	**Conclusions**
Chemical Compatibility	Purpose: To determine visual and dimensional integrity of catheter following exposure to saline, non-ionic and 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 met acceptance criteria and was cleared as part of K151667.
Hub Gauging	Purpose: To determine if catheter hub meets gauging requirement 4.1 of EN 1707. Method: 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.	Hub gauging met acceptance criteria and was cleared as part of K151667.

Performance Data – Animal Study

Animal studies were 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 when used as part of the AXS Universal Aspiration System through user evaluation in an animal model as outlined below in **Table 5**.

Table 5: Performance Data – Animal Study		
Test	**Test Method Summary**	**Conclusions**
In-vivo Efficacy and Safety Evaluation (Arm 1)	Purpose: To assess vessel revascularization and adverse events, if any, associated with a mechanical thrombectomy procedure performed via direct aspiration using the Subject Device compared to the Primary Predicate Device. Method: Porcine test subjects were exposed to aspiration treatment using the AXS Universal Aspiration System and the predicate Penumbra System after a vascular occlusion was artificially induced. Vascular response was assessed by contrast angiography and histopathology.	Subject Device is equivalent to the Primary Predicate in efficacy and safety.
In-vivo Efficacy and Safety Evaluation (Arm 2)	Purpose: To assess the vascular safety profile of treatment by aspiration and navigation of the Subject Device compared to the Primary Predicate Device. Method: Porcine test subjects were exposed to aspiration treatment using the AXS Universal Aspiration System and the predicate Penumbra System under worst-case aspiration force and treatment duration conditions. Vascular response was assessed by contrast angiography and histopathology.	Subject Device is equivalent to the Primary Predicate in safety.
In-vivo Vascular Response (Direct Aspiration)	Purpose: To assess the vascular response of direct aspiration through the Subject Device compared to Primary Predicate device. Method: A porcine model was used to evaluate acute and chronic vessel damage after direct aspiration in vessels sized appropriately to simulate the human M2. Vascular response was assessed by contrast angiography and histopathology.	Subject Device is equivalent to the Primary Predicate in safety.

Performance Data – Clinical

No clinical study was conducted as bench and animal testing was determined sufficient for verification and validation purposes. A review was conducted considering published clinical study articles that featured the Primary Predicate Device. The review demonstrated that equivalent devices published clinical outcomes that supported the proposed indication for use, and the corresponding product code. Given the equivalency of the Subject Device and Primary Predicate Device, the Subject Device is therefore suitable for the proposed indication for use and the associated NRY Product Code.

Shelf Life Testing

The labeled shelf life for the AXS Catalyst Distal Access Catheter is two years. 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. The Shelf Life testing protocol was cleared as part of the reference predicate under **K151667** and is ongoing.

The shelf life for the AXS Universal Aspiration Tubing, AXS Universal Liner Set, and Medela Dominant Flex Pump are established by Medela.

Sterilization

The AXS Catalyst Distal Access Catheter and all system components (including the Rotating Hemostatic Valve, the Tuohy Borst Valve and the Peel Away Introducer Sheath) are sterilized with 100% Ethylene Oxide. The AXS Catalyst Distal Access Catheter and the accessories packaged with the Catheter (RHV, TBV, and the Peel Away Introducer Sheath) are provided sterile to a sterility assurance level (SAL) of 10^{-6}, and are 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.

As reported in the reference predicate clearance as part of **K151667**, 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)

The AXS Universal Aspiration Tubing sterilization information is provided by Medela.

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 were previously provided in **K151667**and are summarized in **Table 6** below.

Table 6: Overview of Biocompatibility Studies Performed on the Subject Device and Cleared as Part of K151667

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 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

Table 6: Overview of Biocompatibility Studies Performed on the Subject Device and Cleared as Part of K151667		
Test Performed / Applicable ISO 10993 Part No.	**Results**	**Conclusion**
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
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	PASS

Table 6: Overview of Biocompatibility Studies Performed on the Subject Device and Cleared as Part of K151667		
Test Performed / Applicable ISO 10993 Part No.	**Results**	**Conclusion**
	was not statistically higher than the negative control. The test articles are not considered to be a potential activator of the complement system.	
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.

The AXS Universal Aspiration Tubing biocompatibility information is provided by Medela.

Conclusion

Stryker Neurovascular has demonstrated the AXS Catalyst Distal Access Catheter when used as part of the AXS Universal Aspiration System is substantially equivalent to the Primary Predicate device (**K090752** and **K160449**) and the Reference Predicate (**K151667**) 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, the bench testing conducted using the Subject Device compared to the Primary Predicate Device, and a review of available scientific evidence from published clinical articles demonstrate that the subject device is suitable for the indication for use with the associated NRY Product Code. Additionally, testing results risk assessment also demonstrate that the benefits of the device outweigh any residual risks when used in accordance with device Instructions for Use.