
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:

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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 Hemostatic Valve (RHV), Tuohy Borst Valve with Sideport, and Peel Away Introducer. The Rotating Hemostatic 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 hemostatic 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 is 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
<u>In-vitro Simulated Use</u> (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.
<u>In-vitro Usability Study</u>	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	<u>Purpose:</u> To determine the aspiration flow rate and lumen integrity of the system when no occlusion is present. <u>Method:</u> 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	<u>Purpose:</u> To determine the maximum force a catheter tip could withstand before buckling. <u>Method:</u> 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	<u>Purpose:</u> 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. <u>Method:</u> 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)	<u>Purpose:</u> To test resistance to tip and lumen collapse during direct aspiration and test tip integrity to tears and missing material. <u>Method:</u> 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	<u>Purpose:</u> To describe the procedure and technique of making dimensional measurements using various measurement equipment. <u>Method:</u> Verify dimensions using specified measurement tool. Record measurements.	Dimensional verification met acceptance criteria and was cleared as part of K151667.
Tip Configuration	<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. <u>Method:</u> 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	<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. <u>Method:</u> 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	<u>Purpose:</u> To measure the maximum force required to cause a test sample to buckle. <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.	Tip buckling met acceptance criteria and was cleared as part of K151667.
Catheter lubricity and durability	<u>Purpose:</u> To determine the lubricity and durability of the coating on the catheter outer shaft. <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.	Coating lubricity and durability met acceptance criteria and was cleared as part of K151667.
Trackability	<u>Purpose:</u> To measure track advance force of catheter over microcatheter. <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.	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	<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. <u>Method:</u> 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	<u>Purpose:</u> 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. <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.	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	<u>Purpose:</u> 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. <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.	Air leak resistance of catheter met acceptance criteria and was cleared as part of K151667.
Catheter Torsional Bond Strength	<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. <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.	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	<u>Purpose:</u> To determine the flexural fatigue on the catheter shaft. <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 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 for kink or damage. Record results.	Flexural fatigue met acceptance criteria and was cleared as part of K151667.
Catheter Kink Radius	<u>Purpose:</u> To measure the kink radius of a catheter at its distal and specific mid-shaft joint section. <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 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	<u>Purpose:</u> To determine visual and dimensional integrity of catheter following exposure to saline, non-ionic and ionic contrast liquids. <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.	Chemical compatibility met acceptance criteria and was cleared as part of K151667.
Hub Gauging	<u>Purpose:</u> To determine if catheter hub meets gauging requirement 4.1 of EN 1707. <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.	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
<u><i>In-vivo</i> Efficacy and Safety Evaluation</u> (Arm 1)	<u>Purpose:</u> 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. <u>Method:</u> 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.
<u><i>In-vivo</i> Efficacy and Safety Evaluation</u> (Arm 2)	<u>Purpose:</u> To assess the vascular safety profile of treatment by aspiration and navigation of the Subject Device compared to the Primary Predicate Device. <u>Method:</u> 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.
<u><i>In-vivo</i> Vascular Response</u> (Direct Aspiration)	<u>Purpose:</u> To assess the vascular response of direct aspiration through the Subject Device compared to Primary Predicate device. <u>Method:</u> 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 ≤ 4 mg)
- Ethylene Chlorohydrin Results: 0.07 mg/device extracted residuals
(EN ISO 10993-7 requirement is average daily dose ≤ 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.

Hello Ms. Beckmann,

Thanks very much. I will let you know if we have any questions or feedback once we have had time to review. (b)(4)

(b)(4)

Thanks,

Dhanya Williams, M.S.

Biologist/Scientific Reviewer

Center for Devices and Radiological Health (CDRH)

Office of Device Evaluation (ODE)

U.S. Food and Drug Administration

Tel: 301-796-6498

dhanya.williams@fda.hhs.gov

[cid:image001.png@01D1C57E.DFA022A0]<<http://www.fda.gov/>>

[cid:image002.jpg@01D1C57E.DFA022A0]<<https://www.facebook.com/FDA>>

[cid:image003.jpg@01D1C57E.DFA022A0] <https://twitter.com/US_FDA>

[cid:image004.jpg@01D1C57E.DFA022A0] <<http://www.youtube.com/user/USFoodandDrugAdmin>>

[cid:image005.jpg@01D1C57E.DFA022A0] <<http://www.flickr.com/photos/fdaphotos/>>

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From: Beckmann, Angelica [mailto:angelica.beckmann@stryker.com]

Sent: Wednesday, March 07, 2018 11:41 PM

To: Williams, Dhanya K <Dhanya.Kumar@fda.hhs.gov>

Cc: Allison, John <John.Allison@stryker.com>; Mateus, Jennifer <Jennifer.Mateus@stryker.com>; K173841@docs.fda.gov; Ellis, Kristin (Contractor) <kristin.ellis@stryker.com>

Subject: RE: K173841 - Interactive request #1 - Updated (b)(4)

Dear Ms. Williams,

(b)(4)

Please feel free to call me or send email with any additional requests.

The updated 510K summary will be provided tomorrow.

Best regards,

Angelica Beckmann

Director Regulatory Affairs

Stryker Neurovascular

47900 Bayside Pkwy

Fremont, CA 94538

510-413-2900 Office

(b)(6)

Mobile

angelica.beckmann@stryker.com<mailto:angelica.beckmann@stryker.com>

From: Williams, Dhanya K [mailto:Dhanya.Kumar@fda.hhs.gov]

Sent: Wednesday, March 7, 2018 6:02 AM

To: Beckmann, Angelica

<angelica.beckmann@stryker.com<mailto:angelica.beckmann@stryker.com>>

Cc: Allison, John <John.Allison@stryker.com<mailto:John.Allison@stryker.com>>; Mateus, Jennifer <Jennifer.Mateus@stryker.com<mailto:Jennifer.Mateus@stryker.com>>; K173841@docs.fda.gov<mailto:K173841@docs.fda.gov>; Williams, Dhanya K <Dhanya.Kumar@fda.hhs.gov<mailto:Dhanya.Kumar@fda.hhs.gov>>

Subject: K173841 - Interactive request #1 - Updated (b)(4)

Hello Ms. Beckmann,

Thank you for your email. As Ms. Anderson noted, I am the lead reviewer for your submission, K173841, and we are still in the process of reviewing your deficiency responses. I will be in touch with you in the next day or two regarding any additional items that need to be addressed as we continue our review, however in the meantime, please address the following:

(b)(4)

(b)(4)

(b)(4) You mentioned in your email below that you would like to discuss some questions over the phone. Please let me know if you would be available at 12pm or 12:30pm EST for a brief call, as I would be happy to address any outstanding questions you may have and clarify the request above. I look forward to speaking with you.

Thank you,

Dhanya Williams, M.S.

Biologist/Scientific Reviewer

Center for Devices and Radiological Health (CDRH)

Office of Device Evaluation (ODE)

U.S. Food and Drug Administration

Tel: 301-796-6498

dhanya.williams@fda.hhs.gov<mailto:dhanya.williams@fda.hhs.gov>

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[cid:image002.jpg@01D1C57E.DFA022A0]<<https://www.facebook.com/FDA>>

[cid:image003.jpg@01D1C57E.DFA022A0]<https://twitter.com/US_FDA>

[cid:image004.jpg@01D1C57E.DFA022A0]<<http://www.youtube.com/user/USFoodandDrugAdmin>>

[cid:image005.jpg@01D1C57E.DFA022A0]<<http://www.flickr.com/photos/fdaphotos/>>

[cid:image006.jpg@01D1C57E.DFA022A0]
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From: Anderson, Leigh

Sent: Wednesday, March 07, 2018 7:30 AM

To: 'Beckmann, Angelica'

<angelica.beckmann@stryker.commailto:angelica.beckmann@stryker.com>>

Cc: Allison, John <John.Allison@stryker.commailto:John.Allison@stryker.com>>; Mateus, Jennifer <Jennifer.Mateus@stryker.commailto:Jennifer.Mateus@stryker.com>>; Zheng, Xiaolin <Xiaolin.Zheng@fda.hhs.govmailto:Xiaolin.Zheng@fda.hhs.gov>>; Williams, Dhanya K <Dhanya.Kumar@fda.hhs.govmailto:Dhanya.Kumar@fda.hhs.gov>>

Subject: RE: K173841-A1 - Updated (b)(4)

Dear Ms. Beckmann,

Thank you for your email.

Ms. Dhanya Williams is the Lead Reviewer for K173841, and I have forwarded the email to her, as well as copied her on this reply. Ms. Williams can assist with questions specific to K173841 and review of the submission.

Regards,

Leigh Anderson

Biomedical Engineer

Neurointerventional Devices Branch (NIDB)

Division of Neurological and Physical Medicine Devices (DNPMD)

Center for Devices and Radiological Health (CDRH)

Office of Device Evaluation (ODE)

U.S. Food and Drug Administration

Tel: 301-796-5613

leigh.anderson@fda.hhs.govmailto:leigh.anderson@fda.hhs.gov>

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<https://www.research.net/s/cdrhcustomerservice?O=400&D=460&B=463&E=&S=E>

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From: Beckmann, Angelica [mailto:angelica.beckmann@stryker.com]

Sent: Tuesday, March 06, 2018 6:04 PM

To: Anderson, Leigh <Leigh.Anderson@fda.hhs.govmailto:Leigh.Anderson@fda.hhs.gov>>

Cc: Allison, John <John.Allison@stryker.commailto:John.Allison@stryker.com>>; Mateus, Jennifer <Jennifer.Mateus@stryker.commailto:Jennifer.Mateus@stryker.com>>; Zheng, Xiaolin <Xiaolin.Zheng@fda.hhs.govmailto:Xiaolin.Zheng@fda.hhs.gov>>

Subject: K173841-A1 - Updated (b)(4)

Importance: High

Dear Ms. Anderson,

I hope this e-mail finds you well.

(b)(4)

(b)(4)

I would also like to understand the next steps for the interactive review of K173481.

Kind regards,

Angelica Beckmann

Director Regulatory Affairs

Stryker Neurovascular

47900 Bayside Pkwy

Fremont, CA 94538

510-413-2900 Office

(b)(6)

Mobile

angelica.beckmann@stryker.com<mailto:angelica.beckmann@stryker.com>

Hello all,

I am setting up this brief call with your team and NIDB branch chief Dr. Xiaolin Zheng to discuss your AXS Catalyst (K173841) submission in regards to the

(b)(4)

Right now I have set this call up for 12:30pm EST, however please let me know if you would like me to reschedule for 1:30pm EST instead.

Thank you,
Dhanya Williams
Tel: 301-796-6498

WEBEX Info:

-- Do not delete or change any of the following text: --

(b)(4)



Response to Interactive Request for K173841-S001, Traditional 510(k)

AXS Catalyst™ Distal Access Catheter

March 13, 2018

Stryker Neurovascular
47900 Bayside Parkway
Fremont, CA 94538

Stryker Neurovascular

Submission Date:

Response to Interactive Request #2 for K173841-S001, Traditional 510(k)

March 12, 2018

AXS Catalyst Distal Access Catheter

Table of Contents

Table of Contents	2
List of Appendices	3
Section 1 Response to Question #5 from FDA Interactive Request #2	4
Section 2 Response to Question #6 from FDA Interactive Request	5

Stryker Neurovascular

Response to Interactive Request #2 for K173841-S001, Traditional 510(k)

AXS Catalyst Distal Access Catheter

Submission Date:

March 12, 2018

List of Appendices

Appendix 1 (b)(4) AXS Catalyst DFU redlined version

Appendix 2 (b)(4) AXS Catalyst DFU clean version

Appendix 3 510(k) Summary redlined version

Appendix 4 510(k) Summary clean version

Stryker Neurovascular

Response to Interactive Request #2 for K173841-S001, Traditional 510(k)

AXS Catalyst Distal Access Catheter

Submission Date:

March 12, 2018

Section 1 Response to Question #5 from FDA Interactive Request #2

(b)(4)

(b)(4)

Stryker Neurovascular

Response to Interactive Request #2 for K173841-S001, Traditional 510(k)

AXS Catalyst Distal Access Catheter

Submission Date:

March 12, 2018

Appendix 1

(b)(4)

AXS Catalyst DFU redlined version

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Stryker Neurovascular

Response to Interactive Request #2 for K173841-S001, Traditional 510(k)

AXS Catalyst Distal Access Catheter

Submission Date:

March 12, 2018

Appendix 2

(b)(4)

AXS Catalyst DFU clean version



AXS Catalyst®

Distal Access Catheter

NOTE: This Catheter has two separate indications for use. Read the Directions for Use carefully.

AXS Catalyst®

Distal Access Catheter

Rx ONLY

Caution: Federal Law (USA) restricts this device to sale by or on the order of a physician.

WARNING

Contents supplied STERILE using an ethylene oxide (EO) process. Do not use if sterile barrier is damaged. If damage is found, call your Stryker Neurovascular representative.

For single use only. Do not reuse, reprocess or resterilize. Reuse, reprocessing or resterilization may compromise the structural integrity of the device and/or lead to device failure which, in turn, may result in patient injury, illness or death. Reuse, reprocessing or resterilization may also create a risk of contamination of the device and/or cause patient infection or cross-infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to injury, illness or death of the patient.

After use, dispose of product and packaging in accordance with hospital, administrative and/or local government policy.

DEVICE DESCRIPTION

The AXS Catalyst Distal Access Catheter is a single lumen, variable stiffness catheter designed for use in facilitating the insertion and guidance of appropriately sized interventional devices into the peripheral and neurovascular 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.

User Information

The AXS Catalyst Distal Access Catheter should only be used by physicians trained in interventional endovascular procedures.

Contents

One (1) AXS Catalyst Distal Access Catheter

One (1) Rotating Hemostatic Valve (RHV)

One (1) Tuohy Borst Valve with sideport

Two (2) Peel-away introducer sheaths

Table 1. Compatibility Information

Catheter	Inner Diameter mm (in)	Outer Diameter F (mm) [in]	Effective length (cm)	Overall length (cm)
AXS Catalyst 5	1.47 (0.058)	Prox: 5.6F (1.86) [0.073] Dist: 5.3F (1.76) [0.069]	115, 132	120, 137
AXS Catalyst 6	1.52 (0.060)	Prox: 6.0F (2.01) [0.079] Dist: 5.4F (1.81) [0.071]	132	137

Accessory	Length
RHV	7cm
Tuohy Borst with Sideport	3.5cm

INTENDED USE/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.

CONTRAINDICATIONS

None known.

WARNINGS

- Limited testing has been performed with solutions such as contrast media, and saline. The use of these catheters for delivery of solutions other than the types that have been tested for compatibility is not recommended.
- Not intended for use with power injectors.
- If flow through catheter becomes restricted, do not attempt to clear catheter lumen by infusion. Doing so may cause catheter damage or patient injury. Remove and replace catheter.
- Never advance or withdraw an intravascular device against resistance until the cause of the resistance is determined by fluoroscopy. Movement of the device against resistance could dislodge a clot, perforate a vessel wall, or damage the device.

PRECAUTIONS

- Carefully inspect all devices prior to use. Verify size, length, and condition are suitable for the specific procedure. Ensure the catheter's labeled outer diameter is smaller than the treatment vessel diameter. Do not use a device that has been damaged in any way. Damaged device may cause complications.
- To control the proper introduction, movement, positioning and removal of the catheter within the vascular system, users should employ standard clinical angiographic and fluoroscopic practices and techniques throughout the interventional procedure.
- Use the product prior to the "Use By" date printed on the label.
- To prevent thrombus formation and contrast media crystal formation, maintain a constant infusion of appropriate flush solution through catheter lumen.
- Torquing the catheter may cause damage which could result in kinking or separation of the catheter shaft.

ADVERSE EVENTS

Potential adverse events associated with the use of catheters or with the endovascular procedures include, but are not limited to:

- Access site complications
- Allergic reaction
- Aneurysm perforation
- Aneurysm rupture
- Death
- Embolism (air, foreign body, plaque, thrombus)
- Hematoma
- Hemorrhage
- Infection
- Ischemia
- Neurological deficits
- Pseudoaneurysm
- Stroke
- Transient Ischemic Attack
- Vasospasm
- Vessel dissection
- Vessel occlusion
- Vessel perforation
- Vessel rupture
- Vessel thrombosis

Use of device requires fluoroscopy which presents potential risks to physicians and patients associated with x-ray exposure. Possible risks include, but are not limited to, the following:

- Alopecia
- Burns ranging in severity from skin reddening to ulcers
- Cataracts
- Delayed neoplasia

Adverse Event Reporting

Please notify your Stryker Neurovascular representative immediately if a device malfunctions or patient complication or injury is experienced or suspected. Please make every attempt to retain any suspect device, its associated components and their packaging for return to Stryker Neurovascular.

HOW SUPPLIED

Stryker Neurovascular products are sterile and non-pyrogenic in unopened packaging that is designed to maintain sterility unless the primary product pouch has been opened or damaged.

Do not use if package is opened or damaged.

Do not use if labeling is incomplete or illegible.

Handling and Storage

Store in a cool, dry, dark place.

OPERATIONAL INSTRUCTIONS

Required Additional Items

- Continuous flush set up

PREPARATIONS FOR USE

1. Set-up continuous flush through sheath or guide catheter lumen.
2. Select an appropriately sized catheter based on intended procedure and anatomy.
3. Gently remove contents from pouch using standard sterile technique

Caution: Flush the packaging hoop prior to removal of product to activate the hydrophilic coating of the catheter. Once hydrated, do not allow to dry.

4. Gently remove the catheter and accessories from the hoop and inspect prior to use to verify that they are undamaged. If any damage, replace with a new device.
5. Attach compatible RHV or Tuohy Borst valve based on intended procedure and associated devices, then flush RHV/Tuohy Borst valve and catheter lumen.
6. Set up continuous flush through catheter.

DIRECTIONS FOR USE

1. Gently insert catheter tip through a compatible sheath or guide catheter and over an appropriately sized guidewire.
(Optional) Use the peel-away introducer sheath to assist in insertion of the catheter tip into the sheath/guide catheter valve. Once the catheter is inserted, retract and remove the peel-away introducer sheath.
2. Under fluoroscopic guidance, advance the catheter through the vasculature to the desired location.
3. Once the catheter is at the desired location, insert appropriately sized interventional devices into the selected blood vessel.
4. If used with a retriever, apply aspiration to the catheter using a 60mL syringe during withdrawal of the retrieval device.
5. Continue aspirating until retriever and microcatheter are withdrawn from the catheter.

Note: If using a retriever and withdrawal of the device is difficult, simultaneously withdraw the catheter, microcatheter and retriever as a unit into the sheath/ guide catheter. Remove sheath/guide catheter if necessary.

Table 2. Flow rate

Media (100%)	Size	Approximate Average Flow rate at 43.5 psi (300 Ppa), (ml/min)
--------------	------	---

Saline	0.058 x 115	438
	0.058 x 132	405
	0.060 x 132	445
Omnipaque®-300 (Non-ionic Contrast)	0.058 x 115	158
	0.058 x 132	141
	0.060 x 132	156
MD-76R (Ionic Contrast)	0.058 x 115	103
	0.058 x 132	91
	0.060 x 132	102

WARRANTY

Stryker Neurovascular warrants that reasonable care has been used in the design and manufacture of this instrument. **This warranty is in lieu of and excludes all other warranties not expressly set forth herein, whether express or implied by operation of law or otherwise, including, but not limited to, any implied warranties of merchantability or fitness for a particular purpose.** Handling, storage, cleaning and sterilization of this instrument as well as other factors relating to the patient, diagnosis, treatment, surgical procedures and other matters beyond Stryker Neurovascular's control directly affect the instrument and the results obtained from its use. Stryker Neurovascular's obligation under this warranty is limited to the repair or replacement of this instrument and Stryker

Neurovascular shall not be liable for any incidental or consequential loss, damage or expense directly or indirectly arising from the use of this instrument. Stryker Neurovascular neither assumes, nor authorizes any other person to assume for it, any other or additional liability or responsibility in connection with this instrument. **Stryker Neurovascular assumes no liability with respect to instruments reused, reprocessed or resterilized and makes no warranties, express or implied, including but not limited to merchantability or fitness for a particular purpose, with respect to such instruments.**

Omnipaque is a trademark of GE Healthcare.

AXS Universal Aspiration System

Rx ONLY

Caution: Federal Law (USA) restricts this device to sale by or on the order of a physician.

WARNING

Contents supplied STERILE using an ethylene oxide (EO) process. Do not use if sterile barrier is damaged. If damage is found, call your Stryker Neurovascular representative.

The AXS Catalyst Distal Access Catheter is for single use only. Do not reuse, reprocess or resterilize. Reuse, reprocessing or resterilization may compromise the structural integrity of the device and/or lead to device failure which, in turn, may result in patient injury, illness or death. Reuse, reprocessing or resterilization may also create a risk of contamination of the device and/or cause patient infection or cross-infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to injury, illness or death of the patient.

After use, dispose of product and packaging in accordance with hospital, administrative and/or local government policy.

DEVICE DESCRIPTION

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 Universal Aspiration System is designed to remove thrombus from the neurovasculature using continuous aspiration. The AXS Catalyst Distal Access Catheter delivers aspiration from the Medela Dominant Flex Pump directly to the site of the occlusion to remove the clot. 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 Hemostatic Valve (RHV), Tuohy Borst Valve with Sideport, and Peel Away Introducer. The Rotating Hemostatic 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.

User Information

The AXS Universal Aspiration System should only be used by physicians trained in interventional endovascular procedures.

Contents

One (1) AXS Catalyst Distal Access Catheter

One (1) Rotating Hemostatic Valve (RHV)
 One (1) Tuohy Borst Valve with sideport
 Two (2) Peel-away introducer sheaths

Table 1. Compatibility Information

Catheter	Inner Diameter mm (in)	Outer Diameter F (mm) [In]	Effective length (cm)	Overall length (cm)
AXS Catalyst 5	1.47 (0.058)	Prox: 5.6F (1.86) [0.073] Dist: 5.3F (1.76) [0.069]	115, 132	120, 137
AXS Catalyst 6	1.52 (0.060)	Prox: 6.0F (2.01) [0.079] Dist: 5.4F (1.81) [0.071]	132	137

Accessory	Length
RHV	7cm
Tuohy Borst with Sideport	3.5cm

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.

CONTRAINDICATIONS

None known.

WARNINGS

- Limited testing has been performed with solutions such as contrast media, and saline. The use of these catheters for delivery of solutions other than the types that have been tested for compatibility is not recommended.
- Not intended for use with power injectors.
- If flow through catheter becomes restricted, do not attempt to clear catheter lumen by infusion. Doing so may cause catheter damage or patient injury. Remove and replace catheter.
- Never advance or withdraw an intravascular device against resistance until the cause of the resistance is determined by fluoroscopy. Movement of the device against resistance could dislodge a clot, perforate a vessel wall, or damage the device.
- Excessive aspiration may cause patient complications.

PRECAUTIONS

- Carefully inspect all devices prior to use. Verify size, length, and condition are suitable for the specific procedure. Ensure the catheter's labeled outer diameter is smaller than the treatment vessel diameter. Do not use a device that has been damaged in any way. Damaged device may cause complications.
- To control the proper introduction, movement, positioning and removal of the catheter within the vascular system, users should employ standard clinical angiographic and fluoroscopic practices and techniques throughout the interventional procedure.
- Use the product prior to the "Use By" date printed on the label.
- To prevent thrombus formation and contrast media crystal formation, maintain a constant infusion of appropriate flush solution through catheter lumen.

- Torquing the catheter may cause damage which could result in kinking or separation of the catheter shaft.

ADVERSE EVENTS

Potential adverse events associated with the use of catheters or with the endovascular procedures include, but are not limited to:

- Access site complications
- Allergic reaction
- Aneurysm perforation
- Aneurysm rupture
- Death
- Embolism (air, foreign body, plaque, thrombus)
- Hematoma
- Hemorrhage
- Infection
- Ischemia
- Neurological deficits
- Pseudoaneurysm
- Stroke
- Transient Ischemic Attack
- Vasospasm
- Vessel dissection
- Vessel occlusion
- Vessel perforation
- Vessel rupture
- Vessel thrombosis

Use of device requires fluoroscopy which presents potential risks to physicians and patients associated with x-ray exposure.

Possible risks include, but are not limited to, the following:

- Alopecia
- Burns ranging in severity from skin reddening to ulcers
- Cataracts
- Delayed neoplasia

Adverse Event Reporting

Please notify your Stryker Neurovascular representative immediately if a device malfunctions or patient complication or injury is experienced or suspected. Please make every attempt to retain any suspect device, its associated components and their packaging for return to Stryker Neurovascular.

HOW SUPPLIED

Stryker Neurovascular products are sterile and non-pyrogenic in unopened packaging that is designed to maintain sterility unless the primary product pouch has been opened or damaged.

Do not use if package is opened or damaged.

Do not use if labeling is incomplete or illegible.

Handling and Storage

Store in a cool, dry, dark place.

OPERATIONAL INSTRUCTIONS

Required Additional Items

- Continuous flush set up

PREPARATIONS FOR USE

1. Set-up continuous flush through sheath or guide catheter lumen.
2. Select an appropriately sized catheter based on intended procedure and anatomy.
3. Gently remove contents from pouch using standard sterile technique

Caution: Flush the packaging hoop prior to removal of product to activate the hydrophilic coating of the catheter. Once hydrated, do not allow to dry.

4. Gently remove the catheter and accessories from the hoop and inspect prior to use to verify that they are undamaged. If any damage, replace with a new device.
5. Attach compatible RHV or Tuohy Borst valve based on intended procedure and associated devices, then flush RHV/Tuohy Borst valve and catheter lumen.
6. Set up continuous flush through catheter.
7. Attach the AXS Universal Aspiration Tubing to the Medela Dominant Flex Pump and ensure the aspiration control valve on the tubing is closed. Turn on the Medela Dominant Flex Pump (refer to the Medela Dominant Flex Pump manual). Confirm that the Medela Dominant Flex Pump reads -68kPa to -98kPa [-510mmHg to -735mmHg].

DIRECTIONS FOR USE

1. Gently insert catheter tip through a compatible sheath or guide catheter and over an appropriately sized guidewire.
(Optional) Use the peel-away introducer sheath to assist in insertion of the catheter tip into the sheath/guide catheter valve. Once the catheter is inserted, retract and remove the peel-away introducer sheath.
2. Under fluoroscopic guidance, advance the catheter through the vasculature to the desired location.
3. Tighten the RHV/Tuohy Borst valve to prevent backflow.
4. Connect the AXS Universal Aspiration Tubing to the side port of the rotating hemostasis valve of the AXS Catalyst Distal Access Catheter. To apply aspiration, open the aspiration tubing clamp.
5. Continue to aspirate until the clot is withdrawn.
6. If flow through catheter becomes restricted, do not attempt to clear catheter lumen by infusion. Doing so may cause catheter damage or patient injury. Remove catheter under aspiration and flush catheter outside of patient. If flush is unsuccessful, replace catheter.
7. If not damaged the AXS Catalyst Distal Access Catheter may be used for up to three (3) clot retrieval attempts. A clot retrieval attempt is one (1) advancement and complete withdrawal cycle of the distal access catheter.

Table 2. Flow rate

Media (100%)	Size	Approximate Average Flow rate at 43.5 psi (300 Ppa), (ml/min)
Saline	0.058 x 115	438
	0.058 x 132	405
	0.060 x 132	445
Omnipaque®-300 (Non-Ionic Contrast)	0.058 x 115	158
	0.058 x 132	141
	0.060 x 132	156
MD-76R (Ionic Contrast)	0.058 x 115	103
	0.058 x 132	91
	0.060 x 132	102

WARRANTY

Stryker Neurovascular warrants that reasonable care has been used in the design and manufacture of this instrument. **This warranty is in lieu of and excludes all other warranties not expressly set forth herein, whether express or implied by operation of law or otherwise, including, but not limited to, any implied warranties of merchantability or fitness for a particular purpose.** Handling, storage, cleaning and sterilization of this instrument as well as other factors relating to the patient, diagnosis, treatment, surgical procedures and other matters beyond Stryker Neurovascular's control directly affect the instrument and the results obtained from its use. Stryker Neurovascular's obligation under this warranty is limited to the repair or replacement of this instrument and Stryker

Neurovascular shall not be liable for any incidental or consequential loss, damage or expense directly or indirectly arising from the use of this instrument. Stryker Neurovascular neither assumes, nor authorizes any other person to assume for it, any other or additional liability or responsibility in connection with this instrument. **Stryker Neurovascular assumes no liability with respect to instruments reused, reprocessed or resterilized and makes no warranties, express or implied, including but not limited to merchantability or fitness for a particular purpose, with respect to such instruments.**

Omnipaque is a trademark of GE Healthcare.



**Australian
Sponsor Address**

Stryker Australia Pty Ltd
8 Herbert Street
St Leonards, NSW 2065
Australia



**Legal
Manufacturer**

Stryker Neurovascular
47900 Bayside Parkway
Fremont, CA 94538
USA
USA Customer Service 855-91 NEURO (916-3876)



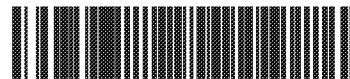
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NV00022382-01

Stryker Neurovascular

Submission Date:

Response to Interactive Request #2 for K173841-S001, Traditional 510(k)

March 12, 2018

AXS Catalyst Distal Access Catheter

Appendix 3

510(k) Summary redlined version

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Stryker Neurovascular

Submission Date:

Response to Interactive Request #2 for K173841-S001, Traditional 510(k)

March 12, 2018

AXS Catalyst Distal Access Catheter

Appendix 4

510(k) Summary clean version

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Response to Interactive Request for K173841-S001, Traditional 510(k)

AXS Catalyst™ Distal Access Catheter

March 8, 2018

Stryker Neurovascular
47900 Bayside Parkway
Fremont, CA 94538

Stryker Neurovascular

Submission Date:

Response to Interactive Request for K173841-S001, Traditional 510(k)

December 17, 2017

AXS Catalyst Distal Access Catheter

Table of Contents

Section 1	Response to Question #1 from FDA Interactive Request	4
Section 2	Response to Question #2 from FDA Interactive Request	6
Section 3	Response to Question #3 from FDA Interactive Request	7
Section 4	Response to Question #4 from FDA Interactive Request	8

Stryker Neurovascular

Submission Date:

Response to Interactive Request for K173841-S001, Traditional 510(k)

December 17, 2017

AXS Catalyst Distal Access Catheter

List of Appendices

Appendix 1 (b)(4) AXS Catalyst DFU redline

Appendix 2 (b)(4) AXS Catalyst DFU clean

Appendix 3 510(k) Summary

Appendix 4 Indications For Use

Stryker Neurovascular

Response to Interactive Request for K173841-S001, Traditional 510(k)

AXS Catalyst Distal Access Catheter

Submission Date:

December 17, 2017

Section 1 Response to Question #1 from FDA Interactive Request

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Stryker Neurovascular

Submission Date:

Response to Interactive Request for K173841-S001, Traditional 510(k)

December 17, 2017

AXS Catalyst Distal Access Catheter

Appendix 1

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AXS Catalyst DFU redline

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Stryker Neurovascular

Submission Date:

Response to Interactive Request for K173841-S001, Traditional 510(k)

December 17, 2017

AXS Catalyst Distal Access Catheter

Appendix 2

(b)(4)

AXS Catalyst DFU clean

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Stryker Neurovascular

Submission Date:

Response to Interactive Request for K173841-S001, Traditional 510(k)

December 17, 2017

AXS Catalyst Distal Access Catheter

Appendix 3
510(k) Summary

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Stryker Neurovascular

Submission Date:

Response to Interactive Request for K173841-S001, Traditional 510(k)

December 17, 2017

AXS Catalyst Distal Access Catheter

Appendix 4
Indications For Use

Indications for Use

(b)(4)

Hello Ms. Beckmann,

(b)(4)

Regards,

Dhanya Williams, M.S.

Biologist/Scientific Reviewer

Center for Devices and Radiological Health (CDRH)

Office of Device Evaluation (ODE)

U.S. Food and Drug Administration

Tel: 301-796-6498

dhanya.williams@fda.hhs.gov

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[cid:image002.jpg@01D1C57E.DFA022A0] <<https://www.facebook.com/FDA>>

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[cid:image005.jpg@01D1C57E.DFA022A0] <<http://www.flickr.com/photos/fdaphotos/>>

[cid:image006.jpg@01D1C57E.DFA022A0]
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From: Beckmann, Angelica [mailto:angelica.beckmann@stryker.com]

Sent: Thursday, March 08, 2018 2:59 PM

To: Williams, Dhanya K <Dhanya.Kumar@fda.hhs.gov>

Cc: Mateus, Jennifer <Jennifer.Mateus@stryker.com>; K173841@docs.fda.gov; Allison, John <John.Allison@stryker.com>

Subject: RE: K173841 - Interactive request #1 - Updated (b)(4)

Dear Ms. Williams,

Enclosed are the responses to FDA's Interactive Request #1 regarding the 510(k) Submission K173841. The requested information is contained within the attached pdf file.

Please feel free to call me or send email with any additional requests.

Best regards,

Angelica Beckmann

Director Regulatory Affairs

Stryker Neurovascular

47900 Bayside Pkwy

Fremont, CA 94538

(b)(6)

Mobile

angelica.beckmann@stryker.com<mailto:angelica.beckmann@stryker.com>

From: Williams, Dhanya K [mailto:Dhanya.Kumar@fda.hhs.gov]

Sent: Wednesday, March 7, 2018 6:02 AM

To: Beckmann, Angelica

<angelica.beckmann@stryker.com<mailto:angelica.beckmann@stryker.com>>

Cc: Allison, John <John.Allison@stryker.com<mailto:John.Allison@stryker.com>>; Mateus,

Jennifer <Jennifer.Mateus@stryker.com<mailto:Jennifer.Mateus@stryker.com>>;

K173841@docs.fda.gov<mailto:K173841@docs.fda.gov>; Williams, Dhanya K

<Dhanya.Kumar@fda.hhs.gov<mailto:Dhanya.Kumar@fda.hhs.gov>>

Subject: K173841 - Interactive request #1 - Updated (b)(4)

Hello Ms. Beckmann,

Thank you for your email. As Ms. Anderson noted, I am the lead reviewer for your submission, K173841, and we are still in the process of reviewing your deficiency responses. I will be in touch with you in the next day or two regarding any additional items that need to be addressed as we continue our review, however in the meantime, please address the following:

(b)(4)

(b)(4)

Thank you,

Dhanya Williams, M.S.

Biologist/Scientific Reviewer

Center for Devices and Radiological Health (CDRH)

Office of Device Evaluation (ODE)

U.S. Food and Drug Administration

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From: Anderson, Leigh

Sent: Wednesday, March 07, 2018 7:30 AM

To: 'Beckmann, Angelica'

<angelica.beckmann@stryker.com<<mailto:angelica.beckmann@stryker.com>>>

Cc: Allison, John <John.Allison@stryker.com<<mailto:John.Allison@stryker.com>>>; Mateus,

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Jennifer <Jennifer.Mateus@stryker.com<mailto:Jennifer.Mateus@stryker.com>>; Zheng, Xiaolin <Xiaolin.Zheng@fda.hhs.gov<mailto:Xiaolin.Zheng@fda.hhs.gov>>; Williams, Dhanya K <Dhanya.Kumar@fda.hhs.gov<mailto:Dhanya.Kumar@fda.hhs.gov>>

Subject: RE: K173841-A1 - Updated (b)(4)

Dear Ms. Beckmann,

Thank you for your email.

Ms. Dhanya Williams is the Lead Reviewer for K173841, and I have forwarded the email to her, as well as copied her on this reply. Ms. Williams can assist with questions specific to K173841 and review of the submission.

Regards,

Leigh Anderson

Biomedical Engineer

Neurointerventional Devices Branch (NIDB)

Division of Neurological and Physical Medicine Devices (DNPMMD)

Center for Devices and Radiological Health (CDRH)

Office of Device Evaluation (ODE)

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From: Beckmann, Angelica [mailto:angelica.beckmann@stryker.com]

Sent: Tuesday, March 06, 2018 6:04 PM

To: Anderson, Leigh <Leigh.Anderson@fda.hhs.gov<mailto:Leigh.Anderson@fda.hhs.gov>>

Cc: Allison, John <John.Allison@stryker.com<mailto:John.Allison@stryker.com>>; Mateus, Jennifer <Jennifer.Mateus@stryker.com<mailto:Jennifer.Mateus@stryker.com>>; Zheng, Xiaolin <Xiaolin.Zheng@fda.hhs.gov<mailto:Xiaolin.Zheng@fda.hhs.gov>>

Subject: K173841-A1 - Updated (b)(4)

Importance: High

Dear Ms. Anderson,

I hope this e-mail finds you well.

(b)(4)

(b)(4)

(b)(4)

I would also like to understand the next steps for the interactive review of K173481.

Kind regards,

Angelica Beckmann

Director Regulatory Affairs

Stryker Neurovascular

47900 Bayside Pkwy

Fremont, CA 94538

510-413-2900 Office

(b)(6)

Mobile

angelica.beckmann@stryker.com<mailto:angelica.beckmann@stryker.com>

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 Hemostatic Valve (RHV), Tuohy Borst Valve with Sideport, and Peel Away Introducer. The Rotating Hemostatic 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 hemostatic 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 is 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
<u>In-vitro Simulated Use</u> (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.
<u>In-vitro Usability Study</u>	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	<u>Purpose:</u> To determine the aspiration flow rate and lumen integrity of the system when no occlusion is present. <u>Method:</u> 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	<u>Purpose:</u> To determine the maximum force a catheter tip could withstand before buckling. <u>Method:</u> 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	<u>Purpose:</u> 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. <u>Method:</u> 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)	<u>Purpose:</u> To test resistance to tip and lumen collapse during direct aspiration and test tip integrity to tears and missing material. <u>Method:</u> 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	<u>Purpose:</u> To describe the procedure and technique of making dimensional measurements using various measurement equipment. <u>Method:</u> Verify dimensions using specified measurement tool. Record measurements.	Dimensional verification met acceptance criteria and was cleared as part of K151667.
Tip Configuration	<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. <u>Method:</u> 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	<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. <u>Method:</u> 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	<u>Purpose:</u> To measure the maximum force required to cause a test sample to buckle. <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.	Tip buckling met acceptance criteria and was cleared as part of K151667.
Catheter lubricity and durability	<u>Purpose:</u> To determine the lubricity and durability of the coating on the catheter outer shaft. <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.	Coating lubricity and durability met acceptance criteria and was cleared as part of K151667.
Trackability	<u>Purpose:</u> To measure track advance force of catheter over microcatheter. <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.	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	<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. <u>Method:</u> 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	<u>Purpose:</u> 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. <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.	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	<u>Purpose:</u> 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. <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.	Air leak resistance of catheter met acceptance criteria and was cleared as part of K151667.
Catheter Torsional Bond Strength	<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. <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.	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	<u>Purpose:</u> To determine the flexural fatigue on the catheter shaft. <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 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 for kink or damage. Record results.	Flexural fatigue met acceptance criteria and was cleared as part of K151667.
Catheter Kink Radius	<u>Purpose:</u> To measure the kink radius of a catheter at its distal and specific mid-shaft joint section. <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 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	<u>Purpose:</u> To determine visual and dimensional integrity of catheter following exposure to saline, non-ionic and ionic contrast liquids. <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.	Chemical compatibility met acceptance criteria and was cleared as part of K151667.
Hub Gauging	<u>Purpose:</u> To determine if catheter hub meets gauging requirement 4.1 of EN 1707. <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.	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
<u><i>In-vivo</i> Efficacy and Safety Evaluation</u> (Arm 1)	<u>Purpose:</u> 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. <u>Method:</u> 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.
<u><i>In-vivo</i> Efficacy and Safety Evaluation</u> (Arm 2)	<u>Purpose:</u> To assess the vascular safety profile of treatment by aspiration and navigation of the Subject Device compared to the Primary Predicate Device. <u>Method:</u> 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.
<u><i>In-vivo</i> Vascular Response</u> (Direct Aspiration)	<u>Purpose:</u> To assess the vascular response of direct aspiration through the Subject Device compared to Primary Predicate device. <u>Method:</u> 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 ≤ 4 mg)
- Ethylene Chlorohydrin Results: 0.07 mg/device extracted residuals
(EN ISO 10993-7 requirement is average daily dose ≤ 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.

Hello Ms. Beckmann,

(b)(4)

Thank you,

Dhanya Williams, M.S.

Biologist/Scientific Reviewer

Center for Devices and Radiological Health (CDRH)

Office of Device Evaluation (ODE)

U.S. Food and Drug Administration

Tel: 301-796-6498

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From: Beckmann, Angelica [mailto:angelica.beckmann@stryker.com]

Sent: Thursday, March 08, 2018 11:52 PM

To: Williams, Dhanya K <Dhanya.Kumar@fda.hhs.gov>

Cc: Mateus, Jennifer <Jennifer.Mateus@stryker.com>; K173841@docs.fda.gov; Zheng, Xiaolin <Xiaolin.Zheng@fda.hhs.gov>; Allison, John <John.Allison@stryker.com>

Subject: K173841-S001 - Interactive request #1 rev 2

Dear Ms. Williams,

Upon further consideration, Stryker would like to provide an updated version of the responses to FDA's Interactive Request #1.

(b)(4)

(b)(4)

Please feel free to call me or send email with any additional requests.

Best regards,

Angelica Beckmann

Director Regulatory Affairs

Stryker Neurovascular

47900 Bayside Pkwy

Fremont, CA 94538

(b)(6)

Mobile

angelica.beckmann@stryker.com<mailto:angelica.beckmann@stryker.com>

Indications for Use

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)

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To: angelica.beckmann@stryker.com
CC: DCCLetters [DCCLetters@fda.hhs.gov]
Subject: K173841 Acknowledgment Letter
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Acknowledgment Letter

12/18/2017

Angelica Beckmann, Director, Regulatory Affairs
Stryker
47900 Bayside Parkway
Fremont, CA 94538
UNITED STATES

Dear Angelica Beckmann:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has received your submission. This submission has been assigned the unique document control number below. All future correspondence regarding this submission should be identified prominently with the number assigned and should be submitted to the Document Control Center at the above letterhead address. Failure to do so may result in processing delays. If you believe the information identified below is incorrect, please notify the Program Operations Staff at (301) 796-5640.

Submission Number: K173841

Received: 12/18/2017

Applicant: Stryker

Device: AXS Catalyst Distal Access Catheter 058 x 115cm; AXS Catalyst Distal Access Catheter 058 x 132cm; AXS Catalyst Distal Access Catheter 060 x 132cm

We will notify you when the review of this submission has been completed or if any additional information is required. For information about CDRH review regulations and policies, please refer to <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/default.htm>.

Sincerely yours,

Center for Devices and Radiological Health

Hello Ms. Beckmann,

(b)(4)

Please feel free to email me or call me at 301-796-6498 if you need any clarification.

If anything else is identified as being deficient or in need of address as we finalize our review I will contact you as soon as possible, however at this time I do not anticipate any further changes to the labeling (in particular) if you are able to address the two items above.

Thank you,

Dhanya Williams, M.S.
Biologist/Scientific Reviewer
Center for Devices and Radiological Health (CDRH)
Office of Device Evaluation (ODE)
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U.S. FOOD & DRUG
ADMINISTRATION

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 - 

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

Enclosure

Ms. Williams,
Thank you for your quick response.

Best regards,

Angelica Beckmann
Director Regulatory Affairs
Stryker Neurovascular
47900 Bayside Pkwy
Fremont, CA 94538
510-413-2900 Office
(b)(6) Mobile
angelica.beckmann@stryker.com

From: Williams, Dhanya K [mailto:Dhanya.Kumar@fda.hhs.gov]
Sent: Thursday, March 8, 2018 9:00 PM
To: Beckmann, Angelica <angelica.beckmann@stryker.com>
Cc: Mateus, Jennifer <Jennifer.Mateus@stryker.com>; K173841@docs.fda.gov; Zheng, Xiaolin <Xiaolin.Zheng@fda.hhs.gov>; Allison, John <John.Allison@stryker.com>; Williams, Dhanya K <Dhanya.Kumar@fda.hhs.gov>
Subject: RE: K173841-S001 - Interactive request #1 rev 2

Hello Ms. Beckmann,

We will (b)(4) you have provided and I will get back to you with any additional questions by close of business Monday.

Thank you,

Dhanya Williams, M.S.
Biologist/Scientific Reviewer
Center for Devices and Radiological Health (CDRH)
Office of Device Evaluation (ODE)
U.S. Food and Drug Administration
Tel: 301-796-6498
dhanya.williams@fda.hhs.gov

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From: Beckmann, Angelica [mailto:angelica.beckmann@stryker.com]
Sent: Thursday, March 08, 2018 11:52 PM
To: Williams, Dhanya K <Dhanya.Kumar@fda.hhs.gov>
Cc: Mateus, Jennifer <Jennifer.Mateus@stryker.com>; K173841@docs.fda.gov; Zheng, Xiaolin <Xiaolin.Zheng@fda.hhs.gov>; Allison, John <John.Allison@stryker.com>
Subject: K173841-S001 - Interactive request #1 rev 2

Dear Ms. Williams,

(b)(4)

Please feel free to call me or send email with any additional requests.

Best regards,

Angelica Beckmann

Director Regulatory Affairs
Stryker Neurovascular
47900 Bayside Pkwy
Fremont, CA 94538
[REDACTED] Mobile
angelica.beckmann@stryker.com

Hello all,

I am setting up this brief call with your team and NIDB branch chief Dr. Xiaolin Zheng to discuss your AXS Catalyst (K173841) submission in regards to the (b)(4)

(b)(4)

Right now I have set this call up for 12:30pm EST, however please let me know if you would like me to reschedule for 1:30pm EST instead.

Thank you,

Dhanya Williams

Tel: 301-796-6498

WEBEX Info:

-- Do not delete or change any of the following text. --

(b)(4)



U.S. FOOD & DRUG
ADMINISTRATION

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

Indications for Use

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 Hemostatic Valve (RHV), Tuohy Borst Valve with Sideport, and Peel Away Introducer. The Rotating Hemostatic 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 hemostatic 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 is 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
<u>In-vitro Simulated Use</u> (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.
<u>In-vitro Usability Study</u>	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	<u>Purpose:</u> To determine the aspiration flow rate and lumen integrity of the system when no occlusion is present. <u>Method:</u> 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	<u>Purpose:</u> To determine the maximum force a catheter tip could withstand before buckling. <u>Method:</u> 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	<u>Purpose:</u> 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. <u>Method:</u> 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)	<u>Purpose:</u> To test resistance to tip and lumen collapse during direct aspiration and test tip integrity to tears and missing material. <u>Method:</u> 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	<u>Purpose:</u> To describe the procedure and technique of making dimensional measurements using various measurement equipment. <u>Method:</u> Verify dimensions using specified measurement tool. Record measurements.	Dimensional verification met acceptance criteria and was cleared as part of K151667.
Tip Configuration	<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. <u>Method:</u> 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	<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. <u>Method:</u> 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	<u>Purpose:</u> To measure the maximum force required to cause a test sample to buckle. <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.	Tip buckling met acceptance criteria and was cleared as part of K151667.
Catheter lubricity and durability	<u>Purpose:</u> To determine the lubricity and durability of the coating on the catheter outer shaft. <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.	Coating lubricity and durability met acceptance criteria and was cleared as part of K151667.
Trackability	<u>Purpose:</u> To measure track advance force of catheter over microcatheter. <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.	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	<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. <u>Method:</u> 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	<u>Purpose:</u> 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. <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.	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	<u>Purpose:</u> 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. <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.	Air leak resistance of catheter met acceptance criteria and was cleared as part of K151667.
Catheter Torsional Bond Strength	<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. <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.	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	<u>Purpose:</u> To determine the flexural fatigue on the catheter shaft. <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 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 for kink or damage. Record results.	Flexural fatigue met acceptance criteria and was cleared as part of K151667.
Catheter Kink Radius	<u>Purpose:</u> To measure the kink radius of a catheter at its distal and specific mid-shaft joint section. <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 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	<u>Purpose:</u> To determine visual and dimensional integrity of catheter following exposure to saline, non-ionic and ionic contrast liquids. <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.	Chemical compatibility met acceptance criteria and was cleared as part of K151667.
Hub Gauging	<u>Purpose:</u> To determine if catheter hub meets gauging requirement 4.1 of EN 1707. <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.	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
<u><i>In-vivo</i> Efficacy and Safety Evaluation</u> (Arm 1)	<u>Purpose:</u> 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. <u>Method:</u> 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.
<u><i>In-vivo</i> Efficacy and Safety Evaluation</u> (Arm 2)	<u>Purpose:</u> To assess the vascular safety profile of treatment by aspiration and navigation of the Subject Device compared to the Primary Predicate Device. <u>Method:</u> 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.
<u><i>In-vivo</i> Vascular Response</u> (Direct Aspiration)	<u>Purpose:</u> To assess the vascular response of direct aspiration through the Subject Device compared to Primary Predicate device. <u>Method:</u> 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 ≤ 4 mg)
- Ethylene Chlorohydrin Results: 0.07 mg/device extracted residuals
(EN ISO 10993-7 requirement is average daily dose ≤ 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.

Dear Ms. Williams,

(b)(4)

Please feel free to call me or send email with any additional requests.

The updated 510K summary will be provided tomorrow.

Best regards,

Angelica Beckmann

Director Regulatory Affairs

Stryker Neurovascular

47900 Bayside Pkwy

Fremont, CA 94538

510-413-2900 Office

(b)(6)

Mobile

angelica.beckmann@stryker.com<mailto:angelica.beckmann@stryker.com>

From: Williams, Dhanya K [mailto:Dhanya.Kumar@fda.hhs.gov]

Sent: Wednesday, March 7, 2018 6:02 AM

To: Beckmann, Angelica <angelica.beckmann@stryker.com>

Cc: Allison, John <John.Allison@stryker.com>; Mateus, Jennifer
<Jennifer.Mateus@stryker.com>; K173841@docs.fda.gov; Williams, Dhanya K
<Dhanya.Kumar@fda.hhs.gov>

Subject: K173841 - Interactive request #1 - Updated (b)(4)

Hello Ms. Beckmann,

Thank you for your email. As Ms. Anderson noted, I am the lead reviewer for your submission, K173841, and we are still in the process of reviewing your deficiency responses. I will be in touch with you in the next day or two regarding any additional items that need to be addressed as we continue our review, however in the meantime, please address the following:

(b)(4)

(b)(4)

Thank you,

Dhanya Williams, M.S.

Biologist/Scientific Reviewer

Center for Devices and Radiological Health (CDRH)

Office of Device Evaluation (ODE)

U.S. Food and Drug Administration

Tel: 301-796-6498

dhanya.williams@fda.hhs.gov<mailto:dhanya.williams@fda.hhs.gov>

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[cid:image003.jpg@01D1C57E.DFA022A0] <https://twitter.com/US_FDA>

[cid:image004.jpg@01D1C57E.DFA022A0] <<http://www.youtube.com/user/USFoodandDrugAdmin>>

[cid:image005.jpg@01D1C57E.DFA022A0] <<http://www.flickr.com/photos/fdaphotos/>>

[cid:image006.jpg@01D1C57E.DFA022A0]
<<http://www.fda.gov/AboutFDA/ContactFDA/StayInformed/RSSFeeds/default.htm>>

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From: Anderson, Leigh

Sent: Wednesday, March 07, 2018 7:30 AM

To: 'Beckmann, Angelica'
<angelica.beckmann@stryker.com<mailto:angelica.beckmann@stryker.com>>

Cc: Allison, John <John.Allison@stryker.com<mailto:John.Allison@stryker.com>>; Mateus, Jennifer <Jennifer.Mateus@stryker.com<mailto:Jennifer.Mateus@stryker.com>>; Zheng, Xiaolin <Xiaolin.Zheng@fda.hhs.gov<mailto:Xiaolin.Zheng@fda.hhs.gov>>; Williams, Dhanya K <Dhanya.Kumar@fda.hhs.gov<mailto:Dhanya.Kumar@fda.hhs.gov>>

Subject: RE: K173841-A1 - Updated (b)(4)

Dear Ms. Beckmann,

Thank you for your email.

Ms. Dhanya Williams is the Lead Reviewer for K173841, and I have forwarded the email to her, as well as copied her on this reply. Ms. Williams can assist with questions specific to K173841 and review of the submission.

Regards,

Leigh Anderson

Biomedical Engineer

Neurointerventional Devices Branch (NIDB)

Division of Neurological and Physical Medicine Devices (DNPMD)

Center for Devices and Radiological Health (CDRH)

Office of Device Evaluation (ODE)

U.S. Food and Drug Administration

Tel: 301-796-5613

leigh.anderson@fda.hhs.gov<mailto:leigh.anderson@fda.hhs.gov>

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From: Beckmann, Angelica [mailto:angelica.beckmann@stryker.com]

Sent: Tuesday, March 06, 2018 6:04 PM

To: Anderson, Leigh <Leigh.Anderson@fda.hhs.gov<mailto:Leigh.Anderson@fda.hhs.gov>>

Cc: Allison, John <John.Allison@stryker.com<mailto:John.Allison@stryker.com>>; Mateus, Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Jennifer <Jennifer.Mateus@stryker.com<mailto:Jennifer.Mateus@stryker.com>>; Zheng, Xiaolin <Xiaolin.Zheng@fda.hhs.gov<mailto:Xiaolin.Zheng@fda.hhs.gov>>

Subject: K173841-A1 - Updated (b)(4)

Importance: High

Dear Ms. Anderson,

I hope this e-mail finds you well.

(b)(4)

(b)(4)

I would also like to understand the next steps for the interactive review of K173481.

Kind regards,

Angelica Beckmann

Director Regulatory Affairs

Stryker Neurovascular

47900 Bayside Pkwy

Fremont, CA 94538

510-413-2900 Office

(b)(4)

Mobile

angelica.beckmann@stryker.com<mailto:angelica.beckmann@stryker.com>



Memorandum

K173841

Office of Device Evaluation

Date: January 26, 2018

To: Dhanya Williams
CDRH/ODE/DNPMD/NIDB

From: Elizabeth Katz, PhD, PhD, CDRH/ODE



Elizabeth J. Katz -S
2018.01.26 18:18:14
-05'00'

Consult: CON180227

Sponsor: Stryker Medical

US Reps.:

Product: AXS Catalyst Distal Access Catheter

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Hello Ms. Beckmann,

We will review the (b)(4) you have provided and I will get back to you with any additional questions by close of business Monday.

Thank you,

Dhanya Williams, M.S.
Biologist/Scientific Reviewer
Center for Devices and Radiological Health (CDRH)
Office of Device Evaluation (ODE)
U.S. Food and Drug Administration
Tel: 301-796-6498
dhanya.williams@fda.hhs.gov

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From: Beckmann, Angelica [mailto:angelica.beckmann@stryker.com]
Sent: Thursday, March 08, 2018 11:52 PM
To: Williams, Dhanya K <Dhanya.Kumar@fda.hhs.gov>
Cc: Mateus, Jennifer <Jennifer.Mateus@stryker.com>; K173841@docs.fda.gov; Zheng, Xiaolin <Xiaolin.Zheng@fda.hhs.gov>; Allison, John <John.Allison@stryker.com>
Subject: K173841-S001 - Interactive request #1 rev 2

Dear Ms. Williams,

(b)(4)

Please feel free to call me or send email with any additional requests.

Best regards,

Angelica Beckmann
Director Regulatory Affairs
Stryker Neurovascular
47900 Bayside Pkwy
Fremont, CA 94538
(b)(6) Mobile
angelica.beckmann@stryker.com

From: Williams, Dhanya K [Dhanya.Kumar@fda.hhs.gov]
Sent: 3/7/2018 2:01:42 PM
To: 'Beckmann, Angelica' [angelica.beckmann@stryker.com]
CC: Allison, John [John.Allison@stryker.com]; Mateus, Jennifer [Jennifer.Mateus@stryker.com]; K173841@docs.fda.gov; Williams, Dhanya K [Dhanya.Kumar@fda.hhs.gov]
Subject: K173841 - Interactive request #1 - Updated (b)(4)

Hello Ms. Beckmann,

Thank you for your email. As Ms. Anderson noted, I am the lead reviewer for your submission, K173841, and we are still in the process of reviewing your deficiency responses. I will be in touch with you in the next day or two regarding any additional items that need to be addressed as we continue our review, however in the meantime, please address the following:

(b)(4)

Thank you,

Dhanya Williams, M.S.
Biologist/Scientific Reviewer
Center for Devices and Radiological Health (CDRH)
Office of Device Evaluation (ODE)
U.S. Food and Drug Administration
Tel: 301-796-6498
dhanya.williams@fda.hhs.gov



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Sent: Wednesday, March 07, 2018 7:30 AM
To: 'Beckmann, Angelica' <angelica.beckmann@stryker.com>
Cc: Allison, John <John.Allison@stryker.com>; Mateus, Jennifer <Jennifer.Mateus@stryker.com>; Zheng, Xiaolin <Xiaolin.Zheng@fda.hhs.gov>; Williams, Dhanya K <Dhanya.Kumar@fda.hhs.gov>
Subject: RE: K173841-A1 - Updated (b)(4)

Dear Ms. Beckmann,

Thank you for your email.

Ms. Dhanya Williams is the Lead Reviewer for K173841, and I have forwarded the email to her, as well as copied her on this reply. Ms. Williams can assist with questions specific to K173841 and review of the submission.

Regards,

Leigh Anderson
Biomedical Engineer
Neurointerventional Devices Branch (NIDB)
Division of Neurological and Physical Medicine Devices (DNPMD)
Center for Devices and Radiological Health (CDRH)
Office of Device Evaluation (ODE)
U.S. Food and Drug Administration

Tel: 301-796-5613

leigh.anderson@fda.hhs.gov

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From: Beckmann, Angelica [<mailto:angelica.beckmann@stryker.com>]

Sent: Tuesday, March 06, 2018 6:04 PM

To: Anderson, Leigh <Leigh.Anderson@fda.hhs.gov>

Cc: Allison, John <John.Allison@stryker.com>; Mateus, Jennifer <Jennifer.Mateus@stryker.com>; Zheng, Xiaolin <Xiaolin.Zheng@fda.hhs.gov>

Subject: K173841-A1 - Updated (b)(4)

Importance: High

Dear Ms. Anderson,
I hope this e-mail finds you well.

(b)(4)

(b)(4)

I would also like to understand the next steps for the interactive review of K173481.

Kind regards,

Angelica Beckmann
Director Regulatory Affairs
Stryker Neurovascular
47900 Bayside Pkwy
Fremont, CA 94538
510-413-2900 Office
(b)(6) Mobile
angelica.beckmann@stryker.com

Thank you Ms. Williams,
I will check the Stryker team availability and let you know.

Best regards
Angelica

-----Original Appointment-----

From: Williams, Dhanya K [mailto:Dhanya.Kumar@fda.hhs.gov]

Sent: Wednesday, March 7, 2018 7:44 AM

To: Zheng, Xiaolin; Beckmann, Angelica; Allison, John; Mateus, Jennifer; K173841@docs.fda.gov

Subject: K173841 - Updates to labeling

When: Wednesday, March 7, 2018 12:30 PM-1:00 PM (UTC-05:00) Eastern Time (US & Canada).

Where: Webex

Hello all,

I am setting up this brief call with your team and NIDB branch chief Dr. Xiaolin Zheng to discuss your AXS Catalyst (K173841) submission in regards to the

(b)(4)

Right now I have set this call up for 12:30pm EST, however please let me know if you would like me to reschedule for 1:30pm EST instead.

Thank you,
Dhanya Williams
Tel: 301-796-6498

WEBEX Info:

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(b)(4)

IMPORTANT NOTICE: Please note that this WebEx service allows audio and other information sent during the session to be recorded, which may be discoverable in a legal matter. By joining this session, you automatically consent to such recordings. If you do not consent to being recorded, discuss your concerns with the host or do not join the session.

Hello Ms. Beckmann,

We are nearing the completion of our review, however after (b)(4) (b)(4), "Response to FDA Interactive Request #1 Rev 2 (002)" that you provided interactively on 3/8/18, we have identified two items that need to be addressed:

(b)(4)

Please feel free to email me or call me at 301-796-6498 if you need any clarification.

If anything else is identified as being deficient or in need of address as we finalize our review I will contact you as soon as possible, however at this time I do not anticipate any further changes to the (b)(4) (in particular) if you are able to address the two items above.

Thank you,

Dhanya Williams, M.S.

Biologist/Scientific Reviewer

Center for Devices and Radiological Health (CDRH)

Office of Device Evaluation (ODE)

U.S. Food and Drug Administration

Tel: 301-796-6498

dhanya.williams@fda.hhs.gov

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Ms. Beckmann,

Yes, you can call me at 301-796-6498. I am also available right now if that would help, otherwise 12:30pm EST would be fine.

Thank you,

Dhanya Williams, M.S.
Biologist/Scientific Reviewer
Center for Devices and Radiological Health (CDRH)
Office of Device Evaluation (ODE)
U.S. Food and Drug Administration
Tel: 301-796-6498
dhanya.williams@fda.hhs.gov

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From: Beckmann, Angelica [mailto:angelica.beckmann@stryker.com]
Sent: Wednesday, March 07, 2018 9:12 AM
To: Williams, Dhanya K <Dhanya.Kumar@fda.hhs.gov>
Cc: Allison, John <John.Allison@stryker.com>; Mateus, Jennifer <Jennifer.Mateus@stryker.com>; K173841@docs.fda.gov
Subject: RE: K173841 - Interactive request #1 - Updated (b)(4)

Ms. Williams,
Thank you for your e-mail.
I will be available for a phone call at 12:30 pm (EST).
Should I call your desk phone number?

Regards

Angelica

From: Williams, Dhanya K [mailto:Dhanya.Kumar@fda.hhs.gov]
Sent: Wednesday, March 7, 2018 6:02 AM
To: Beckmann, Angelica <angelica.beckmann@stryker.com>
Cc: Allison, John <John.Allison@stryker.com>; Mateus, Jennifer <Jennifer.Mateus@stryker.com>; K173841@docs.fda.gov; Williams, Dhanya K <Dhanya.Kumar@fda.hhs.gov>
Subject: K173841 - Interactive request #1 - Updated (b)(4)

Hello Ms. Beckmann,

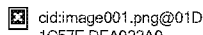
Thank you for your email. As Ms. Anderson noted, I am the lead reviewer for your submission, K173841, and we are still in the process of reviewing your deficiency responses. I will be in touch with you in the next day or two regarding any additional items that need to be addressed as we continue our review, however in the meantime, please address the following:

(b)(4)

(b)(4)

Thank you,

Dhanya Williams, M.S.
Biologist/Scientific Reviewer
Center for Devices and Radiological Health (CDRH)
Office of Device Evaluation (ODE)
U.S. Food and Drug Administration
Tel: 301-796-6498
dhanya.williams@fda.hhs.gov



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Subject: RE: K173841-A1 - Updated (b)(4)

Dear Ms. Beckmann,

Thank you for your email.

Ms. Dhanya Williams is the Lead Reviewer for K173841, and I have forwarded the email to her, as well as copied her on this reply. Ms. Williams can assist with questions specific to K173841 and review of the submission.

Regards,

Leigh Anderson
Biomedical Engineer
Neurointerventional Devices Branch (NIDB)
Division of Neurological and Physical Medicine Devices (DNPMD)
Center for Devices and Radiological Health (CDRH)
Office of Device Evaluation (ODE)
U.S. Food and Drug Administration
Tel: 301-796-5613
leigh.anderson@fda.hhs.gov

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Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

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Sent: Tuesday, March 06, 2018 6:04 PM
To: Anderson, Leigh <Leigh.Anderson@fda.hhs.gov>
Cc: Allison, John <john.Allison@stryker.com>; Mateus, Jennifer <jennifer.Mateus@stryker.com>; Zheng, Xiaolin <Xiaolin.Zheng@fda.hhs.gov>
Subject: K173841-A1 - Updated [(b)(4)]
Importance: High

Dear Ms. Anderson,
I hope this e-mail finds you well.

(b)(4)

I would also like to understand the next steps for the interactive review of K173481.

Kind regards,

Angelica Beckmann
Director Regulatory Affairs
Stryker Neurovascular
47900 Bayside Pkwy
Fremont, CA 94538
510-413-2900 Office

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

(b)(6) Mobile
angelica.beckmann@stryker.com

Hello Ms. Beckmann,

(b)(4)

Thanks,

Dhanya Williams, M.S.
Biologist/Scientific Reviewer
Center for Devices and Radiological Health (CDRH)
Office of Device Evaluation (ODE)
U.S. Food and Drug Administration
Tel: 301-796-6498
dhanya.williams@fda.hhs.gov

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From: Beckmann, Angelica [mailto:angelica.beckmann@stryker.com]
Sent: Wednesday, March 07, 2018 11:41 PM
To: Williams, Dhanya K <Dhanya.Kumar@fda.hhs.gov>
Cc: Allison, John <John.Allison@stryker.com>; Mateus, Jennifer <Jennifer.Mateus@stryker.com>; K173841@docs.fda.gov; Ellis, Kristin (Contractor) <kristin.ellis@stryker.com>
Subject: RE: K173841 - Interactive request #1 - Updated (b)(4)

Dear Ms. Williams,

(b)(4)

Best regards,

Angelica Beckmann
Director Regulatory Affairs
Stryker Neurovascular
47900 Bayside Pkwy
Fremont, CA 94538
510-412-2900 Office
(b)(6) Mobile
angelica.beckmann@stryker.com

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Subject: K173841 - Interactive request #1 - Updated (b)(4)

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(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

(b)(4)

Thank you,

Dhanya Williams, M.S.
Biologist/Scientific Reviewer
Center for Devices and Radiological Health (CDRH)
Office of Device Evaluation (ODE)
U.S. Food and Drug Administration
Tel: 301-796-6498
dhanya.williams@fda.hhs.gov

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Cc: Allison, John <John.Allison@stryker.com>; Mateus, Jennifer <Jennifer.Mateus@stryker.com>; Zheng, Xiaolin <Xiaolin.Zheng@fda.hhs.gov>; Williams, Dhanya K <Dhanya.Kumar@fda.hhs.gov>
Subject: RE: K173841-A1 - Updated (b)(4)

Dear Ms. Beckmann,

Thank you for your email.

Ms. Dhanya Williams is the Lead Reviewer for K173841, and I have forwarded the email to her, as well as copied her on this reply. Ms. Williams can assist with questions specific to K173841 and review of the submission.

Regards,

Leigh Anderson
Biomedical Engineer
Neurointerventional Devices Branch (NIDB)
Division of Neurological and Physical Medicine Devices (DNPMD)
Center for Devices and Radiological Health (CDRH)
Office of Device Evaluation (ODE)
U.S. Food and Drug Administration
Tel: 301-796-5613
leigh.anderson@fda.hhs.gov

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Cc: Allison, John <John.Allison@stryker.com>; Mateus, Jennifer <Jennifer.Mateus@stryker.com>; Zheng, Xiaolin <Xiaolin.Zheng@fda.hhs.gov>
Subject: K173841-A1 - (b)(4)
Importance: High

Dear Ms. Anderson,
I hope this e-mail finds you well.

(b)(4)

I would also like to understand the next steps for the interactive review of K173481.

Kind regards,

Angelica Beckmann
Director Regulatory Affairs
Stryker Neurovascular
47900 Bayside Pkwy
Fremont, CA 94538
510-413-2900 Office
[REDACTED] Mobile
angelica.beckmann@stryker.com

Dear Ms. Williams,

Enclosed are the responses to FDA's Interactive Request #1 regarding the 510(k) Submission K173841. The requested information is contained within the attached pdf file.

Please feel free to call me or send email with any additional requests.

Best regards,

Angelica Beckmann

Director Regulatory Affairs

Stryker Neurovascular

47900 Bayside Pkwy

Fremont, CA 94538

(b)(6) Mobile

angelica.beckmann@stryker.com<mailto:angelica.beckmann@stryker.com>

From: Williams, Dhanya K [mailto:Dhanya.Kumar@fda.hhs.gov]

Sent: Wednesday, March 7, 2018 6:02 AM

To: Beckmann, Angelica <angelica.beckmann@stryker.com>

Cc: Allison, John <John.Allison@stryker.com>; Mateus, Jennifer <Jennifer.Mateus@stryker.com>; K173841@docs.fda.gov; Williams, Dhanya K <Dhanya.Kumar@fda.hhs.gov>

Subject: K173841 - Interactive request #1 - Updated (b)(4)

Hello Ms. Beckmann,

Thank you for your email. As Ms. Anderson noted, I am the lead reviewer for your submission, K173841, and we are still in the process of reviewing your deficiency responses. I will be in touch with you in the next day or two regarding any additional items that need to be addressed as we continue our review, however in the meantime, please address the following:

(b)(4)

(b)(4)

Thank you,

Dhanya Williams, M.S.

Biologist/Scientific Reviewer

Center for Devices and Radiological Health (CDRH)

Office of Device Evaluation (ODE)

U.S. Food and Drug Administration

Tel: 301-796-6498

dhanya.williams@fda.hhs.gov<<mailto:dhanya.williams@fda.hhs.gov>>

[cid:image001.png@01D1C57E.DFA022A0]<<http://www.fda.gov/>>

[cid:image002.jpg@01D1C57E.DFA022A0]<<https://www.facebook.com/FDA>>

[cid:image003.jpg@01D1C57E.DFA022A0] <https://twitter.com/US_FDA>

[cid:image004.jpg@01D1C57E.DFA022A0] <<http://www.youtube.com/user/USFoodandDrugAdmin>>

[cid:image005.jpg@01D1C57E.DFA022A0] <<http://www.flickr.com/photos/fdaphotos/>>

[cid:image006.jpg@01D1C57E.DFA022A0]

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From: Anderson, Leigh

Sent: Wednesday, March 07, 2018 7:30 AM

To: 'Beckmann, Angelica'

<angelica.beckmann@stryker.commailto:angelica.beckmann@stryker.com>>

Cc: Allison, John <John.Allison@stryker.commailto:John.Allison@stryker.com>>; Mateus, Jennifer <Jennifer.Mateus@stryker.commailto:Jennifer.Mateus@stryker.com>>; Zheng, Xiaolin <Xiaolin.Zheng@fda.hhs.govmailto:Xiaolin.Zheng@fda.hhs.gov>>; Williams, Dhanya K <Dhanya.Kumar@fda.hhs.govmailto:Dhanya.Kumar@fda.hhs.gov>>

Subject: RE: K173841-A1 - Updated (b)(4)

Dear Ms. Beckmann,

Thank you for your email.

Ms. Dhanya Williams is the Lead Reviewer for K173841, and I have forwarded the email to her, as well as copied her on this reply. Ms. Williams can assist with questions specific to K173841 and review of the submission.

Regards,

Leigh Anderson

Biomedical Engineer

Neurointerventional Devices Branch (NIDB)

Division of Neurological and Physical Medicine Devices (DNPMD)

Center for Devices and Radiological Health (CDRH)

Office of Device Evaluation (ODE)

U.S. Food and Drug Administration

Tel: 301-796-5613

leigh.anderson@fda.hhs.govmailto:leigh.anderson@fda.hhs.gov>

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Subject: K173841-A1 - Updated (b)(4)

Importance: High

Dear Ms. Anderson,

I hope this e-mail finds you well.

(b)(4)

(b)(4)

I would also like to understand the next steps for the interactive review of K173481.

Kind regards,

Angelica Beckmann

Director Regulatory Affairs

Stryker Neurovascular

47900 Bayside Pkwy

Fremont, CA 94538

510-413-2900 Office

(b)(6)

Mobile

angelica.beckmann@stryker.com<mailto:angelica.beckmann@stryker.com>

Dear Ms. Williams,

(b)(4)

Best regards,

Angelica Beckmann
Director Regulatory Affairs
Stryker Neurovascular
47900 Bayside Pkwy
Fremont, CA 94538
510-413-2900 Office
(b)(6) Mobile
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Cc: Allison, John <John.Allison@stryker.com>; Mateus, Jennifer <Jennifer.Mateus@stryker.com>; K173841@docs.fda.gov; Williams, Dhanya K <Dhanya.Kumar@fda.hhs.gov>
Subject: K173841 - Interactive request #1 - Updated (b)(4)

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(b)(4)

Thank you,

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Biologist/Scientific Reviewer

Center for Devices and Radiological Health (CDRH)

Office of Device Evaluation (ODE)

U.S. Food and Drug Administration

Tel: 301-796-6498

dhanya.williams@fda.hhs.gov

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Cc: Allison, John <john.allison@stryker.com>; Mateus, Jennifer <jennifer.mateus@stryker.com>; Zheng, Xiaolin <Xiaolin.Zheng@fda.hhs.gov>; Williams, Dhanya K <Dhanya.Kumar@fda.hhs.gov>

Subject: RE: K173841-A1 - Updated[(b)(4)]

Dear Ms. Beckmann,

Thank you for your email.

Ms. Dhanya Williams is the Lead Reviewer for K173841, and I have forwarded the email to her, as well as copied her on this reply. Ms. Williams can assist with questions specific to K173841 and review of the submission.

Regards,

Leigh Anderson

Biomedical Engineer

Neurointerventional Devices Branch (NIDB)

Division of Neurological and Physical Medicine Devices (DNPMD)

Center for Devices and Radiological Health (CDRH)

Office of Device Evaluation (ODE)

U.S. Food and Drug Administration

Tel: 301-796-5613

leigh.anderson@fda.hhs.gov

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To: Anderson, Leigh <Leigh.Anderson@fda.hhs.gov>

Cc: Allison, John <john.allison@stryker.com>; Mateus, Jennifer <jennifer.mateus@stryker.com>; Zheng, Xiaolin <Xiaolin.Zheng@fda.hhs.gov>

Subject: K173841-A1 - Updated[(b)(4)]

Importance: High

Dear Ms. Anderson,

I hope this e-mail finds you well.

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOI STATUS@fda.hhs.gov or 301-796-8118.

(b)(4)

I would also like to understand the next steps for the interactive review of K173481.

Kind regards,

Angelica Beckmann
Director Regulatory Affairs
Stryker Neurovascular
47900 Bayside Pkwy
Fremont, CA 94538
510-412-2900 Office
(b)(6) Mobile
angelica.beckmann@stryker.com

Hello Ms. Beckmann,

Thank you very much. We will review and be back in touch if we need anything else or have any questions.

Regards,

Dhanya Williams, M.S.
Biologist/Scientific Reviewer
Center for Devices and Radiological Health (CDRH)
Office of Device Evaluation (ODE)
U.S. Food and Drug Administration
Tel: 301-796-6498
dhanya.williams@fda.hhs.gov

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From: Beckmann, Angelica [mailto:angelica.beckmann@stryker.com]

Sent: Tuesday, March 13, 2018 11:57 AM

To: Williams, Dhanya K <Dhanya.Kumar@fda.hhs.gov>

Cc: K173841@docs.fda.gov

Subject: RE: K173841 - Interactive request #2 (b)(4)

Importance: High

Dear Ms. Williams,

Thank you for your e-mail.

Enclosed are the responses to FDA's Interactive Request regarding additional information needed. The requested information is contained within the attached pdf file.

Please feel free to call me or send email with any additional requests.

Best regards,

Angelica Beckmann
Director Regulatory Affairs
Stryker Neurovascular
47900 Bayside Pkwy
Fremont, CA 94538
(b)(6) Mobile
angelica.beckmann@stryker.com

From: Williams, Dhanya K [mailto:Dhanya.Kumar@fda.hhs.gov]

Sent: Monday, March 12, 2018 11:24 AM

To: Beckmann, Angelica <angelica.beckmann@stryker.com>

Cc: K173841@docs.fda.gov; Williams, Dhanya K <Dhanya.Kumar@fda.hhs.gov>

Subject: K173841 - Interactive request #2 (b)(4)

Importance: High

Hello Ms. Beckmann,

We are nearing the completion of our review, however after reviewing your most recent version of labeling, "Response to FDA Interactive Request #1 Rev 2 (002)" that you provided interactively on 3/8/18, we have identified two items that need to be addressed:

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

(b)(4)

Please feel free to email me or call me at 301-796-6498 if you need any clarification.

(b)(4)

Thank you,

Dhanya Williams, M.S.
Biologist/Scientific Reviewer
Center for Devices and Radiological Health (CDRH)
Office of Device Evaluation (ODE)
U.S. Food and Drug Administration
Tel: 301-796-6498
dhanya.williams@fda.hhs.gov

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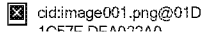
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Hello Ms. Beckmann,

Sorry I was unable to respond to your email on Friday but I was out of the office due to an unexpected family matter. By now you should have received notification of the clearance of K173841. We appreciate your quick responses to the additional information that was needed during the review period. Please let me know if you have any questions.

Thank you,

Dhanya Williams, M.S.
Biologist/Scientific Reviewer
Center for Devices and Radiological Health (CDRH)
Office of Device Evaluation (ODE)
U.S. Food and Drug Administration
Tel: 301-796-6498
dhanya.williams@fda.hhs.gov



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From: Beckmann, Angelica [mailto:angelica.beckmann@stryker.com]
Sent: Friday, March 16, 2018 5:37 PM
To: Williams, Dhanya K <Dhanya.Kumar@fda.hhs.gov>
Subject: K173841

Hi Dhanya,
Sorry for bothering you on a Friday afternoon.
But I would like to know if we should expect to hear from FDA about the clearance today.
I appreciate it if you can let me know.

Best regards

Angelica Beckmann
Director Regulatory Affairs
Stryker Neurovascular
47900 Bayside Pkwy
Fremont, CA 94538
[REDACTED] Mobile
angelica.beckmann@stryker.com

Please see **updated time** to 1:30pm upon sponsor's request.

Hello all,

I am setting up this brief call with your team and NIDB branch chief Dr. Xiaolin Zheng to discuss your AXS Catalyst (K173841) submission in regards to the
(b)(4)

(b)(4)

Right now I have set this call up for 12:30pm EST, however please let me know if you would like me to reschedule for 1:30pm EST instead.

Thank you,
Dhanya Williams
Tel: 301-796-6498

WEBEX Info:

-- Do not delete or change any of the following text --

(b)(4)



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ADMINISTRATION

Build Correspondence

Convert to PDF

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,

**LETTER SHOULD BE DATED BEFORE SIGNING,
AND MUST BE SIGNED OUT OF CTS ON THE
DATE INDICATED ON THE LETTER.**

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

Enclosure

February 8, 2018</br></br>

Substantive Review Notification - Proceed Interactively

<p>FDA has completed a substantive review of your submission K173841 and has determined that we will work with you to resolve outstanding deficiencies through an Interactive Review process. Any outstanding deficiencies will be provided to you during the Interactive Review process.</p>

<p>*** This is a system-generated email notification ***</p>

Dear Ms. Williams,

Thank you for your e-mail.

Enclosed are the responses to FDA's Interactive Request regarding additional information needed. The requested information is contained within the attached pdf file.

Please feel free to call me or send email with any additional requests.

Best regards,

Angelica Beckmann
Director Regulatory Affairs
Stryker Neurovascular
47900 Bayside Pkwy
Fremont, CA 94538
(b)(6) Mobile
angelica.beckmann@stryker.com

From: Williams, Dhanya K [mailto:Dhanya.Kumar@fda.hhs.gov]
Sent: Monday, March 12, 2018 11:24 AM
To: Beckmann, Angelica <angelica.beckmann@stryker.com>
Cc: K173841@docs.fda.gov; Williams, Dhanya K <Dhanya.Kumar@fda.hhs.gov>
Subject: K173841 - Interactive request #2 - (b)(4)
Importance: High

Hello Ms. Beckmann,

We are nearing the completion of our review, however after (b)(4) "Response to FDA Interactive Request #1 Rev 2 (002)" that you provided interactively on 3/8/18, we have identified two items that need to be addressed:

(b)(4)

Please feel free to email me or call me at 301-796-6498 if you need any clarification.

(b)(4)

Thank you,

Dhanya Williams, M.S.
Biologist/Scientific Reviewer
Center for Devices and Radiological Health (CDRH)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Office of Device Evaluation (ODE)
U.S. Food and Drug Administration
Tel. 301-796-6498
dhanya.williams@fda.hhs.gov

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Stryker Neurovascular

Submission Date:

Response to Interactive Request #2 for K173841-S001, Traditional 510(k)

March 12, 2018

AXS Catalyst Distal Access Catheter

Appendix 3

510(k) Summary redlined version

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January 2, 2018</br></br>

Acceptance Review Notification - Accepted

<p>An administrative acceptance review was conducted on your premarket notification (510(k)) K173841, and it was found to contain all of the necessary elements and information needed to proceed with the substantive review. We will contact you should we require any additional information during the course of the substantive review. The lead reviewer assigned to your submission is Dhanya Williams.</p>

<p>*** This is a system-generated email notification ***</p>

Dear Ms. Williams,

(b)(4)

Please feel free to call me or send email with any additional requests.

Best regards,

Angelica Beckmann

Director Regulatory Affairs

Stryker Neurovascular

47900 Bayside Pkwy

Fremont, CA 94538

(b)(6)

Mobile

angelica.beckmann@stryker.com<mailto:angelica.beckmann@stryker.com>

Dear Ms. Williams,

(b)(4)

Please feel free to call me or send email with any additional requests.

Best regards,

Angelica Beckmann
Director Regulatory Affairs
Stryker Neurovascular
47900 Bayside Pkwy
Fremont, CA 94538
(b)(6) Mobile
angelica.beckmann@stryker.com



Premarket Notification Traditional 510(k)

AXS Catalyst™ Distal Access Catheter

December 14, 2017

Stryker Neurovascular
47900 Bayside Parkway
Fremont, CA 94538

Contact: Angelica Beckmann
510-413-2900

Section 001 Table of Contents

Volume Number	Section Number	Description	Page Number
001	001	Table of Contents	Section 001 Page 2
001	002	Traditional 510(k) RTA Checklist	Section 002 Page 2
001	003	Medical Device User Fee Cover Sheet Form 3601	Section 003 Page 2
001	004	CDRH Premarket Review Submission Cover Sheet FDA Form 3514	Section 004 Page 2
		Section 004 Attachment 4A, Standards Utilization	Attachment 4A Page 2
		Section 004 Attachment 4B, Standards Data Reports	Attachment 4B Page 2
001	005	510(k) Company Cover Letter	Section 005 Page 2
001	006	Indications for Use Statement	Section 006 Page 2
001	007	510(k) Summary	Section 007 Page 2
		Section 007, Attachment 7A, 510(k) Summary Redline	Attachment 7A Page 2
001	008	Truthful and Accuracy Statement	Section 008 Page 2
001	009	Class III Summary and Certification	Section 009 Page 2
001	010	Financial Certification or Disclosure Statement	Section 010 Page 2
001	011	Executive Summary	Section 011 Page 2
		Section 011, Attachment 11A (b)(4)	Attachment 11A Page 2
		(b)(4)	
		Section 011, Attachment 11B (b)(4)	Attachment 11B Page 2
		(b)(4)	
		Section 011, Attachment 11C, Medela AG Letter of Authority	Attachment 11C Page 2
001	012	Device Description	Section 012 Page 2
		Section 012, Attachment 12A, Medela AG Right to Reference	Attachment 12A Page 2
001	013	Substantial Equivalence Discussion	Section 013 Page 2
001	014	Proposed Labeling	Section 014 Page 2

Volume Number	Section Number	Description	Page Number
		Section 014, Attachment 14A, (b)(4), Directions For Use Redline	Attachment 14A Page 2
		Section 014, Attachment 14B, (b)(4), Directions For Use Clean Copy	Attachment 14B Page 2
		Section 014, Attachment 14C, AXS Universal Aspiration Tubing 077.0193	Attachment 14C Page 2
		Section 014, Attachment 14D, AXS Universal Line Set 077.0194	Attachment 14D Page 2
		Section 014, Attachment 14E, AXS Universal Line Set with Desiccant	Attachment 14E Page 2
001	015	Sterilization and Shelf Life	Section 015 Page 2
		Section 015, Attachment 15A, (b)(4) Packaging Technical Report, Sterile Barrier Microbial Barrier	Attachment 15A Page 2
		Section 015, Attachment 15B, (b)(4) AXS Catalyst Catheter Packaging Design Verification and Aging Report	Attachment 15B Page 2
001	016	Biocompatibility	Section 016 Page 2
001	017	Software	Section 017 Page 2
001	018	Electromagnetic Compatibility and Electrical Safety	Section 018 Page 2
002	019	Performance Testing - Bench	Section 019 Page 2
		Section 019 Attachment 19A, (b)(4) Protocol, Design Validation Study for the AXS Catalyst Distal Access Catheters in a Flow Model with Clot Aspiration	Attachment 19A Page 2
		Section 019 Attachment 19B, (b)(4) DVal Report, Design Validation Study for the AXS Catalyst Distal Access Catheters in a Flow Model with Clot Aspiration	Attachment 19B Page 2
		Section 019 Attachment 19C, (b)(4) Product Characterization Technical Report, AXS Catalyst Catheter	Attachment 19C Page 2
		Section 019, Attachment 19D, (b)(4) Neurovascular Challenge Path Justification	Attachment 19D Page 2
		Section 019, Attachment 19E, (b)(4) Redline	Attachment 19E Page 2

Volume Number	Section Number	Description	Page Number
002	020	Performance Testing - Animal	Section 020 Page 2
		Section 020 Attachment 20A, (b)(4) (b)(4) Report – GLP Efficacy and Safety Evaluation of the Stryker AXS Aspiration Solution for Neurothrombectomy in a Chronic Swine Model	Attachment 20A Page 2
002	021	Clinical Information	Section 021 Page 2
		Section 021 Attachment 21A, (b)(4) AXS Catalyst Catheter US Clinical Experience Summary (CES)	Attachment 21A Page 2

Section 002 Traditional 510(k) Refuse to Accept Checklist

The Traditional 510(k) Refuse to Accept Checklist is provided on the following pages for reviewer convenience with location notations.

Section 002 Traditional 510(k) RTA Checklist

Acceptance Checklist For Traditional 510(k)s

510(k) #: _____ Date Received by DCC: _____

Lead Reviewer: _____

Branch: NIDB

Division: DNPMD

Center/Office: ODE

Preliminary Questions	Yes	No	N/A	
1. Is the product a device (per section 201(h) of the FD&C Act) or a combination product (per 21 CFR 3.2(e)) with a device constituent part subject to review in a 510(k)?	X			
2. Is the submission with the appropriate Center?	X			
3. If a Request for Designation (RFD) was submitted for the device or combination product with a device constituent part and assigned to your center, identify the RFD# and confirm the following: a) Is the device or combination product the same (e.g., design, formulation) as that presented in the RFD submission? b) Are the indications for use for the device or combination product identified in the 510(k) the same as those identified in the RFD submission?			X	
4. Is this device type eligible for a 510(k) submission?	X			
5. Is there a pending PMA for the same device with the same indications for use?		X		
6. If clinical studies have been submitted, is the submitter the subject of an Application Integrity Policy (AIP)?			X	
Organizational Elements	Yes	No	N/A	Page #
1. Submission contains a Table of Contents.	X			Section 001, page 2
2. Each section is labeled (e.g., headings or tabs designating Device Description section, Labeling section, etc.).	X			through out
3. All pages of the submission are numbered.	X			through out
4. Type of 510(k) is identified (i.e., Traditional, Abbreviated, or Special)	X			Section 004, page 2

Elements of a Complete Submission (RTA Items) (21 CFR 807.87 unless otherwise indicated)						
			Yes	No	N/A	Page #
A. Administrative						
1.	All content used to support the submission is written in English (including translations of test reports, literature articles, etc.).		X			Through out
2.	Submission identifies the following (FDA recommends use of the CDRH Premarket Review Submission Cover Sheet [Form 3514]):		Cover sheet included Section 004			
	a.	Device trade/proprietary name	X			Section 007, page 2
	b.	Device class and panel or Classification regulation or Statement that device has not been classified with rationale for that conclusion	X			Section 007, page 2
3.	Submission contains an Indications for Use Statement with Rx and/or OTC designated (see also 21 CFR 801.109).		X			Section 006, page 2
4.	Submission contains a 510(k) Summary (21CFR 807.92) or 510(k) Statement (21 CFR 807.93).		X			Section 007, page 2
5.	Submission contains a Truthful and Accuracy Statement per 21 CFR 807.87(k).		X			Section 008, page 2
6.	Submission is a Class III 510(k) Device.		X			Section 009, page 2
	a.	Contains Class III Summary and Certification			X	
7.	Submission contains clinical data.					
	a.	Submission includes completed Financial Certification (FDA Form 3454) or Disclosure (FDA Form 3455) information for each covered clinical study included in the submission.			X	Only publicly available articles included
	b.	Submission includes completed Certification of Compliance with requirement of ClinicalTrials.gov Data Bank (FDA Form 3674) (42 U.S.C. 282(j)(5)(B)) for each applicable device clinical trial included in the submission.			X	Only publicly available articles included
8.	The submission identifies prior submissions for the same device included in the current submission (e.g., submission numbers for a prior not substantially equivalent [NSE] determination, prior deleted or withdrawn 510(k), Pre-Submission, IDE, PMA, etc.). OR States that there were no prior submissions for the subject device.		X			Section 011, page 2

		a.	If there were prior submissions, the submitter has identified where in the current submission any issues related to a determination of substantial equivalence from prior submissions for this device are addressed.	X			Section 011, page 2
B. Device Description				Yes	No	N/A	Page #
	9.		The device has a device-specific guidance document, special controls document, and/or requirements in a device-specific regulation regarding device description that is applicable to the subject device.				
		a.	The submission addresses device description recommendations outlined in the device-specific guidance. OR The submission provides an alternative approach intended to address the applicable statutory and/or regulatory criteria.			X	N/A
		b.	The submission includes device description information that addresses relevant mitigation measures set forth in a special controls document or device-specific regulation applicable to the device. OR The submission uses alternative mitigation measures and provides rationale why the alternative measures provide an equivalent assurance of safety and effectiveness.	X			Section 012
	10.		Descriptive information is present and consistent within the submission (e.g. the device description section is consistent with the device description in labeling).	X			Section 012
	11.		The submission includes descriptive information for the device, including the following:				
		a.	A description of the principle of operation or mechanism of action for achieving the intended effect.	X			Section 012, page 15
		b.	A description of proposed conditions of use, such as surgical techniques of implants; anatomical location of use; user interface; how the device interacts with other devices; and/or how the device interacts with the patient.	X			Section 012, pages 16-17
		c.	A list and description of each device for which clearance is requested.	X			Section 012, page 4
		d.	Submission contains representative engineering drawing(s), schematics, illustrations, photos and/or figures of the device. OR Submission includes a statement that engineering drawings, schematics, etc. are not applicable to the device (e.g., device is a reagent and figures are not pertinent to describe the device).	X			Section 012

	12.	Device is intended to be marketed with multiple components, accessories, and/or as part of a system.	X			Section 012
	a.	Submission includes a list of all components and accessories to be marketed with the subject device.	X			Section 012, pages 7 and 11
	b.	Submission includes a description (as detailed in item 11a., 11b., and 11d. above) of each component or accessory.	X			Section 012
	c.	A 510(k) number is provided for each component or accessory that received a prior 510(k) clearance. AND A statement is provided that identifies components or accessories that have not received prior 510(k) clearance.	X			Section 012, pages 7 and 11
C. Substantial Equivalence Discussion			Yes	No	N/A	Page #
	13.	Submitter has identified a predicate device(s), including the following information:	X			Section 013, page 2
	a.	Predicate device identifier provided (e.g., 510(k) number, de novo number, reclassified PMA number, regulation number if exempt or statement that the predicate is a pre-amendment device).	X			Section 013, page 2
	b.	The identified predicate(s) is consistent throughout the submission (e.g., the predicates identified in the Substantial Equivalence section is the same as that listed in the 510(k) Summary (if applicable) and that used in comparative performance testing.	X			throughout
	14.	Submission includes a comparison of the following for the predicate(s) and subject device and a discussion why any difference between the subject and predicate(s) do not impact safety and effectiveness (see section 513(i)(1)(A) of the FD&C Act and 21 CFR 807.87(f)).				
	a.	Indications for Use	X			Section 013, page 9
	b.	Technology, including features, materials, and principles of operation	X			Section 013, pages 10-18
D. Proposed Labeling (see also 21 CFR parts 801 and 809 as applicable)			Yes	No	N/A	Page #
	15.	Submission includes proposed package labels and labeling (e.g., instructions for use, package insert, operator's manual).	X			Section 014
	a.	Indications for use are stated in labeling and are identical to Indications for Use form and 510(k) Summary (if 510(k) Summary provided)	X			Section 014, Attachment 14B
	b.	Labeling includes: - Statements of conditions, purposes of uses for which the device is intended (e.g., hazards,	X			Section 014, Attachment 14B

		warnings, precautions, contraindications) (21 CFR 801.5) AND - Includes adequate directions for use (see 21 CFR 801.5) OR - Submission states that device qualifies for exemption per 21 CFR 801 Subpart D				
	16.	Labeling includes name and place of business of the manufacturer, packer, or distributor (21 CFR 801.1)	X			Section 014
	17.	Labeling includes the prescription statement (see 21 CFR 801.109(b)(1)) or RX Only symbol (see also Section 502(a) of the FD&C Act and FDA's guidance "Alternative to Certain Prescription Device Labeling Requirements").	X			Section 014, Attachment 14B
	18.	The device has a device-specific guidance document, special controls document, and/or requirements in a device-specific regulation regarding labeling that is applicable to the subject device.			X	N/A
	a.	The submission addresses labeling recommendations outlined in the device-specific guidance. OR The submission provides an alternative approach intended to address the applicable statutory and/or regulatory criteria.			X	N/A
	b.	The submission includes labeling information that addresses relevant mitigation measures set forth in a special controls document or device-specific regulation applicable to the device. OR The submission uses alternative mitigation measures and provides rationale why the alternative measures provide an equivalent assurance of safety and effectiveness.			X	N/A
	19.	If the device is an in vitro diagnostic device, provided labeling includes all applicable information required per 21 CFR 809.10.			X	N/A
E.	Sterilization		Yes	No	N/A	Page #
	Submission states that the device, and/or accessories, and/or components are: ☒ Provided sterile, intended to be single-use ☐ Requires processing during its use-life ☐ Non-sterile when used (and no processing required) ☐ Information regarding the sterility status of the device is not provided (if this box is checked, please also check one of the two boxes below) ☐ Sterility status not needed for this device (e.g., software-only device)		X			Section 015, page 2

	☐ Sterility status needed or need unclear					
20.	Assessment of the need for cleaning and subsequent disinfection or sterilization information.					
	a.	Identification of device, and/or accessories, and/or components that are provided sterile.	X			Section 015, page 2
	b.	Identification of device, and/or accessories, and/or components that are end user sterilized or disinfected.	X			Section 015, page 6
	c.	Identification of device, and/or accessories, and/or components that are reusable.	X			Section 015, page 6
21.	If the device, and/or accessory, and/or a component is provided sterile:					
	a.	Sterilization method is stated for each component (including dose for radiation sterilization)	X			Section 015, page 2
	b.	A description of method to validate the sterilization parameters is provided for each proposed sterilization method (e.g., half-cycle method and full citation of FDA-recognized standard, including date).	X			Section 015, page 2
	c.	For devices sterilized using chemical sterilants such as ethylene oxide (EO) and hydrogen peroxide, submission states maximum levels of sterilant residuals remaining on the device and sterilant residual limits.	X			Section 015, page 3
	d.	Sterility Assurance Level (SAL) stated	X			Section 015, page 2
	e.	Submission includes description of packaging	X			Section 012, page 33
	f.	For products labeled "non-pyrogenic", a description of the method used to make the determination stated (e.g. limulus amebocyte lysate (LAL).	X			Section 015, page 9
22.	If the device, and/or accessory, and/or a component is reusable or end user sterilized or disinfected:		X			Section 015, page 6
	a.	Cleaning method is provided in labeling for each device, and/or accessory, and/or component.	X			Section 015, page 6
	b.	Disinfection method is provided in labeling for each device, and/or accessory, and/or component.	X		X	N/A
	c.	Sterilization method is provided in labeling for each device and/or accessory, and/or component.			X	N/A
	d.	Device types in this submission are listed in Appendix E of the FDA's guidance "Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling."			X	N/A
	i.	If device types in this submission are included in Appendix E of the reprocessing guidance, the submission includes protocols and test reports for validating the reprocessing instructions.			X	N/A
23.	The device has a device-specific guidance document, special controls document, and/or requirement in a device-				X	N/A

		specific regulation regarding sterility and/or reprocessing that is applicable to the subject device.				
	a.	The submission addresses sterility and/or reprocessing recommendations outlined in the device-specific guidance. OR The submission provides an alternative approach intended to address the applicable statutory and/or regulatory criteria.			X	N/A
	b.	The submission includes sterility and/or reprocessing information that addresses relevant mitigation measures set forth in a special controls document or device-specific regulation applicable to the device. OR The submission uses alternative mitigation measures and provides rationale why the alternative measures provide an equivalent assurance of safety and effectiveness.	X			Section 015
F.	Shelf-Life		Yes	No	N/A	Page #
	24.	Proposed shelf-life/expiration date stated. OR Statement that shelf-life is not applicable because of low likelihood of time-dependent product degradation.	X			Section 015, page 6
	25.	For a sterile device, submission includes summary of methods used to establish that device packaging will maintain a sterile barrier for the entirety of the proposed shelf-life.	X			Section 015, page 7-8
	26.	Submission includes summary of methods used to establish that device performance is maintained for the entirety of the proposed shelf-life (e.g., mechanical properties, coating integrity, pH, osmolality, etc.). OR Statement why performance data is not needed to establish maintenance of device performance characteristics over the shelf-life period.	X			Section 015, page 7-8
G.	Biocompatibility		Yes	No	N/A	Page #
	Submission states that there: ☒ Are direct or indirect patient-contacting components ☐ Are no direct or indirect patient-contacting components ☐ Information regarding patient contact status of the device is not provided (if this box checked, please also check one of the two boxes below) ☐ Patient contact information not needed for this device (e.g., software-only device) ☐ Patient contact information is needed or need unclear		X			Section 012, page 18-25
	27.	Submission includes a list identifying each patient-contacting device component (e.g. implant, delivery	X			Section 012, page 18-25

		catheter) and associated materials of construction for each component, including identification of color additives, if present.				
	28.	Submission identifies contact classification (e.g. surface-contacting, less than 24 hour duration) for each patient-contacting device component (e.g., implant, delivery catheter).	X			Section 016, page 2
	29.	Biocompatibility assessment of patient-contacting components. Submission includes: Test protocol (including identification and description of test article), methods, pass/fail criteria, and results provided for each completed test. OR A statement that biocompatibility testing is not needed with a rationale (e.g., materials and manufacturing/processing are identical to the predicate).	X			Section 016, page 2
H.	Software		Yes	No	N/A	Page #
		Submission states that the device: ☐ Does contain software/firmware ☒ Does not contain software/firmware ☐ Information on whether device contains software/firmware is not provided (if this box checked, please also check one of the two boxes below) ☐ Software/firmware information not needed for this device (e.g., surgical suture, condom) ☐ Software/firmware information is needed or need unclear	X			Section 017, page 2
	30.	Submission includes a statement of software level of concern and rationale for the software level of concern			X	N/A
	31.	All applicable software documentation provided based on level of concern identified by the submitter, as described in Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices, or the submission includes information to establish that the submitter has otherwise met the applicable statutory or regulatory criteria through an alternative approach (i.e., the submitter has identified an alternate approach with a rationale).			X	N/A
I.	Electrical Safety and EMC		Yes	No	N/A	Page #
		Electrical Safety: Submission states that the device: ☐ Does require electrical safety evaluation ☐ Does not require electrical safety evaluation ☐ Does not require electrical safety evaluation Information on whether device requires electrical safety evaluation not provided (if this box checked, please also check one of the two boxes below)	X			Section 018, page 2

	☐ Electrical safety information not needed for this device (e.g., surgical suture, condom) ☐ Electrical safety information needed or need unclear				
32.	Submission includes evaluation of electrical safety (e.g., per IEC 60601-1, or equivalent FDA-recognized standard, and if applicable, a device-specific standard). OR Submission includes electrical safety evaluation using methods or standards that are not FDA-recognized and submission includes information to establish that the submitter has otherwise met the applicable statutory or regulatory criteria through this alternative approach (i.e., the submitter has identified alternate methods or standards with a rationale).			X	N/A
	EMC: Submission states that the device: ☐ Does require EMC evaluation ☒ Does not require EMC evaluation. ☐ Information on whether device requires EMC evaluation not provided (if this box checked, please also check one of the two boxes below) ☐ EMC information not needed for this device (e.g., surgical suture, condom) ☐ EMC information needed or need unclear	X			Section 018, page 2
33.	Submission includes evaluation of electromagnetic compatibility (e.g., per IEC 60601-1-2 or equivalent FDA-recognized standard and if applicable, a device-specific standard). OR Submission includes electromagnetic compatibility evaluation using methods or standards that are not FDA-recognized and submission includes information to establish that the submitter has otherwise met the applicable statutory or regulatory criteria through this alternative approach (i.e., the submitter has identified alternate methods or standards with a rationale).			X	N/A
J. Performance Data General		Yes	No	N/A	Page #
34.	Full test report is provided for each completed test. A full test report includes: objective of the test, description of the test methods and procedures, study endpoint(s), pre-defined pass/fail criteria, results summary, conclusions.	X			Section 019, Attachments 19A, 19B, and 19C Section 020, Attachment 20A
a.	Submission includes an explanation of how the data generated from each test report supports a finding of				Section 019

			substantial equivalence (e.g., comparison to predicate device testing, dimensional analysis, etc.).				
	35.		The device has a device-specific guidance document, special controls document, and/or requirement in a device-specific regulation regarding performance data that is applicable to the subject device	X			
		a.	The submission addresses performance data recommendations outlined in the device-specific guidance OR The submission provides an alternative approach intended to address the applicable statutory and/or regulatory criteria.	X			Section 019, Section 020, Section 021
		b.	The submission includes performance data that addresses relevant mitigation measures set forth in a special controls document or device-specific regulation applicable to the device. OR The submission uses alternative mitigation measures and provides rationale why the alternative measures provide an equivalent assurance of safety and effectiveness.			X	N/A
	36.		If literature is referenced in the submission, submission includes:	X			Section 021, Attachment 21A
		a.	Legible reprints or a summary of each article.	X			Section 021, Attachment 21A
		b.	Discussion of how each article is applicable to support the substantial equivalence of the subject device to the predicate.	X			Section 021, Attachment 21A
	37.		For each completed animal study, the submission provides the following:				
		a.	Submission includes a study protocol which includes all elements as outlined in 21 CFR 58.120				Section 020, Attachment 20A
		b.	Submission includes final study report which includes all elements outlined in 21 CFR 58.185				Section 020, Attachment 20A
		c.	Submission contains a statement that the study was conducted in compliance with applicable requirements in the GLP regulation (21 CFR Part 58), or, if the study was not conducted in compliance with the GLP regulation, the submission explains why the noncompliance would not impact the validity of the study data provided to support a substantial equivalence determination.				Section 020, page 2

K.	Performance Characteristics – In Vitro Diagnostic Devices Only (see also 21 CFR 809.10(b)(12))	Yes	No	N/A	Page #
	Submission indicates that device: ☐ Is an in vitro diagnostic device ☒ Is not an in vitro diagnostic device			X	Section 012, page 3
	38. Submission includes the following studies, as appropriate for the device type, including associated protocol descriptions, study results and line data.			X	N/A not an IVD
	a. Precision/reproducibility			X	N/A not an IVD
	b. Accuracy (includes as appropriate linearity; calibrator or assay traceability; calibrator and/or assay stability protocol and acceptance criteria; assay cut-off; method comparison or comparison to clinical outcome: matrix comparison; and clinical reference range or cutoff.				N/A not an IVD
	c. Sensitivity (detection limits, LoB, LoD, LoQ where relevant for the device type).			X	N/A not an IVD
	d. Analytical specificity			X	N/A not an IVD
	39. The device has a device-specific guidance document, special controls document, and/or requirement in a device-specific regulations regarding performance data that is applicable to the subject device.			X	N/A not an IVD
	a. The submission addresses performance data recommendations outlined in the device-specific guidance. OR The submission provides an alternative approach intended to address the applicable statutory and/or regulatory criteria.			X	N/A not an IVD
	b. The submission includes performance data that addresses relevant mitigation measures set forth in a special controls document or device-specific regulation applicable to the device. OR The submission uses alternative mitigation measures and provides rationale why the alternative measures provide an equivalent assurance of safety and effectiveness.			X	N/A not an IVD

Section 003 Medical Device User Fee Cover Sheet Form 3601

The Medical Device User Fee Cover Sheet (Form FDA 3601) is provided on the following pages.

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION MEDICAL DEVICE USER FEE COVER SHEET		PAYMENT IDENTIFICATION NUMBER: (b)(4) Write the Payment Identification number on your check.	
A completed cover sheet must accompany each original application or supplement subject to fees. If payment is sent by U.S. mail or courier, please include a copy of this completed form with payment. Payment and mailing instructions can be found at: http://www.fda.gov/oc/mdufma/coversheet.html			
1. COMPANY NAME AND ADDRESS (include name, street address, city state, country, and post office code) STRYKER CORP NEUROVASCULAR DIVISION 47900 BAYSIDE PKWY FREMONT CA 94538 US		2. CONTACT NAME (b)(6) 31 OCT 2017 Simon Yuan 2.1 E-MAIL ADDRESS simon.yuan@stryker.com 2.2 TELEPHONE NUMBER (include Area code) 510-4132878 2.3 FACSIMILE (FAX) NUMBER (Include Area code)	
1.1 EMPLOYER IDENTIFICATION NUMBER (EIN) *****9739			
3. TYPE OF PREMARKET APPLICATION (Select one of the following in each column; if you are unsure, please refer to the application descriptions at the following web site: http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm345263.htm) <u>Select an application type:</u> ☒ Premarket notification(510(k)); except for third party ☐ 513(g) Request for Information ☐ Biologics License Application (BLA) ☐ Premarket Approval Application (PMA) ☐ Modular PMA ☐ Product Development Protocol (PDP) ☐ Premarket Report (PMR) ☐ 30-Day Notice ☐ De Novo Request 3.1 Select a center ☒ CDRH ☐ CBER 3.2 Select one of the types below ☒ Original Application <u>Supplement Types:</u> ☐ Efficacy (BLA) ☐ Panel Track (PMA, PMR, PDP) ☐ Real-Time (PMA, PMR, PDP) ☐ 180-day (PMA, PMR, PDP)			
4. ARE YOU A SMALL BUSINESS? (See the instructions for more information on determining this status) ☐ YES, I meet the small business criteria and have submitted the required qualifying documents to FDA ☒ NO, I am not a small business 4.1 If Yes, please enter your Small Business Decision Number:			
5. FDA WILL NOT ACCEPT YOUR SUBMISSION IF YOUR COMPANY HAS NOT PAID AN ESTABLISHMENT REGISTRATION FEE THAT IS DUE TO FDA. HAS YOUR COMPANY PAID ALL ESTABLISHMENT REGISTRATION FEES THAT ARE DUE TO FDA? ☒ YES (All of your establishments have registered and paid the fee, or this is your first device and you will register and pay the fee within 30 days after entering into an operation that requires you to register and submit device listing information.) ☐ NO (If you currently market a medical device and your establishment is required to register and submit device listing information, FDA will not accept your submission until you have paid all fees due to FDA. See http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/RegistrationandListing/ucm053165.htm for additional information)			
6. IS THIS PREMARKET APPLICATION COVERED BY ANY OF THE FOLLOWING USER FEE EXCEPTIONS? IF SO, CHECK THE APPLICABLE EXCEPTION. ☐ This application is the first PMA submitted by a qualified small business, including any affiliates ☐ This biologics application is submitted under section 351 of the Public Health Service Act for a product licensed for further manufacturing use only ☐ The sole purpose of the application is to support conditions of use for a pediatric population ☐ The application is submitted by a state or federal government entity for a device that is not to be distributed commercially			
7. IS THIS A SUPPLEMENT TO A PREMARKET APPLICATION FOR WHICH FEES WERE WAIVED DUE TO SOLE USE IN A PEDIATRIC POPULATION THAT NOW PROPOSES CONDITION OF USE FOR ANY ADULT POPULATION? (If so, the application is subject to the fee that applies for an original premarket approval application (PMA)). ☐ YES ☒ NO			
PAPERWORK REDUCTION ACT STATEMENT Public reporting burden for this collection of information is estimated to average 18 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to the address below. Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118			

Department of Health and Human Services, Food and Drug Administration, Office of Chief Information Officer, 8455 Colesville Road, COLE-14-14253 Silver Spring, MD 20993-0002
[Please do NOT return this form to the above address, except as it pertains to comments on the burden estimate.]

8. USER FEE PAYMENT AMOUNT SUBMITTED FOR THIS PREMARKET APPLICATION

(b)(4)

31-Oct-2017

Form FDA 3001 (08-00)

["Close Window"](#) [Print Cover sheet](#)

Section 004 CDRH Premarket Review Submission Cover Sheet FDA Form 3514

The completed CDRH Premarket Review Submission Cover Sheet (Form FDA 3514) is provided in the following pages.

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION CDRH PREMARKET REVIEW SUBMISSION COVER SHEET		Form Approval OMB No. 0910-0120 Expiration Date: June 30, 2020 See PRA Statement on page 5.	
Date of Submission 12/14/2017		User Fee Payment ID Number (b)(4)	
FDA Submission Document Number (if known)			
SECTION A TYPE OF SUBMISSION			
PMA ☐ Original Submission ☐ Premarket Report ☐ Modular Submission ☐ Amendment ☐ Report ☐ Report Amendment ☐ Licensing Agreement	PMA & HDE Supplement ☐ Regular (180 day) ☐ Special ☐ Panel Track (PMA Only) ☐ 30-day Supplement ☐ 30-day Notice ☐ 135-day Supplement ☐ Real-time Review ☐ Amendment to PMA & HDE Supplement ☐ Other	PDP ☐ Original PDP ☐ Notice of Completion ☐ Amendment to PDP	510(k) ☒ Original Submission: ☒ Traditional ☐ Special ☐ Abbreviated (Complete section I, Page 5) ☐ Additional Information: ☐ Third Party
IDE ☐ Original Submission ☐ Amendment ☐ Supplement		Humanitarian Device Exemption (HDE) ☐ Original Submission ☐ Amendment ☐ Supplement ☐ Report ☐ Report Amendment	Class II Exemption Petition ☐ Original Submission ☐ Additional Information
Evaluation of Automatic Class III Designation (De Novo) ☐ Original Submission ☐ Additional Information		Request for Feedback ☐ Pre-Submission ☐ Informational Meeting ☐ Submission Issue Meeting ☐ Day 100 Meeting ☐ Agreement Meeting ☐ Determination Meeting ☐ Study Risk Determination ☐ Other (specify):	
Other Submission ☐ 513(g) ☐ Other (describe submission):			
Have you used or cited Standards in your submission? ☒ Yes ☐ No (if Yes, please complete Section I, Page 5)			
SECTION B SUBMITTER, APPLICANT OR SPONSOR			
Company / Institution Name Stryker		Establishment Registration Number (if known) 3008853977	
Division Name (if applicable) Neurovascular		Phone Number (including area code) 510-413-2900	
Street Address 47900 Bayside Parkway		FAX Number (including area code) 510-413-2558	
City Fremont	State / Province CA	ZIP/Postal Code 94538	Country USA
Contact Name Angelica Beckmann			
Contact Title Director, Regulatory Affairs		Contact E-mail Address angelica.beckmann@stryker.com	
SECTION C APPLICATION CORRESPONDENT (e.g., consultant, if different from above)			
Company / Institution Name N/A			
Division Name (if applicable)		Phone Number (including area code)	
Street Address		FAX Number (including area code)	
City	State / Province	ZIP Code	Country
Contact Name			
Contact Title		Contact E-mail Address	

SECTION D1 REASON FOR APPLICATION - PMA, PDP, OR HDE		
☐ New Device ☐ Withdrawal ☐ Additional or Expanded Indications ☐ Request for Extension ☐ Post-approval Study Protocol ☐ Request for Applicant Hold ☐ Request for Removal of Applicant Hold ☐ Request to Remove or Add Manufacturing Site	☐ Change in design, component, or specification: ☐ Software / Hardware ☐ Color Additive ☐ Material ☐ Specifications ☐ Other (specify below)	☐ Location change: ☐ Manufacturer ☐ Sterilizer ☐ Packager ☐ Report Submission: ☐ Annual or Periodic ☐ Post-approval Study ☐ Adverse Reaction ☐ Device Defect ☐ Amendment
☐ Process change: ☐ Manufacturing ☐ Packaging ☐ Sterilization ☐ Other (specify below)	☐ Labeling change: ☐ Indications ☐ Instructions ☐ Performance Characteristics ☐ Shelf Life ☐ Trade Name ☐ Other (specify below)	☐ Change in Ownership ☐ Change in Correspondent ☐ Change of Applicant Address
☐ Response to FDA correspondence:		
☐ Other Reason (specify):		
SECTION D2 REASON FOR APPLICATION - IDE		
☐ New Device ☐ New Indication ☐ Addition of Institution ☐ Expansion / Extension of Study ☐ IRB Certification ☐ Termination of Study ☐ Withdrawal of Application ☐ Unanticipated Adverse Effect ☐ Notification of Emergency Use ☐ Compassionate Use Request ☐ Treatment IDE ☐ Continued Access	☐ Change in: ☐ Correspondent / Applicant ☐ Design / Device ☐ Informed Consent ☐ Manufacturer ☐ Manufacturing Process ☐ Protocol - Feasibility ☐ Protocol - Other ☐ Sponsor ☐ Report submission: ☐ Current Investigator ☐ Annual Progress Report ☐ Site Waiver Report ☐ Final	☐ Response to FDA Letter Concerning: ☐ Conditional Approval ☐ Deemed Approved ☐ Deficient Final Report ☐ Deficient Progress Report ☐ Deficient Investigator Report ☐ Disapproval ☐ Request Extension of Time to Respond to FDA ☐ Request Meeting ☐ Request Hearing
☐ Other Reason (specify):		
SECTION D3 REASON FOR SUBMISSION - 510(k)		
☐ New Device	☒ Additional or Expanded Indications	☐ Change in Technology
☐ Other Reason (specify):		

SECTION E ADDITIONAL INFORMATION ON 510(K) SUBMISSIONS							
Product codes of devices to which substantial equivalence is claimed						Summary of, or statement concerning, safety and effectiveness information	
1	DQY	2	NRV	3		4	
5		6		7		8	
						☒ 510 (k) summary attached ☐ 510 (k) statement	
Information on devices to which substantial equivalence is claimed (if known)							
	510(k) Number		Trade or Proprietary or Model Name		Manufacturer		
1	K090752	1	Reperfusion Catheter	1	Penumbra, Inc.		
2	K151667	2	AXS Catalyst Distal Access Catheter	2	Stryker Neurovascular		
3	K160449	3	Penumbra Reperfusion Catheter	3	Penumbra, Inc.		
4		4		4			
5		5		5			
6		6		6			
SECTION F PRODUCT INFORMATION - APPLICATION TO ALL APPLICATIONS							
Common or usual name or classification name							
Percutaneous Catheter							
	Trade or Proprietary or Model Name for This Device			Model Number			
1	AXS Catalyst Distal Access Catheter 058 x 115cm			1	M003IC0581150		
2	AXS Catalyst Distal Access Catheter 058 x 132cm			2	M003IC0581320		
3	AXS Catalyst Distal Access Catheter 060 x 132cm			3	M003IC0601320		
4				4			
5				5			
FDA document numbers of all prior related submissions (regardless of outcome)							
1	K151667	2	(b)(4)	3	(b)(4)	4	K170329
5		6		7		8	
9		10		11		12	
Data Included in Submission							
☐ Laboratory Testing ☐ Animal Trials ☐ Human Trials							
SECTION G PRODUCT CLASSIFICATION - APPLICATION TO ALL APPLICATIONS							
Product Code	C.F.R. Section (if applicable)			Device Class			
DQY, NRV	21 CFR 870.1250			☐ Class I ☒ Class II			
Classification Panel				☐ Class III ☐ Unclassified			
Neurology							
Indications (from labeling)							
(b)(4)							

Note: Submission of the information entered in Section H does not affect the need to submit device establishment registration.		FDA Document Number (if known)	
SECTION H MANUFACTURING / PACKAGING / STERILIZATION SITES RELATING TO A SUBMISSION			
☒ Original ☐ Add ☐ Delete	Facility Establishment Identifier (FEI) Number		☐ Manufacturer ☒ Contract Sterilizer ☐ Contract Manufacturer ☐ Repackager / Relabeler
Company / Institution Name (b)(4)		Establishment Registration Number (b)(4)	
Division Name (if applicable) (b)(4)		Phone Number (including area code) (b)(4)	
Street Address (b)(4)		FAX Number (including area code) (b)(4)	
City (b)(4)		State / Province (b)(4)	ZIP Code (b)(4)
Contact Name (b)(4)		Contact Title (b)(4)	Contact E-mail Address (b)(4)
☒ Original ☐ Add ☐ Delete	Facility Establishment Identifier (FEI) Number 1721676		☒ Manufacturer ☐ Contract Sterilizer ☐ Contract Manufacturer ☐ Repackager / Relabeler
Company / Institution Name Stryker Neurovascular Cork		Establishment Registration Number 3008881809	
Division Name (if applicable)		Phone Number (including area code) 510-413-2900	
Street Address Business and Technology Park		FAX Number (including area code)	
City Model Farm Road		State / Province Cork	ZIP Code Ireland
Contact Name Angelica Beckmann		Contact Title Director, Regulatory Affairs	Contact E-mail Address angelica.beckmann@stryker.com
☐ Original ☐ Add ☐ Delete	Facility Establishment Identifier (FEI) Number		☐ Manufacturer ☐ Contract Sterilizer ☐ Contract Manufacturer ☐ Repackager / Relabeler
Company / Institution Name		Establishment Registration Number	
Division Name (if applicable)		Phone Number (including area code)	
Street Address		FAX Number (including area code)	
City		State / Province	ZIP Code Country
Contact Name		Contact Title	Contact E-mail Address

SECTION I		UTILIZATION OF STANDARDS			
Note: Complete this section if your application or submission cites standards or includes a "Declaration of Conformity to a Recognized Standard" statement.					
1	Standards No. Please see Section 004 Attachment 4A for a complete list.	Standards Organization	Standards Title	Version	Date
2	Standards No.	Standards Organization	Standards Title	Version	Date
3	Standards No.	Standards Organization	Standards Title	Version	Date
4	Standards No.	Standards Organization	Standards Title	Version	Date
5	Standards No.	Standards Organization	Standards Title	Version	Date
6	Standards No.	Standards Organization	Standards Title	Version	Date
7	Standards No.	Standards Organization	Standards Title	Version	Date
Please include any additional standards to be cited on a separate page.					
This section applies only to requirements of the Paperwork Reduction Act of 1995. *DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF ADDRESS BELOW.* The burden time for this collection of information is estimated to average 0.5 hour per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to: Department of Health and Human Services Food and Drug Administration Office of Chief Information Officer Paperwork Reduction Act (PRA) Staff 1350 Piccard Drive, Room 400 Rockville, MD 20850 <i>An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.</i>					

Section 004 CDRH Premarket Review Submission Cover Sheet FDA Form 3514

Attachment 4A – Utilization of Standards

Attachment is individually paginated.

Section 004 Attachment 4A - Utilization of Standards

	Standards No.	Standards Organization	Standards Title	Version	Date
1	EN 556-1	CEN	Sterilization of Medical Devices – Requirements for medical devices to be labeled “Sterile” Part 1: Requirements for Terminally Sterilized Medical Devices	2001 + AC 2006	2001/ 2006
2	EN 1041	CEN	Information supplied by the manufacturer or medical devices	2008/A1:2013	2008/ 2013
3	EN ISO 14971	CEN	Medical Devices – Application of risk management to medical devices	2012	2012
4	EN 62366	CEN	Medical Devices – Application of Usability engineering to medical devices	2008	2008
5	EN 1707	CEN	Conical Fittings with a 6% (Luer) taper for syringes, needles and certain other medical equipment – Lock Fittings	1996	1996
6	EN ISO 10555-1	CEN	Sterile, single-use intravascular	2013	2013

	Standards No.	Standards Organization	Standards Title	Version	Date
			catheters – Part 1 General Catheters		
7	EN ISO 10993-1	CEN	Biological Evaluation of medical devices Part 1: Evaluation and testing within a risk management process	2009 + AC: 2010	2009/2010
8	EN ISO 10993-4	CEN	Biological Evaluation of medical devices Part 4: Selection of tests for interactions with blood	2009	2009
9	EN ISO 10993-5	CEN	Biological Evaluation of medical devices Part 5: Test for in vitro cytotoxicity	2009	2009
10	EN ISO 10993-7	CEN	Biological Evaluation of medical devices Part 7: Ethylene oxide sterilization residuals	2008	2008
11	EN ISO 10993-10	CEN	Biological evaluation of medical devices Part 10: Tests for irritation and skin sensitization	2013	2013
12	EN ISO 10993-11	CEN	Biological evaluation of medical devices Part 11: Tests for systemic toxicity	2009	2009

	Standards No.	Standards Organization	Standards Title	Version	Date
13	EN ISO 10993-18	CEN	Biological evaluation of medical devices Part 18: Chemical characterization of materials	2009	2009
14	EN ISO 11135-1	CEN	Sterilization of health care products – Ethylene Oxide – Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices.	2014	2014
15	EN ISO 11607-1 11607-2	CEN	Packaging for terminally sterilized medical devices Part 1: Requirements for Materials, Sterile Barrier Systems and Packaging Systems Part 2: Validation Requirements for Forming, Sealing, and Assembly Processes	2014	2014

	Standards No.	Standards Organization	Standards Title	Version	Date
16	EN ISO 15223-1	CEN	Medical devices – Symbols to be used with medical device labels, labeling and information to be supplied	2012 + Corr 1:2012	2012
17	ISTA 2A	ISTA	Series Partial Simulation Performance Test Procedure	2012	2012
18	ASTM F2096-11	ASTM	Standard Test Method for Detecting Gross Leaks in Packaging by Internal Pressurization (Bubble Test)	2011	2011
19	ASTM F88/F 88M	ASTM	Standard Test Method for Seal Strength of Flexible Barrier Materials	2009	2009
20	ASTM F1886/F 1886M-09 (reapproved 2013)	ASTM	Standard Test Method for Determining Integrity of Seals for Flexible Packaging for Visual Inspection	2009 (re-approved in 2013)	2009/2013
21	ASTM F1980-07 (reapproved 2011)	ASTM	Standard Guide for Accelerated Aging of Sterile Barrier Systems of Medical Devices	2007/reapproved 2011)	2007/reapproved 2011)

	Standards No.	Standards Organization	Standards Title	Version	Date
22	ASTM F1929-12	ASTM	Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration	2012	2012
23	ASTM F1608-16	ASTM	Standard Test Method for Microbial Ranking of Porous Packaging Materials (Exposure Chamber Method)	2016	2016
24	ASTM F2638-12	ASTM	Standard Test Method for Using Aerosol Filtration for Measuring the Performance of Porous Packaging Materials as a Surrogate Microbial Barrier	2012	2012

As the intent of this submission is to add an indication for use, the majority of the standards listed above are provided for reference and the associated testing was cleared as part of **K151667**. For reviewer convenience, a listing of the supporting documents and their location are provided below. The standards utilized in the assessment of the AXS Catalyst™ Distal Access Catheter are as follows:

Area	Standards	Supporting Documents and Location
Design Verification & Validation	EN ISO 10555-1: 2013	• K151667, Attachment E-1: (b)(4) DV Protocol (b)(4) AXS Catalyst Distal Access Catheter • K151667, Attachment E-2: (b)(4) Design Verification testing report
	EN 1707: 1996	• K151667, Attachment E-3: (b)(4) Accelerated Aging (b)(4) Protocol, AXS Catalyst Distal Access Catheter • K151667, Attachment E-4: (b)(4) Design Verification testing report (b)(4)
	EN 62366: 2008	• K151667, Attachment E-5: (b)(4) Accelerated Aging Protocol, AXS Catalyst Distal Access Catheter (b)(4) • K151667, Attachment E-6: (b)(4), RT Aging Protocol, AXS Catalyst Distal Access Catheter (b)(4) • K151667, Attachment E-7: (b)(4) GLP Protocol, Design Validation Study for the AXS Catalyst Distal Access Catheter, in the Animal and In Vitro Models • K151667, Attachment E-8: (b)(4) GLP Report, Design Validation Study for the AXS Catalyst Distal Access Catheter, in the Animal and In Vitro Models • K151667, Attachment E-9: (b)(4) Packaging Design Verification and Aging Protocol • K151667, Attachment E-10: (b)(4) Packaging Design Verification and Aging Report
Biosafety Assessment	EN ISO 10993-1:2009/AC:2010	• K151667, Attachment E-11: (b)(4) Biocompatibility Report
	EN ISO 10993-4:2009	• K151667, Attachment E-11: (b)(4) Biocompatibility Report, Attachments 9-13, 18
	EN ISO 10993-5:2009	• K151667, Attachment E-11: (b)(4) Biocompatibility Report, Attachments 4, 17

Area	Standards	Supporting Documents and Location
	EN ISO 10993-10:2013	• K151667, Attachment E-11: (b)(4) - Biocompatibility Report, Attachments 5, 6
	EN ISO 10993-11:2009	• K151667, Attachment E-11: (b)(4) - Biocompatibility Report, Attachments 7, 8
	EN ISO 10993-18:2009	• K151667, Attachment E-11: (b)(4) - Biocompatibility Report, Attachments 14, 15, 19, 20
Sterility Assurance	EN ISO 11135-1:2014	• K151667, Attachment E-12: (b)(4) - EO Sterilization Evaluation • K151667, Attachment E-13: (b)(4) - EO Sterilization Qualification Protocol • K151667, Attachment E-14: (b)(4) - EO Sterilization Qualification Report
	EN 556-1:2001/AC:2006	• Summary Report Table of FDA form 3564 in K151667, Attachment D
	EN ISO 10993-7:2008/AC:2009	• K151667, Attachment E-14: (b)(4) - EO Sterilization Qualification Report
Packaging	EN ISO 11607-1:2009/A1:2014	• K151667, Attachment E-10: (b)(4) - AXS Catalyst Catheter Packaging Design Verification and Aging Report
	EN ISO 11607-2:2006/A1:2014	• Summary Report Table of FDA form 3564 in K151667, Attachment D
Labeling	EN 1041:2008/A1:2013	• Summary Report Table of FDA form 3564 in K151667, Attachment D
	EN ISO 15223-1:2012/AC:2012	
Risk Management	EN ISO 14971:2012	• Summary Report Table of FDA form 3564 in K151667, Attachment D

Area	Standards	Supporting Documents and Location
Test Methods	ASTM F 2096-04, Standard Test Method for Detecting Gross Leaks in Porous-Medical Packaging by Internal Pressurization (Bubble Test)	• K151667, S001, C-1
	ASTM F 88/F88 M-09, Standard Test Method for Determining Integrity of Seals for Medical Packaging by Visual Inspection	• K151667, S001, C-2
	ASTM F 1886/F1886M- 09, Standard Test Method for Determining Integrity of Seals for Medical Packaging by Visual Inspection	• K151667, S001, C-3
	ASTM F1980, Standard Guide for Accelerated Aging of Sterile Medical Device Packages	• K151667, S001, C-4
	ASTM F 1929-98 (2004) Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration	• K151667, S001, C-5
	ISTA 2A (January 2012): ISTA 2 Series Partial Simulation Performance Test Procedures	• K151667, S001, C-6
	ASTM F1608-16	• Section 015, Attachment 15A: (b)(4) Packaging Technical Report, Sterile Barrier Microbial Barrier

Area	Standards	Supporting Documents and Location
	ASTM F2638-12	• Section 015, Attachment 15A: (b)(4) Packaging Technical Report, Sterile Barrier Microbial Barrier

FDA Standards Data Reports (FDA form 3654) have been completed for each of the standards listed above and are provided in **Section 004, Attach 4B**.

Section 004 CDRH Premarket Review Submission Cover Sheet FDA Form 3514

Attachment 4B – Standards Data Report

Attachment is individually paginated.

Department of Health and Human Services
Food and Drug Administration
STANDARDS DATA REPORT FOR 510(k)s
(To be filled in by applicant)

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).

TYPE OF 510(K) SUBMISSION

☒ Traditional☐ Special☐ AbbreviatedSTANDARD TITLE ¹

EN 556-1:2001 + AC: 2006 - Sterilization of Medical Devices – Requirements for medical devices to be labeled 'Sterile'
Part I: Requirements for Terminally Sterilized Medical Devices

Please answer the following questions

Yes No

Is this standard recognized by FDA ²?☐ ☒FDA Recognition number ³

#

Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?

☐ ☒

Is a summary report ⁴ describing the extent of conformance of the standard used included in the 510(k)?
If no, complete a summary report table.

☐ ☒

Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?

☒ ☐

Does this standard include acceptance criteria?

☒ ☐

If no, include the results of testing in the 510(k).

Does this standard include more than one option or selection of tests?

☐ ☒

If yes, report options selected in the summary report table.

Were there any deviations or adaptations made in the use of the standard?

☐ ☒If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) ⁵?☐ ☐

Were deviations or adaptations made beyond what is specified in the FDA SIS?

☐ ☒

If yes, report these deviations or adaptations in the summary report table.

Were there any exclusions from the standard?

☐ ☒

If yes, report these exclusions in the summary report table.

Is there an FDA guidance ⁶ that is associated with this standard?☐ ☒

If yes, was the guidance document followed in preparation of this 510(k)?

☐ ☐

Title of guidance:

¹ The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

² Authority [21 U.S.C. 360d], <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/default.htm>

³ <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm>

⁴ The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and

address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

⁵ The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm>

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EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE

STANDARD TITLE
EN 556-1:2001 + AC: 2006 - Sterilization of Medical Devices - Requirements for medical devices to be labeled 'Sterile'
Part 1: Requirements for Terminally Sterilized Medical Devices

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE? ☐ Yes ☐ No ☒ N/A
TYPE OF DEVIATION OR OPTION SELECTED *		
DESCRIPTION		
JUSTIFICATION		
SECTION NUMBER	SECTION TITLE	CONFORMANCE? ☐ Yes ☐ No ☒ N/A
TYPE OF DEVIATION OR OPTION SELECTED *		
DESCRIPTION		
JUSTIFICATION		
SECTION NUMBER	SECTION TITLE	CONFORMANCE? ☐ Yes ☐ No ☒ N/A
TYPE OF DEVIATION OR OPTION SELECTED *		
DESCRIPTION		
JUSTIFICATION		

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

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TYPE OF 510(K) SUBMISSION

☒ Traditional☐ Special☐ AbbreviatedSTANDARD TITLE ¹

EN 1041: 2008/A1:2013 - Information supplied by the manufacturer on medical devices

Please answer the following questions

Yes

No

Is this standard recognized by FDA ²?☐☒FDA Recognition number ³

#

Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?

☐☒Is a summary report ⁴ describing the extent of conformance of the standard used included in the 510(k)?☐☒

If no, complete a summary report table.

Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?

☒☐

Does this standard include acceptance criteria?

☐☒

If no, include the results of testing in the 510(k).

Does this standard include more than one option or selection of tests?

☐☒

If yes, report options selected in the summary report table.

Were there any deviations or adaptations made in the use of the standard?

☐☒If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) ⁵?☐☐

Were deviations or adaptations made beyond what is specified in the FDA SIS?

☐☒

If yes, report these deviations or adaptations in the summary report table.

Were there any exclusions from the standard?

☐☒

If yes, report these exclusions in the summary report table.

Is there an FDA guidance ⁶ that is associated with this standard?☐☒

If yes, was the guidance document followed in preparation of this 510k?

☐☐

Title of guidance:

¹ The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

² Authority [21 U.S.C. 360d], <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm>

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EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE

STANDARD TITLE
EN 1041: 2008/A1:2013 - Information supplied by the manufacturer on medical devices

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
1	Scope	☐ Yes ☐ No ☒ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
2	Normative References	☐ Yes ☐ No ☒ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
3	Terms and Definitions	☐ Yes ☐ No ☒ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

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EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE		
STANDARD TITLE EN 1041: 2008/A1:2013 - Information supplied by the manufacturer on medical devices		
CONFORMANCE WITH STANDARD SECTIONS*		
SECTION NUMBER 4	SECTION TITLE Requirements	CONFORMANCE? ☒ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED *		
DESCRIPTION		
JUSTIFICATION		
SECTION NUMBER 5	SECTION TITLE Requirements for Provision of Information	CONFORMANCE? ☒ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED *		
DESCRIPTION		
JUSTIFICATION		
SECTION NUMBER 6	SECTION TITLE Documentation	CONFORMANCE? ☒ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED *		
DESCRIPTION		
JUSTIFICATION		
SECTION NUMBER	SECTION TITLE	CONFORMANCE? ☐ Yes ☐ No ☒ N/A
TYPE OF DEVIATION OR OPTION SELECTED *		
DESCRIPTION		
JUSTIFICATION		

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TYPE OF 510(K) SUBMISSION

☒ Traditional☐ Special☐ AbbreviatedSTANDARD TITLE ¹

EN ISO 14971:2012 - Medical Devices - Application of risk management to medical devices

Please answer the following questions

Yes

No

Is this standard recognized by FDA ²?☐☒FDA Recognition number ³

#

Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?

☐☒Is a summary report ⁴ describing the extent of conformance of the standard used included in the 510(k)?
If no, complete a summary report table.☐☒

Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?

☒☐Does this standard include acceptance criteria?
If no, include the results of testing in the 510(k).☐☒Does this standard include more than one option or selection of tests?
If yes, report options selected in the summary report table.☐☒Were there any deviations or adaptations made in the use of the standard?
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) ⁵?☐☒☐☐Were deviations or adaptations made beyond what is specified in the FDA SIS?
If yes, report these deviations or adaptations in the summary report table.☐☒Were there any exclusions from the standard?
If yes, report these exclusions in the summary report table.☐☒Is there an FDA guidance ⁶ that is associated with this standard?
If yes, was the guidance document followed in preparation of this 510(k)?☐☒☐☐

Title of guidance:

¹ The formatting convention for the title is: {SDO} [numeric identifier] [title of standard] [date of publication]

² Authority [21 U.S.C. 360d], <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm>

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EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE

STANDARD TITLE
EN ISO 14971:2012 - Medical Devices - Application of risk management to medical devices

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER 1	SECTION TITLE Scope	CONFORMANCE? ☐ Yes ☐ No ☒ N/A
TYPE OF DEVIATION OR OPTION SELECTED *		
DESCRIPTION		
JUSTIFICATION		
SECTION NUMBER 2	SECTION TITLE Terms and Definitions	CONFORMANCE? ☐ Yes ☐ No ☒ N/A
TYPE OF DEVIATION OR OPTION SELECTED *		
DESCRIPTION		
JUSTIFICATION		
SECTION NUMBER 3	SECTION TITLE General requirements for risk management	CONFORMANCE? ☒ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED *		
DESCRIPTION		
JUSTIFICATION		

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EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE

STANDARD TITLE

EN ISO 14971:2012 - Medical Devices - Application of risk management to medical devices

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER 4	SECTION TITLE Risk analysis	CONFORMANCE? ☒ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED *		
DESCRIPTION		
JUSTIFICATION		
SECTION NUMBER 5	SECTION TITLE Risk Evaluation	CONFORMANCE? ☒ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED *		
DESCRIPTION		
JUSTIFICATION		
SECTION NUMBER 6	SECTION TITLE Risk Control	CONFORMANCE? ☒ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED *		
DESCRIPTION		
JUSTIFICATION		
SECTION NUMBER 7	SECTION TITLE Evaluation of overall residual risk acceptability	CONFORMANCE? ☒ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED *		
DESCRIPTION		
JUSTIFICATION		

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

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EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE

STANDARD TITLE

EN ISO 14971:2012 - Medical Devices - Application of risk management to medical devices

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER

8

SECTION TITLE

Risk Management Report

CONFORMANCE?

☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

SECTION NUMBER

9

SECTION TITLE

Product and post-production information

CONFORMANCE?

☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

SECTION NUMBER

SECTION TITLE

CONFORMANCE?

☐ Yes ☐ No ☒ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

SECTION NUMBER

SECTION TITLE

CONFORMANCE?

☐ Yes ☐ No ☒ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

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TYPE OF 510(k) SUBMISSION

☒ Traditional

☐ Special

☐ Abbreviated

STANDARD TITLE ¹

EN 62366:2008 - Medical devices - Application of usability engineering to medical devices

Please answer the following questions

Yes

No

Is this standard recognized by FDA ²? ☐ Yes ☒ No

FDA Recognition number ³ #

Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)? ☐ Yes ☒ No

Is a summary report ⁴ describing the extent of conformance of the standard used included in the 510(k)? ☒ Yes ☐ No
If no, complete a summary report table.

Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device? ☒ Yes ☐ No

Does this standard include acceptance criteria? ☐ Yes ☒ No
If no, include the results of testing in the 510(k).

Does this standard include more than one option or selection of tests? ☐ Yes ☒ No
If yes, report options selected in the summary report table.

Were there any deviations or adaptations made in the use of the standard? ☐ Yes ☒ No
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) ⁵? ☐ Yes ☐ No

Were deviations or adaptations made beyond what is specified in the FDA SIS? ☐ Yes ☒ No
If yes, report these deviations or adaptations in the summary report table.

Were there any exclusions from the standard? ☐ Yes ☒ No
If yes, report these exclusions in the summary report table.

Is there an FDA guidance ⁶ that is associated with this standard? ☐ Yes ☒ No
If yes, was the guidance document followed in preparation of this 510(k)? ☐ Yes ☐ No

Title of guidance:

¹ The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

² Authority [21 U.S.C. 360d], <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm>

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EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE

STANDARD TITLE
 EN 62366:2008 - Medical devices - Application of usability engineering to medical devices

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE? ☐ Yes ☐ No ☒ N/A
----------------	---------------	--

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE? ☐ Yes ☐ No ☒ N/A
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TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE? ☐ Yes ☐ No ☒ N/A
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TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

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TF/DD Reference:	(b)(4)	AXS Catalyst™ Distal access catheter
Completed By:	(b)(6)	

International Standard IEC 62366 *Medical devices – Application of usability engineering to medical devices* specifies a Usability Engineering Process for a manufacturer to analyze, specify, design, verify and validate usability, as it relates to basic safety and essential performance of medical equipment. Through application of this Process and successful implementation of the Usability Validation Plan, then residual risks (as defined in ISO 14971) associated with usability of a medical device are presumed to be acceptable, unless there is objective evidence to the contrary.

Historically, IEC 60601-1-6 *Medical electrical equipment Part 1-6: General requirements for basic safety and essential performance — Collateral Standard: Usability* has specified a similar Usability Engineering Process for medical *electrical* equipment. The IEC 60601-1-6:2010 cancelled and replaced IEC 60601-1-6:2006 which was technically revised. The standard was revised to create a bridge that will enable a manufacturer to conform to the requirements in IEC 60601-1 *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance* that make normative reference to IEC 60601-1-6 by employing a Usability Engineering Process which complies with IEC 62366:2007. IEC 60601-1-6:2010 now contains only revisions to definitions in IEC 62366:2007 and a normative reference to that standard. Therefore IEC 60601-1-6:2010 can only be applied in combination with the IEC 62366:2007 standard.

The Usability Engineering Process defined in IEC 62366:2007 is embedded in the Stryker Neurovascular (SNV) design control process through identification of user requirements, development of specifications, risk management, and design verification and validation testing. The procedures and documents contained herein represent the Usability Engineering File for products covered by the design dossier/technical file referenced above and provide evidence conformance to IEC 62366:2007 and inherently IEC 60601-1-6:2010, if applicable to a medical electrical device.

Key SNV procedures and deliverables related to Usability Engineering are shown in the **Table 1**.

Table 1: SNV Design Control and Risk Management

Document Name (number)	Key Deliverables for Usability
(Legacy) Design Control SOP (b)(4)	– Marketing Specification – Product Specification – Design Verification protocols/reports – Design Validation protocols/reports – Directions for Use
(Legacy) Risk Management SOP (b)(4)	– Use/Design FMEA – Risk Management Plan and Report
Design Control SOP (b)(4)	– DIOVV – Design Verification protocols/reports – Design Validation protocols/reports – Directions for Use
Risk Management SOP (b)(4)	– Risk Table

	- Risk Management Plan and Report
--	-----------------------------------

Compliance with IEC 62366:2007 is assessed through audit of the Usability Engineering File, which lists the Usability process requirements and the corresponding evidence of conformance. **Table 2** shows that list and the applicable, generic SNV document type providing evidence of conformance.

Table 2: IEC 62366:2007 Usability Engineering Process

Usability Requirement	SNV Document Type	
	Legacy Design Control SOP (b)(4)	Design Control SOP (b)(4)
5.1 Application specification	- Marketing Specification - Use/Design FMEA	- DIOVV - Risk Table
5.2 Frequently used functions	- Marketing Specification - Use/design FMEA	- DIOVV - Risk Table
5.3.1 Identification of characteristics related to SAFETY	- Use/Design FMEA	- Risk Table
5.3.2 Identification of known or foreseeable HAZARDS and HAZARDOUS SITUATIONS	- Use/Design FMEA - Risk Management Plan and Report	- Risk Table - Risk Management Plan and Report
5.4 PRIMARY OPERATING FUNCTIONS	- Marketing Specification	- DIOVV
5.5 USABILITY SPECIFICATION	- Marketing Specification - Product Specification	- DIOVV
5.6 USABILITY VALIDATION plan	- Design Validation protocols/reports	- Design Validation protocols/reports
5.7 USER INTERFACE design and implementation	- Product Specification - Design Verification protocols/reports	- DIOVV - Design Verification protocols/reports
5.8 USABILITY VERIFICATION	- Design Verification protocols/reports	- Design Verification protocols/reports
5.9 USABILITY VALIDATION	- Design Validation protocols/reports	- Design Validation protocols/reports
6.0 Accompanying Documents	- Directions for Use	- Directions for Use
7.0 Training and materials for training	- Marketing Specification - Directions for Use - Use/Design FMEA	- DIOVV - Directions for Use - Risk Table

Documents specific to the design dossier/technical file referenced above which provide evidence of conformance with IEC 62366:2007 are listed in **Table 3**.

Table 3: IEC 62366:2007 Usability Engineering Process: Evidence of Conformance

SNV Document Type	Evidence of Conformance
DIOVV	(b)(4)
Risk Management Plan and Report	Plan: (b)(4) Report: (b)(4)
Risk Table	(b)(4)
Design Validation protocols/reports	Protocol: (b)(4) Report: (b)(4)
Design Verification protocols/reports	Protocol: (b)(4) Report: (b)(4)
Accelerated Aging protocol/reports (t=7 months)	Protocol: (b)(4) Report: (b)(4)
Accelerated Aging protocol/reports (t=25 months)	Protocol: (b)(4) Report: (b)(4)
Directions for Use	(b)(4) (CE), (b)(4) (US)

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TYPE OF 510(k) SUBMISSION

☒ Traditional☐ Special☐ AbbreviatedSTANDARD TITLE¹

EN 1707:1996 - Conical fittings with a 6% (Luer) taper for syringes, needles, and certain other medical equipment - Lock Fittings

Please answer the following questions

Yes No

Is this standard recognized by FDA²? ☒ ☐FDA Recognition number³ #Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)? ☐ ☒Is a summary report⁴ describing the extent of conformance of the standard used included in the 510(k)? ☒ ☐
If no, complete a summary report table.Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device? ☒ ☐Does this standard include acceptance criteria? ☒ ☐
If no, include the results of testing in the 510(k).Does this standard include more than one option or selection of tests? ☒ ☐
If yes, report options selected in the summary report table.Were there any deviations or adaptations made in the use of the standard? ☐ ☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS)⁵? ☐ ☐Were deviations or adaptations made beyond what is specified in the FDA SIS? ☐ ☒
If yes, report these deviations or adaptations in the summary report table.Were there any exclusions from the standard? ☐ ☒
If yes, report these exclusions in the summary report table.Is there an FDA guidance⁶ that is associated with this standard? ☐ ☒
If yes, was the guidance document followed in preparation of this 510(k)? ☐ ☐

Title of guidance:

¹ The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

² Authority [21 U.S.C. 360d], <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm>

³ <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm>

⁴ The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and

address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

⁵ The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm>

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EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE

EN 1707:1996 - Conical fittings with a 6% (Luer) taper for syringes, needles, and certain other medical equipment - Lock Fittings

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
1	Scope	☐ Yes ☐ No ☒ N/A
TYPE OF DEVIATION OR OPTION SELECTED *		
DESCRIPTION		
JUSTIFICATION		
2	Normative references	☐ Yes ☐ No ☒ N/A
TYPE OF DEVIATION OR OPTION SELECTED *		
DESCRIPTION		
JUSTIFICATION		
3	Dimensions and tolerances	☒ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED *		
(b)(4)		
DESCRIPTION		
(b)(4)		
JUSTIFICATION		
(b)(4)		

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

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EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE

STANDARD TITLE
 EN 1707:1996 - Conical fittings with a 6% (Luer) taper for syringes, needles, and certain other medical equipment - Lock Fittings

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER 4	SECTION TITLE Requirements	CONFORMANCE? ☒ Yes ☐ No ☐ N/A
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TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE? ☐ Yes ☐ No ☒ N/A
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TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE? ☐ Yes ☐ No ☒ N/A
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TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE? ☐ Yes ☐ No ☒ N/A
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TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

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Standard & Title: EN 1707: 1996 - Conical fittings with a 6% (Luer) taper for syringes, needles and certain other medical equipment – Lock Fittings.*

Scope: This European Standard specifies requirements for conical lock fittings with a 6 % (Luer) taper for use with hypodermic syringes and needles and with certain other apparatus for medical use e.g. transfusion equipment. The requirements apply to fittings made of rigid and of semi-rigid materials and include test methods, but exclude provision for more flexible or elastomeric materials.

Note 1: It is not practicable to define the characteristics of rigid or semi-rigid materials with precision, but glass and metal may be considered as typical rigid materials. In contrast many plastics materials may be regarded as semi-rigid.

Note 2: The Luer lock fitting was designed for use at pressures of the order of 300 kPa or lower. Its use in other applications may require consideration to establish its suitability.

* EN 1707:1996 is equivalent to ISO 594-2:1998. EN 1707:1996 requires dimensional and gauging compliance with EN 20594-1:1994, which is equivalent to ISO 594-1:1986

Clause Number	Description	Compliance to Standard (Full/ /Partial / NA)	Compliance Demonstrated by:	Justification
(b)(4)				

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

Department of Health and Human Services
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TYPE OF 510(k) SUBMISSION

☒ Traditional☐ Special☐ AbbreviatedSTANDARD TITLE¹

EN ISO 10555-1:2013 - Sterile, single-use intravascular catheters - Part 1 General requirements

Please answer the following questions

Yes No

Is this standard recognized by FDA?²☒☐FDA Recognition number³

#

Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?

☐☒Is a summary report⁴ describing the extent of conformance of the standard used included in the 510(k)?
If no, complete a summary report table.☒☐

Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?

☒☐Does this standard include acceptance criteria?
If no, include the results of testing in the 510(k).☒☐Does this standard include more than one option or selection of tests?
If yes, report options selected in the summary report table.☒☐Were there any deviations or adaptations made in the use of the standard?
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS)⁵?☐☒☐☐Were deviations or adaptations made beyond what is specified in the FDA SIS?
If yes, report these deviations or adaptations in the summary report table.☐☒Were there any exclusions from the standard?
If yes, report these exclusions in the summary report table.☐☒Is there an FDA guidance⁶ that is associated with this standard?☒☐

If yes, was the guidance document followed in preparation of this 510(k)?

☒☐

Title of guidance:

¹ The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

² Authority [21 U.S.C. 360d], <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm>

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EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE

STANDARD TITLE
EN ISO 10555-1:2013 - Sterile, single-use intravascular catheters - Part 1 General requirements

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
1	Scope	☐ Yes ☐ No ☒ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
2	Normative References	☐ Yes ☐ No ☒ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
3	Terms and definitions	☐ Yes ☐ No ☒ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

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EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE

STANDARD TITLE
 EN ISO 10555-1:2013 - Sterile, single-use intravascular catheters - Part 1 General requirements

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
4	Requirements	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

(b)(4)

DESCRIPTION

(b)(4)

JUSTIFICATION

(b)(4)

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
4	Requirements	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

4.9 Flowrate

DESCRIPTION

(b)(4)

JUSTIFICATION

(b)(4)

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
4	Requirements	☐ Yes ☐ No ☒ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

(b)(4)

DESCRIPTION

(b)(4)

JUSTIFICATION

(b)(4)

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
4	Requirements	☐ Yes ☐ No ☒ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

(b)(4)

DESCRIPTION

(b)(4)

JUSTIFICATION

(b)(4)

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EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE

STANDARD TITLE
EN ISO 10555-1:2013 - Sterile, single-use intravascular catheters - Part 1 General requirements

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
5	Designation of nominal size	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
6	Information to be supplied by the manufacturer	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☒ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☒ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

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Standard & Title: EN ISO 10555-1:2013 – Sterile, single-use intravascular catheters – Part 1 General requirements

Scope: This part of ISO 10555 specifies general requirements for intravascular catheters, supplied in the sterile condition and intended for single use, for any application. It does not apply to intravascular catheter accessories, which will be covered by a separate standard.

Note: Please refer to standard for Figures and Test Methods / Annexes.

Note: Please use this standard template in conjunction with the standard itself as available through IHS. Also the current version of any standards referenced within the template should be used (also available through IHS).

Clause Number	Description	Compliance to Standard (Full / Partial / NA)	Compliance Demonstrated by:	Justification
(b)(4)				

(b)(4)

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(b)(4)

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TYPE OF 510(k) SUBMISSION

☒ Traditional☐ Special☐ AbbreviatedSTANDARD TITLE ¹

EN ISO 10993-1:2009 +AC:2010 - Biological evaluation of medical devices
Part 1: Evaluation and testing within a risk management process

Please answer the following questions

Yes No

Is this standard recognized by FDA ²?☐☒FDA Recognition number ³

#

Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?

☒☐

Is a summary report ⁴ describing the extent of conformance of the standard used included in the 510(k)?
If no, complete a summary report table.

☒☐

Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?

☒☐

Does this standard include acceptance criteria?
If no, include the results of testing in the 510(k).

☐☒

Does this standard include more than one option or selection of tests?
If yes, report options selected in the summary report table.

☒☐

Were there any deviations or adaptations made in the use of the standard?
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) ⁵?

☐☒☐☐

Were deviations or adaptations made beyond what is specified in the FDA SIS?
If yes, report these deviations or adaptations in the summary report table.

☐☒

Were there any exclusions from the standard?
If yes, report these exclusions in the summary report table.

☐☒

Is there an FDA guidance ⁶ that is associated with this standard?
If yes, was the guidance document followed in preparation of this 510(k)?

☐☒☐☐

Title of guidance:

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EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE
EN ISO 10993-1:2009 +AC:2010 - Biological evaluation of medical devices
Part 1: Evaluation and testing within a risk management process

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
6.2.2.2	Cytotoxicity	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

(b)(4)

DESCRIPTION

(b)(4)

JUSTIFICATION

(b)(4)

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
6.2.2.9	Haemocompatibility	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

(b)(4)

DESCRIPTION

(b)(4)

JUSTIFICATION

(b)(4)

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☒ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

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TYPE OF 510(K) SUBMISSION

☒ Traditional☐ Special☐ AbbreviatedSTANDARD TITLE ¹

EN ISO 10993-4:2009 - Biological evaluation of medical devices
Part 4: Selection of tests for interactions with blood

Please answer the following questions

Yes No

Is this standard recognized by FDA ² ?☐ ☒FDA Recognition number ³

#

Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?

☒ ☐

Is a summary report ⁴ describing the extent of conformance of the standard used included in the 510(k)?

☒ ☐

If no, complete a summary report table.

Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?

☒ ☐

Does this standard include acceptance criteria?

☒ ☐

If no, include the results of testing in the 510(k).

Does this standard include more than one option or selection of tests?

☒ ☐

If yes, report options selected in the summary report table.

Were there any deviations or adaptations made in the use of the standard?

☐ ☒If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) ⁵ ?☐ ☐

Were deviations or adaptations made beyond what is specified in the FDA SIS?

☐ ☒

If yes, report these deviations or adaptations in the summary report table.

Were there any exclusions from the standard?

☐ ☒

If yes, report these exclusions in the summary report table.

Is there an FDA guidance ⁶ that is associated with this standard?☐ ☒

If yes, was the guidance document followed in preparation of this 510(k)?

☐ ☐

Title of guidance:

¹ The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

² Authority [21 U.S.C. 360d], <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm>

³ <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm>

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address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

⁵ The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm>

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EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE

STANDARD TITLE
EN ISO 10993-4:2009 - Biological evaluation of medical devices
Part 4: Selection of tests for interactions with blood

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
Table 1	Circulating blood devices - externally communicating	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

(b)(4)

DESCRIPTION

(b)(4)

JUSTIFICATION

(b)(4)

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☒ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☒ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

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PRASaff@fda.hhs.gov

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Food and Drug Administration
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TYPE OF 510(K) SUBMISSION

☒ Traditional☐ Special☐ AbbreviatedSTANDARD TITLE ¹

EN ISO 10993-5:2009 - Biological evaluation of medical devices
Part 5: Test for in vitro cytotoxicity

Please answer the following questions

Yes

No

Is this standard recognized by FDA ² ?☐☒FDA Recognition number ³

#

Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?

☒☐

Is a summary report ⁴ describing the extent of conformance of the standard used included in the 510(k)?
If no, complete a summary report table.

☒☐

Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?

☒☐

Does this standard include acceptance criteria?
If no, include the results of testing in the 510(k).

☒☐

Does this standard include more than one option or selection of tests?
If yes, report options selected in the summary report table.

☐☒

Were there any deviations or adaptations made in the use of the standard?
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) ⁵ ?

☐☒☐☐

Were deviations or adaptations made beyond what is specified in the FDA SIS?
If yes, report these deviations or adaptations in the summary report table.

☐☒

Were there any exclusions from the standard?
If yes, report these exclusions in the summary report table.

☐☒

Is there an FDA guidance ⁶ that is associated with this standard?
If yes, was the guidance document followed in preparation of this 510k?

☐☒☐☒

Title of guidance:

¹ The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

² Authority [21 U.S.C. 360d], <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm>

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EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLESTANDARD TITLE
EN ISO 10993-5:2009 - Biological evaluation of medical devices
Part 5: Test for in vitro cytotoxicity

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
4.1	Sample and control preparation, General	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

(b)(4)

DESCRIPTION

(b)(4)

JUSTIFICATION

(b)(4)

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
4.2.2(c)	Extract Vehicle	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

(b)(4)

DESCRIPTION

(b)(4)

JUSTIFICATION

(b)(4)

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
4.2.3.1	Extract Conditions	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

(b)(4)

DESCRIPTION

(b)(4)

JUSTIFICATION

(b)(4)

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TYPE OF 510(K) SUBMISSION

☒ Traditional☐ Special☐ AbbreviatedSTANDARD TITLE ¹

EN ISO 10993-7:2008/+AC:2009 - Biological evaluation of medical devices
Part 7: Ethylene oxide sterilization residuals

Please answer the following questions

Yes

No

Is this standard recognized by FDA ² ? ☐ ☒FDA Recognition number ³ # _____Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)? ☒ ☐Is a summary report ⁴ describing the extent of conformance of the standard used included in the 510(k)? ☒ ☐
If no, complete a summary report table.Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device? ☒ ☐Does this standard include acceptance criteria? ☒ ☐
If no, include the results of testing in the 510(k).Does this standard include more than one option or selection of tests? ☒ ☐
If yes, report options selected in the summary report table.Were there any deviations or adaptations made in the use of the standard? ☐ ☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) ⁵ ? ☐ ☐Were deviations or adaptations made beyond what is specified in the FDA SIS? ☐ ☒
If yes, report these deviations or adaptations in the summary report table.Were there any exclusions from the standard? ☐ ☒
If yes, report these exclusions in the summary report table.Is there an FDA guidance ⁶ that is associated with this standard? ☐ ☒
If yes, was the guidance document followed in preparation of this 510(k)? ☐ ☐

Title of guidance: _____

¹ The formatting convention for the title is: [SCO] [numeric identifier] [title of standard] [date of publication]

² Authority [21 U.S.C. 360d], <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm>

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EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE		
STANDARD TITLE EN ISO 10993-7:2008/+AC:2009 - Biological evaluation of medical devices Part 7: Ethylene oxide sterilization residuals		
CONFORMANCE WITH STANDARD SECTIONS*		
SECTION NUMBER 5.0	SECTION TITLE Product release	CONFORMANCE? ☒ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED * (b)(4)		
DESCRIPTION (b)(4)		
JUSTIFICATION (b)(4)		
SECTION NUMBER	SECTION TITLE	CONFORMANCE? ☐ Yes ☐ No ☒ N/A
TYPE OF DEVIATION OR OPTION SELECTED *		
DESCRIPTION		
JUSTIFICATION		
SECTION NUMBER	SECTION TITLE	CONFORMANCE? ☐ Yes ☐ No ☒ N/A
TYPE OF DEVIATION OR OPTION SELECTED *		
DESCRIPTION		
JUSTIFICATION		
* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary. † Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.		
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TYPE OF 510(K) SUBMISSION

☒ Traditional☐ Special☐ AbbreviatedSTANDARD TITLE ¹

EN ISO 10993-10:2013 - Biological evaluation of medical devices
Part 10: Tests for irritation and skin sensitization

Please answer the following questions

Yes

No

Is this standard recognized by FDA ²?☐☒FDA Recognition number ³

#

Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?

☒☐

Is a summary report ⁴ describing the extent of conformance of the standard used included in the 510(k)?
If no, complete a summary report table.

☒☐

Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?

☒☐

Does this standard include acceptance criteria?
If no, include the results of testing in the 510(k).

☒☐

Does this standard include more than one option or selection of tests?
If yes, report options selected in the summary report table.

☒☐

Were there any deviations or adaptations made in the use of the standard?
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) ⁵?

☐☒☐☐

Were deviations or adaptations made beyond what is specified in the FDA SIS?
If yes, report these deviations or adaptations in the summary report table.

☐☒

Were there any exclusions from the standard?
If yes, report these exclusions in the summary report table.

☐☒

Is there an FDA guidance ⁶ that is associated with this standard?
If yes, was the guidance document followed in preparation of this 510(k)?

☐☒☐☐

Title of guidance:

¹ The formatting convention for the title is: [SDC] [numeric identifier] [title of standard] [date of publication]

² Authority [21 U.S.C. 360d], <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm>

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EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE		
STANDARD TITLE EN ISO 10993-10:2013 - Biological evaluation of medical devices Part 10: Tests for irritation and skin sensitization		
CONFORMANCE WITH STANDARD SECTIONS*		
SECTION NUMBER Clause 6.0	SECTION TITLE Irritation Tests	CONFORMANCE? ☒ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED * (b)(4)		
DESCRIPTION (b)(4)		
JUSTIFICATION (b)(4)		
SECTION NUMBER Clause 7.0	SECTION TITLE Skin Sensitization Tests	CONFORMANCE? ☐ Yes ☐ No ☒ N/A
TYPE OF DEVIATION OR OPTION SELECTED * (b)(4)		
DESCRIPTION (b)(4)		
JUSTIFICATION (b)(4)		
SECTION NUMBER	SECTION TITLE	CONFORMANCE? ☐ Yes ☐ No ☒ N/A
TYPE OF DEVIATION OR OPTION SELECTED *		
DESCRIPTION		
JUSTIFICATION		
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TYPE OF 510(K) SUBMISSION

☒ Traditional☐ Special☐ AbbreviatedSTANDARD TITLE ¹

EN ISO 10993-11:2009 - Biological evaluation of medical devices
Part 11: Tests for systemic toxicity

Please answer the following questions

Yes

No

Is this standard recognized by FDA ²?☒☐FDA Recognition number ³

#2-176

Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?

☒☐

Is a summary report ⁴ describing the extent of conformance of the standard used included in the 510(k)?

☒☐

If no, complete a summary report table.

Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?

☒☐

Does this standard include acceptance criteria?

☒☐

If no, include the results of testing in the 510(k).

Does this standard include more than one option or selection of tests?

☐☒

If yes, report options selected in the summary report table.

Were there any deviations or adaptations made in the use of the standard?

☐☒If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) ⁵?☐☐

Were deviations or adaptations made beyond what is specified in the FDA SIS?

☐☒

If yes, report these deviations or adaptations in the summary report table.

Were there any exclusions from the standard?

☐☒

If yes, report these exclusions in the summary report table.

Is there an FDA guidance ⁶ that is associated with this standard?☐☒

If yes, was the guidance document followed in preparation of this 510(k)?

☐☐

Title of guidance:

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² Authority [21 U.S.C. 360d], <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm>

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EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE		
STANDARD TITLE EN ISO 10993-11:2009 - Biological evaluation of medical devices Part 11: Tests for systemic toxicity		
CONFORMANCE WITH STANDARD SECTIONS*		
SECTION NUMBER 5	SECTION TITLE Acute systemic toxicity	CONFORMANCE? ☒ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED * (b)(4)		
DESCRIPTION (b)(4)		
JUSTIFICATION (b)(4)		
SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☒ N/A
TYPE OF DEVIATION OR OPTION SELECTED *		
DESCRIPTION		
JUSTIFICATION		
SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☒ N/A
TYPE OF DEVIATION OR OPTION SELECTED *		
DESCRIPTION		
JUSTIFICATION		
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TYPE OF 510(k) SUBMISSION

☒ Traditional☐ Special☐ AbbreviatedSTANDARD TITLE ¹

EN ISO 10993-18: 2009 - Biological evaluation of medical devices
Part 18: Chemical characterization of materials

Please answer the following questions

Yes No

Is this standard recognized by FDA ²?☐☒FDA Recognition number ³

#

Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?

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Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?

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Does this standard include acceptance criteria?

☒☐

If no, include the results of testing in the 510(k).

Does this standard include more than one option or selection of tests?

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If yes, report options selected in the summary report table.

Were there any deviations or adaptations made in the use of the standard?

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Were deviations or adaptations made beyond what is specified in the FDA SIS?

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Were there any exclusions from the standard?

☐☒

If yes, report these exclusions in the summary report table.

Is there an FDA guidance ⁶ that is associated with this standard?☐☒

If yes, was the guidance document followed in preparation of this 510(k)?

☐☐

Title of guidance:

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EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLESTANDARD TITLE
EN ISO 10993-18: 2009 - Biological evaluation of medical devices
Part 18: Chemical characterization of materials

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
Section 6	Characterization	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *
(b)(4)

DESCRIPTION

(b)(4)

JUSTIFICATION

(b)(4)

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☒ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☒ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

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PRASStaff@fda.hhs.gov

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Department of Health and Human Services
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(To be filled in by applicant)

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TYPE OF 510(K) SUBMISSION



Traditional



Special



Abbreviated

STANDARD TITLE ¹

ISO 11135 Second Edition 2014 - Sterilization of health care products - Ethylene oxide - Requirements for the Development, Validation and Routine Control of a Sterilization process for Medical Devices

Please answer the following questions

Yes

No

Is this standard recognized by FDA ²?FDA Recognition number ³

#14-452

Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?



Is a summary report ⁴ describing the extent of conformance of the standard used included in the 510(k)?



If no, complete a summary report table.

Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?



Does this standard include acceptance criteria?



If no, include the results of testing in the 510(k).

Does this standard include more than one option or selection of tests?



If yes, report options selected in the summary report table.

Were there any deviations or adaptations made in the use of the standard?



If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) ⁵?



Were deviations or adaptations made beyond what is specified in the FDA SIS?



If yes, report these deviations or adaptations in the summary report table.

Were there any exclusions from the standard?



If yes, report these exclusions in the summary report table.

Is there an FDA guidance ⁶ that is associated with this standard?



If yes, was the guidance document followed in preparation of this 510k?



Title of guidance:

¹ The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

² Authority [21 U.S.C. 360d], <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm>

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EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE

STANDARD TITLE

ISO 11135 Second Edition 2014 - Sterilization of health care products - Ethylene oxide - Requirements for the Development, Validation and Routine Control of a Sterilization process for Medical Devices

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
9.3.2.3	Performance Qualification - Microbiological	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

(b)(4)

DESCRIPTION

(b)(4)

JUSTIFICATION

(b)(4)

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☒ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☒ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

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TYPE OF 510(K) SUBMISSION

☒ Traditional☐ Special☐ AbbreviatedSTANDARD TITLE¹

EN ISO 11607-1:2009/A1:2014 Packaging for Terminally Sterilized Medical Devices
Part 1: Requirements for Materials, Sterile Barrier Systems and Packaging Systems

Please answer the following questions

Yes No

Is this standard recognized by FDA²?☐☒FDA Recognition number³

#

Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?

☒☐Is a summary report⁴ describing the extent of conformance of the standard used included in the 510(k)?☒☐

If no, complete a summary report table.

Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?

☒☐

Does this standard include acceptance criteria?

☒☐

If no, include the results of testing in the 510(k).

Does this standard include more than one option or selection of tests?

☐☒

If yes, report options selected in the summary report table.

Were there any deviations or adaptations made in the use of the standard?

☐☒If yes, were deviations in accordance with the FDA supplemental information sheet (SIS)⁵?☐☐

Were deviations or adaptations made beyond what is specified in the FDA SIS?

☐☒

If yes, report these deviations or adaptations in the summary report table.

Were there any exclusions from the standard?

☐☒

If yes, report these exclusions in the summary report table.

Is there an FDA guidance⁶ that is associated with this standard?☐☒

If yes, was the guidance document followed in preparation of this 510(k)?

☐☐

Title of guidance:

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EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE

STANDARD TITLE
EN ISO 11607-1:2009/A1:2014 Packaging for Terminally Sterilized Medical Devices
Part 1: Requirements for Materials, Sterile Barrier Systems and Packaging Systems

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE? ☐ Yes ☐ No ☒ N/A
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TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE? ☐ Yes ☐ No ☒ N/A
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TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE? ☐ Yes ☐ No ☒ N/A
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DESCRIPTION

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TYPE OF 510(k) SUBMISSION

☒ Traditional☐ Special☐ AbbreviatedSTANDARD TITLE ¹

EN ISO 11607-2:2006/A1:2014 Packaging for Terminally Sterilized Medical Devices
Part 2: Validation Requirements for Forming, Sealing, and Assembly Processes

Please answer the following questions

Yes

No

Is this standard recognized by FDA ²?☐☒FDA Recognition number ³

#

Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?

☐☒

Is a summary report ⁴ describing the extent of conformance of the standard used included in the 510(k)?

☒☐

If no, complete a summary report table.

Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?

☒☐

Does this standard include acceptance criteria?

☒☐

If no, include the results of testing in the 510(k).

Does this standard include more than one option or selection of tests?

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If yes, report options selected in the summary report table.

Were there any deviations or adaptations made in the use of the standard?

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If yes, report these deviations or adaptations in the summary report table.

Were there any exclusions from the standard?

☐☒

If yes, report these exclusions in the summary report table.

Is there an FDA guidance ⁶ that is associated with this standard?☐☒

If yes, was the guidance document followed in preparation of this 510(k)?

☐☐

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EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE

STANDARD TITLE
 EN ISO 11607-2:2006/A1:2014 Packaging for Terminally Sterilized Medical Devices
 Part 2: Validation Requirements for Forming, Sealing, and Assembly Processes

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE? ☐ Yes ☐ No ☒ N/A
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TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE? ☐ Yes ☐ No ☒ N/A
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TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE? ☐ Yes ☐ No ☒ N/A
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TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

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Standard & Title: EN ISO 11607-1:2009 + A1:2014
Packaging for terminally sterilized medical devices

Standard & Title: EN ISO 11607-2:2006 +A1:2014
Packaging for terminally sterilized medical devices – Part 2: Validation requirements for forming, sealing and assembly processes

EN ISO 11607-1:2009 + A1:2014— Part 1: Requirements for Materials, Sterile Barrier Systems and Packaging Systems

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TYPE OF 510(k) SUBMISSION



Traditional



Special



Abbreviated

STANDARD TITLE ¹

EN ISO 15223-1:2012 +Corr 1:2012 - Medical devices - Symbols to be used with medical device labels, labeling, and information to be supplied

Please answer the following questions

Yes

No

Is this standard recognized by FDA ²?FDA Recognition number ³

#

Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?



Is a summary report ⁴ describing the extent of conformance of the standard used included in the 510(k)?



If no, complete a summary report table.

Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?



Does this standard include acceptance criteria?



If no, include the results of testing in the 510(k).

Does this standard include more than one option or selection of tests?



If yes, report options selected in the summary report table.

Were there any deviations or adaptations made in the use of the standard?



If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) ⁵?



Were deviations or adaptations made beyond what is specified in the FDA SIS?



If yes, report these deviations or adaptations in the summary report table.

Were there any exclusions from the standard?



If yes, report these exclusions in the summary report table.

Is there an FDA guidance ⁶ that is associated with this standard?



If yes, was the guidance document followed in preparation of this 510(k)?



Title of guidance:

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EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE		
STANDARD TITLE EN ISO 15223-1:2012 +Corr 1:2012 - Medical devices - Symbols to be used with medical device labels, labeling, and information to be supplied		
CONFORMANCE WITH STANDARD SECTIONS*		
SECTION NUMBER 1	SECTION TITLE Scope	CONFORMANCE? ☐ Yes ☐ No ☒ N/A
TYPE OF DEVIATION OR OPTION SELECTED *		
DESCRIPTION		
JUSTIFICATION		
SECTION NUMBER 2	SECTION TITLE Normative references	CONFORMANCE? ☐ Yes ☐ No ☒ N/A
TYPE OF DEVIATION OR OPTION SELECTED *		
DESCRIPTION		
JUSTIFICATION		
SECTION NUMBER 3	SECTION TITLE Terms and definitions	CONFORMANCE? ☐ Yes ☐ No ☒ N/A
TYPE OF DEVIATION OR OPTION SELECTED *		
DESCRIPTION		
JUSTIFICATION		
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EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE

STANDARD TITLE
EN ISO 15223-1:2012 +Corr 1:2012 - Medical devices - Symbols to be used with medical device labels, labeling, and information to be supplied

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
4 (sub-section 4.1)	General Requirements (4. Proposal of symbols for adoption)	☐ Yes ☐ No ☒ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
4 (sub-section 4.2)	General Requirements (4.2 Requirements for usage)	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
5	Symbols	☐ Yes ☐ No ☒ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

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TYPE OF 510(k) SUBMISSION



Traditional



Special



Abbreviated

STANDARD TITLE¹

ISTA 2A (January 2012): ISTA 2 Series Partial Simulation Performance Test Procedure

Please answer the following questions

Yes

No

Is this standard recognized by FDA?² 7FDA Recognition number³

#

Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?

Is a summary report⁴ describing the extent of conformance of the standard used included in the 510(k)?

If no, complete a summary report table.

Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?



Does this standard include acceptance criteria?



If no, include the results of testing in the 510(k).

Does this standard include more than one option or selection of tests?



If yes, report options selected in the summary report table.

Were there any deviations or adaptations made in the use of the standard?

If yes, were deviations in accordance with the FDA supplemental information sheet (SIS)?⁵

Were deviations or adaptations made beyond what is specified in the FDA SIS?



If yes, report these deviations or adaptations in the summary report table.

Were there any exclusions from the standard?



If yes, report these exclusions in the summary report table.

Is there an FDA guidance⁶ that is associated with this standard?

If yes, was the guidance document followed in preparation of this 510(k)?



Title of guidance:

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EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE		
STANDARD TITLE ISTA 2A (January 2012): ISTA 2 Series Partial Simulation Performance Test Procedure		
CONFORMANCE WITH STANDARD SECTIONS*		
SECTION NUMBER N/A	SECTION TITLE Preface	CONFORMANCE? ☐ Yes ☐ No ☒ N/A
TYPE OF DEVIATION OR OPTION SELECTED *		
DESCRIPTION		
JUSTIFICATION Normative Reference Only.		
SECTION NUMBER N/A	SECTION TITLE Scope	CONFORMANCE? ☐ Yes ☐ No ☒ N/A
TYPE OF DEVIATION OR OPTION SELECTED *		
DESCRIPTION		
JUSTIFICATION Normative Reference Only.		
SECTION NUMBER N/A	SECTION TITLE Product Damage Tolerance and Degradation Allowance	CONFORMANCE? ☐ Yes ☐ No ☒ N/A
TYPE OF DEVIATION OR OPTION SELECTED *		
DESCRIPTION		
JUSTIFICATION Normative Reference Only.		
* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary. * Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.		
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**EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE**STANDARD TITLE
ISTA 2A (January 2012): ISTA 2 Series Partial Simulation Performance Test Procedure**CONFORMANCE WITH STANDARD SECTIONS***

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
N/A	Samples	☐ Yes ☒ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

(b)(4)

DESCRIPTION

JUSTIFICATION

(b)(4)

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
N/A	Test Sequence	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
N/A	Equipment Required Atmospheric Conditioning	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
N/A	Equipment Required Compression	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

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EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE

STANDARD TITLE
ISTA 2A (January 2012): ISTA 2 Series Partial Simulation Performance Test Procedure

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER N/A	SECTION TITLE Equipment Required Vibration	CONFORMANCE? ☒ Yes ☐ No ☐ N/A
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TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

SECTION NUMBER N/A	SECTION TITLE Equipment Required Shock	CONFORMANCE? ☒ Yes ☐ No ☐ N/A
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TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

SECTION NUMBER N/A	SECTION TITLE Identification of Faces, Edge and Corners	CONFORMANCE? ☒ Yes ☐ No ☐ N/A
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TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

SECTION NUMBER N/A	SECTION TITLE Packaged - Product Weight and Size Measurement	CONFORMANCE? ☒ Yes ☐ No ☐ N/A
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TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

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EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE		
STANDARD TITLE ISTA 2A (January 2012): ISTA 2 Series Partial Simulation Performance Test Procedure		
CONFORMANCE WITH STANDARD SECTIONS*		
SECTION NUMBER N/A	SECTION TITLE Before You Begin Atmospheric Conditioning	CONFORMANCE? ☒ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED *		
DESCRIPTION		
JUSTIFICATION		
SECTION NUMBER N/A	SECTION TITLE Before You Begin Compression Testing	CONFORMANCE? ☒ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED *		
DESCRIPTION		
JUSTIFICATION		
SECTION NUMBER N/A	SECTION TITLE Before You Begin Vibration Testing	CONFORMANCE? ☒ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED *		
DESCRIPTION		
JUSTIFICATION		
SECTION NUMBER N/A	SECTION TITLE Before You Begin Shock Testing	CONFORMANCE? ☒ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED *		
DESCRIPTION		
JUSTIFICATION		
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Department of Health and Human Services
Food and Drug Administration
STANDARDS DATA REPORT FOR 510(k)s
(To be filled in by applicant)

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TYPE OF 510(K) SUBMISSION

☒ Traditional☐ Special☐ AbbreviatedSTANDARD TITLE ¹

ISTA 2A (January 2012): ISTA 2 Series Partial Simulation Performance Test Procedure

Please answer the following questions

Yes

No

Is this standard recognized by FDA ²?☐☒FDA Recognition number ³

#

Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?

☒☐Is a summary report ⁴ describing the extent of conformance of the standard used included in the 510(k)?☒☐

If no, complete a summary report table.

Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?

☒☐

Does this standard include acceptance criteria?

☒☐

If no, include the results of testing in the 510(k).

Does this standard include more than one option or selection of tests?

☐☒

If yes, report options selected in the summary report table.

Were there any deviations or adaptations made in the use of the standard?

☐☒If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) ⁵?☐☐

Were deviations or adaptations made beyond what is specified in the FDA SIS?

☐☒

If yes, report these deviations or adaptations in the summary report table.

Were there any exclusions from the standard?

☐☒

If yes, report these exclusions in the summary report table.

Is there an FDA guidance ⁶ that is associated with this standard?☐☒

If yes, was the guidance document followed in preparation of this 510(k)?

☐☐

Title of guidance:

¹ The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

² Authority [21 U.S.C. 360d], <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm>

³ <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm>

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address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

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EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE		
STANDARD TITLE ISTA 2A (January 2012): ISTA 2 Series Partial Simulation Performance Test Procedure		
CONFORMANCE WITH STANDARD SECTIONS*		
SECTION NUMBER N/A	SECTION TITLE Atmospheric Conditioning Test Block	CONFORMANCE? ☒ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED *		
DESCRIPTION		
JUSTIFICATION		
SECTION NUMBER N/A	SECTION TITLE Compression Test Block	CONFORMANCE? ☒ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED *		
DESCRIPTION		
JUSTIFICATION		
SECTION NUMBER N/A	SECTION TITLE First Vibration Test Block	CONFORMANCE? ☒ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED *		
DESCRIPTION		
JUSTIFICATION		
* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary. ° Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.		
This section applies only to requirements of the Paperwork Reduction Act of 1995. *DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.* The burden time for this collection of information is estimated to average 1 hour per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to: Department of Health and Human Services Food and Drug Administration Office of Chief Information Officer Paperwork Reduction Act (PRA) Staff PRASStaff@fda.hhs.gov <i>"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number."</i>		

EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE

STANDARD TITLE
ISTA 2A (January 2012): ISTA 2 Series Partial Simulation Performance Test Procedure

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
N/A	Shock Test Block	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
N/A	Second Vibration Test Block	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
N/A	Before You Begin Report	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☒ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

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TYPE OF 510(K) SUBMISSION

☒ Traditional☐ Special☐ AbbreviatedSTANDARD TITLE ¹

ASTM F2096-11: Standard Test Method for Detecting Gross Leaks in Packaging by Internal Pressurization (Bubble Test)

Please answer the following questions

Yes

No

Is this standard recognized by FDA ²?☒☐FDA Recognition number ³

#14-359

Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?

☒☐Is a summary report ⁴ describing the extent of conformance of the standard used included in the 510(k)?☒☐

If no, complete a summary report table.

Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?

☒☐

Does this standard include acceptance criteria?

☒☐

If no, include the results of testing in the 510(k).

Does this standard include more than one option or selection of tests?

☒☐

If yes, report options selected in the summary report table.

Were there any deviations or adaptations made in the use of the standard?

☐☒If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) ⁵?☐☐

Were deviations or adaptations made beyond what is specified in the FDA SIS?

☐☒

If yes, report these deviations or adaptations in the summary report table.

Were there any exclusions from the standard?

☐☒

If yes, report these exclusions in the summary report table.

Is there an FDA guidance ⁶ that is associated with this standard?☐☒

If yes, was the guidance document followed in preparation of this 510(k)?

☐☐

Title of guidance:

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EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE		
STANDARD TITLE ASTM F2096-11: Standard Test Method for Detecting Gross Leaks in Packaging by Internal Pressurization (Bubble Test)		
CONFORMANCE WITH STANDARD SECTIONS*		
SECTION NUMBER 1	SECTION TITLE Scope	CONFORMANCE? ☐ Yes ☐ No ☒ N/A
TYPE OF DEVIATION OR OPTION SELECTED *		
DESCRIPTION		
JUSTIFICATION Normative Reference Only.		
SECTION NUMBER 2	SECTION TITLE Referenced Documents	CONFORMANCE? ☐ Yes ☐ No ☒ N/A
TYPE OF DEVIATION OR OPTION SELECTED *		
DESCRIPTION		
JUSTIFICATION Normative Reference Only.		
SECTION NUMBER 3	SECTION TITLE Terminology	CONFORMANCE? ☐ Yes ☐ No ☒ N/A
TYPE OF DEVIATION OR OPTION SELECTED *		
DESCRIPTION		
JUSTIFICATION Normative Reference Only.		
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EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLESTANDARD TITLE
ASTM F2096-11: Standard Test Method for Detecting Gross Leaks in Packaging by Internal Pressurization (Bubble Test)

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
4	Summary of Test Method	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
5	Significance and Use	☐ Yes ☐ No ☒ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
6	Apparatus	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
7	Sampling	☐ Yes ☒ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

(b)(4)

DESCRIPTION

JUSTIFICATION

(b)(4)

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EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE

STANDARD TITLE

ASTM F2096-11: Standard Test Method for Detecting Gross Leaks in Packaging by Internal Pressurization (Bubble Test)

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER

8

SECTION TITLE

Conditioning

CONFORMANCE?

☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

SECTION NUMBER

9

SECTION TITLE

Procedure

CONFORMANCE?

☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

(b)(4)

DESCRIPTION

JUSTIFICATION

(b)(4)

SECTION NUMBER

11

SECTION TITLE

Precision and Bias

CONFORMANCE?

☐ Yes ☐ No ☒ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

(b)(4)

SECTION NUMBER

12

SECTION TITLE

Keywords

CONFORMANCE?

☐ Yes ☐ No ☒ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

Normative Reference Only.

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**EXTENT OF STANDARD CONFORMANCE
SUMMARY REPORT TABLE**

STANDARD TITLE
ASTM F2096-11: Standard Test Method for Detecting Gross Leaks in Packaging by Internal Pressurization (Bubble Test)

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
N/A	Annex	☐ Yes ☐ No ☒ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION
Normative Reference Only.

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☒ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☒ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
		☐ Yes ☐ No ☒ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

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TYPE OF 510(K) SUBMISSION



Traditional



Special



Abbreviated

STANDARD TITLE ¹

ASTM F88/F88M - 09: Standard Test Method for Seal Strength of Flexible Barrier Material

Please answer the following questions

Yes

No

Is this standard recognized by FDA ²?FDA Recognition number ³

#

Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?

Is a summary report ⁴ describing the extent of conformance of the standard used included in the 510(k)?

If no, complete a summary report table.

Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?



Does this standard include acceptance criteria?



If no, include the results of testing in the 510(k).

Does this standard include more than one option or selection of tests?



If yes, report options selected in the summary report table.

Were there any deviations or adaptations made in the use of the standard?

If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) ⁵?

Were deviations or adaptations made beyond what is specified in the FDA SIS?



If yes, report these deviations or adaptations in the summary report table.

Were there any exclusions from the standard?



If yes, report these exclusions in the summary report table.

Is there an FDA guidance ⁶ that is associated with this standard?

If yes, was the guidance document followed in preparation of this 510k?



Title of guidance:

¹ The formatting convention for the title is: (SDO) [numeric identifier] [title of standard] [date of publication]

² Authority [21 U.S.C. 360d], <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm>

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EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE

STANDARD TITLE
 ASTM F88/F88M - 09: Standard Test Method for Seal Strength of Flexible Barrier Material

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER 1	SECTION TITLE Scope	CONFORMANCE? ☐ Yes ☐ No ☒ N/A
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TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION
 Normative Reference Only.

SECTION NUMBER 2	SECTION TITLE Reference Documents	CONFORMANCE? ☐ Yes ☐ No ☒ N/A
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TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION
 Normative Reference Only.

SECTION NUMBER 3	SECTION TITLE Terminology	CONFORMANCE? ☐ Yes ☐ No ☒ N/A
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TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION
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TYPE OF 510(K) SUBMISSION

☒ Traditional☐ Special☐ AbbreviatedSTANDARD TITLE ¹

ASTM F1886/F 1886M-09 (Reapproved 2013): Standard Test Method for Determining Integrity of Seals for Flexible Packaging for Visual Inspection

Please answer the following questions

Yes

No

Is this standard recognized by FDA ²?☒☐FDA Recognition number ³

#14-288

Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?

☒☐

Is a summary report ⁴ describing the extent of conformance of the standard used included in the 510(k)?

☒☐

If no, complete a summary report table.

Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?

☒☐

Does this standard include acceptance criteria?

☒☐

If no, include the results of testing in the 510(k).

Does this standard include more than one option or selection of tests?

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If yes, report options selected in the summary report table.

Were there any deviations or adaptations made in the use of the standard?

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Were deviations or adaptations made beyond what is specified in the FDA SIS?

☐☒

If yes, report these deviations or adaptations in the summary report table.

Were there any exclusions from the standard?

☐☒

If yes, report these exclusions in the summary report table.

Is there an FDA guidance ⁶ that is associated with this standard?☐☒

If yes, was the guidance document followed in preparation of this 510k?

☐☐

Title of guidance:

¹ The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

² Authority [21 U.S.C. 360d], <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm>

³ <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm>

⁴ The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and

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EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE

STANDARD TITLE

ASTM F1886/F 1886M-09 (Reapproved 2013): Standard Test Method for Determining Integrity of Seals for Flexible Packaging for Visual Inspection

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
1	Scope	☐ Yes ☐ No ☒ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

Normative Reference Only.

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
2	Reference Documents	☐ Yes ☐ No ☒ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
3	Terminology	☐ Yes ☐ No ☒ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

Normative Reference Only.

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

♦ Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.

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EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE

STANDARD TITLE
ASTM F1886/F 1886M-09 (Reapproved 2013): Standard Test Method for Determining Integrity of Seals for Flexible Packaging for Visual Inspection

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
4	Summary of Test Method	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
5	Significance of Use	☐ Yes ☐ No ☒ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION
Normative Reference Only.

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
6	Apparatus	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
7	Procedure	☒ Yes ☐ No ☐ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

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EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE

STANDARD TITLE

ASTM F1886/F 1886M-09 (Reapproved 2013): Standard Test Method for Determining Integrity of Seals for Flexible Packaging for Visual Inspection

CONFORMANCE WITH STANDARD SECTIONS***SECTION NUMBER**

8

SECTION TITLE

Precision and Bias

CONFORMANCE?☐ Yes☐ No☒ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

Normative Reference Only.

SECTION NUMBER

9

SECTION TITLE

Keywords

CONFORMANCE?☐ Yes☐ No☒ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

Normative Reference Only.

SECTION NUMBER

N/A

SECTION TITLE

Appendix

CONFORMANCE?☐ Yes☐ No☒ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

Normative Reference Only.

SECTION NUMBER**SECTION TITLE****CONFORMANCE?**☐ Yes☐ No☒ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

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Department of Health and Human Services
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(To be filled in by applicant)

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TYPE OF 510(K) SUBMISSION

☒ Traditional☐ Special☐ AbbreviatedSTANDARD TITLE¹

ASTM F1980-07 (Reapproved 2011): Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices

Please answer the following questions

Yes

No

Is this standard recognized by FDA²?☒☐FDA Recognition number³

#14-229

Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?

☒☐Is a summary report⁴ describing the extent of conformance of the standard used included in the 510(k)?☒☐

If no, complete a summary report table.

Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?

☒☐

Does this standard include acceptance criteria?

☒☐

If no, include the results of testing in the 510(k).

Does this standard include more than one option or selection of tests?

☒☐

If yes, report options selected in the summary report table.

Were there any deviations or adaptations made in the use of the standard?

☐☒If yes, were deviations in accordance with the FDA supplemental information sheet (SIS)⁵?☐☐

Were deviations or adaptations made beyond what is specified in the FDA SIS?

☐☒

If yes, report these deviations or adaptations in the summary report table.

Were there any exclusions from the standard?

☐☒

If yes, report these exclusions in the summary report table.

Is there an FDA guidance⁶ that is associated with this standard?☐☒

If yes, was the guidance document followed in preparation of this 510(k)?

☐☐

Title of guidance:

¹ The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

² Authority [21 U.S.C. 350d], <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm>

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EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE

STANDARD TITLE
 ASTM F1980-07 (Reapproved 2011): Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
1	Scope	☐ Yes ☐ No ☒ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION
 Normative Reference Only.

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
2	Reference Documents	☐ Yes ☐ No ☒ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION
 Normative Reference Only.

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
3	Terminology	☐ Yes ☐ No ☒ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION
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EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE

STANDARD TITLE
ASTM F1980-07 (Reapproved 2011): Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER 4	SECTION TITLE Significance and Use	CONFORMANCE? ☐ Yes ☐ No ☒ N/A
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TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION
Normative Reference Only.

SECTION NUMBER 5	SECTION TITLE Apparatus	CONFORMANCE? ☒ Yes ☐ No ☐ N/A
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TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

SECTION NUMBER 6	SECTION TITLE Accelerated Aging Theory	CONFORMANCE? ☐ Yes ☐ No ☒ N/A
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TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION
Normative Reference Only.

SECTION NUMBER 7	SECTION TITLE Accelerate Aging Plan	CONFORMANCE? ☒ Yes ☐ No ☐ N/A
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TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

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EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE

STANDARD TITLE
ASTM F1980-07 (Reapproved 2011): Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER 8	SECTION TITLE Post Aging Testing Guidance	CONFORMANCE? ☒ Yes ☐ No ☐ N/A
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TYPE OF DEVIATION OR OPTION SELECTED *

(b)(4)

DESCRIPTION

JUSTIFICATION

(b)(4)

SECTION NUMBER 9	SECTION TITLE Report	CONFORMANCE? ☒ Yes ☐ No ☐ N/A
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TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

SECTION NUMBER 10	SECTION TITLE Keywords	CONFORMANCE? ☐ Yes ☐ No ☒ N/A
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TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

Normative Reference Only.

SECTION NUMBER 11	SECTION TITLE Appendices	CONFORMANCE? ☐ Yes ☐ No ☒ N/A
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TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

Normative Reference Only.

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TYPE OF 510(k) SUBMISSION

☒ Traditional☐ Special☐ AbbreviatedSTANDARD TITLE ¹

ASTM 1929-12: Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration

Please answer the following questions

Yes

No

Is this standard recognized by FDA ² ?☒☐FDA Recognition number ³

#14-378

Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?

☒☐Is a summary report ⁴ describing the extent of conformance of the standard used included in the 510(k)?
If no, complete a summary report table.☒☐

Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?

☒☐Does this standard include acceptance criteria?
If no, include the results of testing in the 510(k).☒☐Does this standard include more than one option or selection of tests?
If yes, report options selected in the summary report table.☒☐Were there any deviations or adaptations made in the use of the standard?.....
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) ⁵ ?☐☒☐☐Were deviations or adaptations made beyond what is specified in the FDA SIS?.....
If yes, report these deviations or adaptations in the summary report table.☐☒Were there any exclusions from the standard?
If yes, report these exclusions in the summary report table.☐☒Is there an FDA guidance ⁶ that is associated with this standard?.....
If yes, was the guidance document followed in preparation of this 510(k)?☐☒☐☐

Title of guidance:

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EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE

STANDARD TITLE
ASTM 1929-12: Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
1	Scope	☐ Yes ☐ No ☒ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION
Normative Reference Only.

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
2	Reference Documents	☐ Yes ☐ No ☒ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION
Normative Reference Only.

SECTION NUMBER	SECTION TITLE	CONFORMANCE?
3	Terminology	☐ Yes ☐ No ☒ N/A

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION
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EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE		
STANDARD TITLE ASTM 1929-12: Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration		
CONFORMANCE WITH STANDARD SECTIONS*		
SECTION NUMBER 4	SECTION TITLE Significance and Use	CONFORMANCE? ☐ Yes ☐ No ☒ N/A
TYPE OF DEVIATION OR OPTION SELECTED *		
DESCRIPTION		
JUSTIFICATION Normative Reference Only.		
SECTION NUMBER 5	SECTION TITLE Apparatus	CONFORMANCE? ☒ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED *		
(b)(4)		
DESCRIPTION		
JUSTIFICATION (b)(4)		
SECTION NUMBER 6	SECTION TITLE Safety Precautions	CONFORMANCE? ☒ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED *		
DESCRIPTION		
JUSTIFICATION		
SECTION NUMBER 7	SECTION TITLE Test Specimen	CONFORMANCE? ☒ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED *		
DESCRIPTION		
JUSTIFICATION		
* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary. * Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.		

EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE		
STANDARD TITLE ASTM 1929-12: Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration		
CONFORMANCE WITH STANDARD SECTIONS*		
SECTION NUMBER 8	SECTION TITLE Calibration and Standardization	CONFORMANCE? ☒ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED *		
DESCRIPTION		
JUSTIFICATION		
SECTION NUMBER 9	SECTION TITLE Sampling	CONFORMANCE? ☐ Yes ☒ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED *		
(b)(4)		
DESCRIPTION		
JUSTIFICATION		
(b)(4)		
SECTION NUMBER 10	SECTION TITLE Conditioning	CONFORMANCE? ☒ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED *		
DESCRIPTION		
JUSTIFICATION		
SECTION NUMBER 11	SECTION TITLE Procedure	CONFORMANCE? ☒ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED *		
(b)(4)		
DESCRIPTION		
JUSTIFICATION		
(b)(4)		

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

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EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE		
STANDARD TITLE ASTM 1929-12: Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration		
CONFORMANCE WITH STANDARD SECTIONS*		
SECTION NUMBER 12	SECTION TITLE Report	CONFORMANCE? ☒ Yes ☐ No ☐ N/A
TYPE OF DEVIATION OR OPTION SELECTED *		
DESCRIPTION		
JUSTIFICATION		
SECTION NUMBER 13	SECTION TITLE Precision and Bias	CONFORMANCE? ☐ Yes ☐ No ☒ N/A
TYPE OF DEVIATION OR OPTION SELECTED *		
DESCRIPTION		
JUSTIFICATION Normative Reference Only.		
SECTION NUMBER 14	SECTION TITLE Keywords	CONFORMANCE? ☐ Yes ☐ No ☒ N/A
TYPE OF DEVIATION OR OPTION SELECTED *		
DESCRIPTION		
JUSTIFICATION Normative Reference Only.		
SECTION NUMBER N/A	SECTION TITLE Appendix	CONFORMANCE? ☐ Yes ☐ No ☒ N/A
TYPE OF DEVIATION OR OPTION SELECTED *		
DESCRIPTION		
JUSTIFICATION Normative Reference Only.		
* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary. * Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.		

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TYPE OF 510(K) SUBMISSION



Traditional



Special



Abbreviated

STANDARD TITLE¹

ASTM F1608-16, Standard Test Method For Microbial Ranking Of Porous Packaging Materials (Exposure Chamber Method)

Please answer the following questions

Yes

No

Is this standard recognized by FDA²?FDA Recognition number³

#14-496

Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?

Is a summary report⁴ describing the extent of conformance of the standard used included in the 510(k)?

If no, complete a summary report table.

Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?



Does this standard include acceptance criteria?



If no, include the results of testing in the 510(k).

Does this standard include more than one option or selection of tests?



If yes, report options selected in the summary report table.

Were there any deviations or adaptations made in the use of the standard?

If yes, were deviations in accordance with the FDA supplemental information sheet (SIS)⁵?

Were deviations or adaptations made beyond what is specified in the FDA SIS?



If yes, report these deviations or adaptations in the summary report table.

Were there any exclusions from the standard?



If yes, report these exclusions in the summary report table.

Is there an FDA guidance⁶ that is associated with this standard?

If yes, was the guidance document followed in preparation of this 510k?



Title of guidance:

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EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE

STANDARD TITLE
 ASTM F1608-16, Standard Test Method For Microbial Ranking Of Porous Packaging Materials (Exposure Chamber Method)

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE? ☐ Yes ☐ No ☐ N/A
----------------	---------------	---

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE? ☐ Yes ☐ No ☐ N/A
----------------	---------------	---

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE? ☐ Yes ☐ No ☐ N/A
----------------	---------------	---

TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

* Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 1 hour per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
 Food and Drug Administration
 Office of Chief Information Officer
 Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number."

Department of Health and Human Services
Food and Drug Administration
STANDARDS DATA REPORT FOR 510(k)s
(To be filled in by applicant)

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).

TYPE OF 510(k) SUBMISSION

☒ Traditional☐ Special☐ AbbreviatedSTANDARD TITLE ¹

ASTM F2638-12, Standard Test Method For Using Aerosol Filtration For Measuring The Performance Of Porous Packaging Materials As A Surrogate Microbial Barrier

Please answer the following questions

Yes No

Is this standard recognized by FDA ²? ☒ ☐

FDA Recognition number ³ #14-377

Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)? ☒ ☐

Is a summary report ⁴ describing the extent of conformance of the standard used included in the 510(k)? ☒ ☐
If no, complete a summary report table.

Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device? ☒ ☐

Does this standard include acceptance criteria? ☐ ☒
If no, include the results of testing in the 510(k).

Does this standard include more than one option or selection of tests? ☐ ☒
If yes, report options selected in the summary report table.

Were there any deviations or adaptations made in the use of the standard? ☐ ☒
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS) ⁵? ☐ ☐

Were deviations or adaptations made beyond what is specified in the FDA SIS? ☐ ☒
If yes, report these deviations or adaptations in the summary report table.

Were there any exclusions from the standard? ☐ ☒
If yes, report these exclusions in the summary report table.

Is there an FDA guidance ⁶ that is associated with this standard? ☐ ☒
If yes, was the guidance document followed in preparation of this 510(k)? ☐ ☐

Title of guidance:

¹ The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

² Authority [21 U.S.C. 360d], <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/default.htm>

³ <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm>

⁴ The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and

address of the test laboratory or certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

⁵ The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm>

⁶ The online search for CDRH Guidance Documents can be found at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm>

EXTENT OF STANDARD CONFORMANCE SUMMARY REPORT TABLE

STANDARD TITLE

ASTM F2638-12, Standard Test Method For Using Aerosol Filtration For Measuring The Performance Of Porous Packaging Materials As A Surrogate Microbial Barrier

CONFORMANCE WITH STANDARD SECTIONS*

SECTION NUMBER	SECTION TITLE	CONFORMANCE? ☐ Yes ☐ No ☐ N/A
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TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE? ☐ Yes ☐ No ☐ N/A
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TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

SECTION NUMBER	SECTION TITLE	CONFORMANCE? ☐ Yes ☐ No ☐ N/A
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TYPE OF DEVIATION OR OPTION SELECTED *

DESCRIPTION

JUSTIFICATION

* For completeness list all sections of the standard and indicate whether conformance is met. If a section is not applicable (N/A) an explanation is needed under "justification." Some standards include options, so similar to deviations, the option chosen needs to be described and adequately justified as appropriate for the subject device. Explanation of all deviations or description of options selected when following a standard is required under "type of deviation or option selected," "description" and "justification" on the report. More than one page may be necessary.

* Types of deviations can include an exclusion of a section in the standard, a deviation brought out by the FDA supplemental information sheet (SIS), a deviation to adapt the standard to the device, or any adaptation of a section.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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Department of Health and Human Services
Food and Drug Administration
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Section 005 510(k) Company Cover Letter

The 510(k) Cover Letter is duplicated at the beginning of the submission and in the pages that follow.



December 14, 2017

U.S. Food and Drug Administration
Center for Devices and Radiological Health (CDRH)
Document Mail Center – WO66-G609
10903 New Hampshire Avenue
Silver Spring, Maryland 20993-0002

Re: Traditional 510(k) Submission
Stryker Neurovascular's AXS Catalyst™ Distal Access Catheter

Regulation Number:	21 CFR 870.1250
Trade Name or Proprietary Name:	AXS Catalyst™ Distal Access Catheter
Common Name or Classification Name:	Percutaneous Catheter
Regulation Class:	Class II
Product Code:	DQY, and proposed addition of NRY

To Whom It May Concern:

Pursuant to Section 510(k) of the Federal Food, Drug and Cosmetic Act, and in conformance with 21 CFR 807, Stryker Neurovascular hereby submits this Traditional 510(k) requesting review and clearance of an additional indication for use for the subject device as well as a request for an additional product code, NRY.

(b)(4)

This notification adds an indication for use for the AXS Catalyst™ Distal Access Catheter to include aspiration (with the associated NRY Product Code) when used as part of the aspiration system, and to add a warning to the labeling and additional operating



instructions to reflect the additional indication for aspiration. The aspiration system consists of the AXS Catalyst™ Distal Access Catheter and the aspiration accessories (Medela Dominant Flex Pump with Suction Jar, AXS Universal Aspiration Tubing, and AXS Universal Liner Set).

Substantial equivalence is claimed to the Penumbra Aspiration System which consists of the Penumbra Pump MAX, Penumbra Reperfusion Catheter, and Penumbra Aspiration Tubing (K160449) as a primary predicate and the AXS Catalyst™ Distal Access Catheter (K151667) as a reference predicate.

The AXS Catalyst™ Distal Access Catheter product family is comprised of the following intermediate catheter subtypes:

- AXS Catalyst™ 5 Distal Access Catheter
- AXS Catalyst™ 6 Distal Access Catheter

There are no changes to the design of the catheter, and testing was conducted for the purpose of supporting the additional indication for use and the addition of the new Product Code NRY.

As part of this submission, the AXS Catalyst Catheters have been shown to be safe and effective at aspirating clots using aspiration systems that provide at least -68 kPa [-20.08 in HG]. Stryker has partnered with Medela AG, who manufactures a pump at the required specifications, to offer a neurovascular recanalization aspiration solution. The pump and accessories are legally manufactured by Medela AG, and the catheter is manufactured by Stryker, however these pieces may be marketed together. This arrangement is covered under a distribution, quality, and co-marketing agreements. The Dominant Flex Pump and accessories were used for testing to support this 510(k). Medela's Dominant Flex Pump was recently cleared under K170329.

Stryker will be distributing the components legally manufactured by Medela AG. The components will enter Stryker's distribution center as finished goods and no modifications will be made.

The AXS Catalyst Distal Access Catheter when used as part of the aspiration system has the following similarities to the predicate devices cleared under the above listed premarket notifications:

- Similar intended use/indications for use
- Same or similar materials
- Same or similar design
- Same or similar operating principles



Successful non-clinical testing results support that the additional indication for use with the corresponding product code is appropriate. Additionally, the testing results demonstrated that the AXS Catalyst Distal Access Catheter when used as part of the aspiration system is as safe and effective as the predicate devices.

Risk assessments have been reviewed in accordance with EN ISO 14971. The conclusions drawn from risk assessments, bench testing, and animal testing as well as a review of publicly available clinical evidence for the primary predicate is that the AXS Catalyst Distal Access Catheters when used as part of the aspiration system are substantially equivalent to the predicate devices. The device performs as designed, is suitable for the additional indication for use, and the benefits of the device outweigh any residual risks when used in accordance with device Instructions for Use.

Stryker Neurovascular considers its intent to market this proposed device as confidential commercial information and requests that it be treated as such by FDA. Stryker has taken precautions to protect the confidentiality of the intent to market these devices and understands that the submission to the government of false information is prohibited by 18 U.S.C. 1001 and 21 U.S.C. 331 (q).

Two copies of this submission are being provided; one paper copy and one electronic copy. The electronic copy of the submission is included on the provided electronic drive. The electronic copy is an exact duplicate of the paper copy with the exception of a duplicate of the Company Cover Letter placed at the beginning of the submission.

Thank you in advance for your consideration of our notification. If there are questions, please feel free to contact me at the email address or number listed below.

Sincerely,

(b)(6)

Angelica Beckmann
Director, Regulatory Affairs
Stryker Neurovascular
47900 Bayside Parkway
Fremont, California 94538
510-413-2900
angelica.beckmann@stryker.com

Section 006 Indications for Use Statement

The Indications for Use Statement (FDA Form 3881) follows this page.

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.

(b)(4)

Section 007 510(k) Summary

The 510(k) Summary is provided on the following pages.

Section 007 510(k) Summary

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Section 007 510(k) Summary

Attachment 7A – 510(k) Summary Redline

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Section 008 Truthful and Accuracy Statement

The Truthful and Accuracy Statement is provided on the following pages.

Section 008 Truthful and Accuracy Statement

TRUTHFUL AND ACCURATE STATEMENT

Pursuant to 21 CFR 807.87(k), I certify that, in my capacity as Director Regulatory Affairs for Stryker Neurovascular, I believe to the best of my knowledge, that all data and information submitted in this premarket notification are truthful and accurate, and that no material fact has been omitted.

(b)(6)

Signature ✓

Angelica Beckmann, Director Regulatory Affairs

Typed Name and Title

Stryker Neurovascular

Company

December 14, 2017

Date

Not yet assigned

Premarket Notification (510(k) Number

Section 009 Class III Summary and Certification

The Class III Summary and Certification is provided on the following pages.

Section 009 Class III Summary and Certification

The AXS Catalyst™ Distal Access Catheter devices are Class II devices per 21 CFR 870.1250. Class III is not applicable for the subject device.

Section 010 Financial Certification or Disclosure

The Financial Disclosure is provided on the following pages.

Section 010 Financial Certification or Disclosure Statement

Not applicable. The summary of clinical evidence was derived from published clinical study information rather than a Stryker Neurovascular sponsored clinical trial.

Section 011 Executive Summary

The Executive Summary is provided on the following pages.

Section 011 Executive Summary

Submission Background:

This new Traditional 510(k) submission (b)(4)

(b)(4)

Section 011, Table 1: Associated Prior Submissions and FDA Feedback			
Submission #	Dated	Reason	Attachment Location*
K151667	Submitted on June 18, 2015 Cleared on November 13, 2015	Original 510(k)	N/A
(b)(4)			

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(b)(4)

Purpose of the Submission:

Device Trade Name: AXS Catalyst™ Distal Access Catheter

Common Name: Percutaneous Catheter

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

Product Code: DQY, Proposed addition of NRY

The subject device, AXS Catalyst™ Distal Access Catheter, was cleared under K151667.

The purpose of the submission is an addition of an indication for use to include aspiration (with the associated NRY Product Code), and the addition of a warning to labeling with additional operating instructions to make clear that the device may be

used for aspiration with an external source of vacuum.

(b)(4)

As part of this submission, the AXS Catalyst Catheters have been shown to be safe and effective at aspirating clots using aspiration systems that provide at least -68 kPa [-20.08

in Hg].

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Device Description:

The AXS Catalyst™ Distal Access Catheter is a sterile single use, single lumen, variable stiffness catheter designed for use in 1) facilitating the insertion and guidance of appropriately sized interventional devices into the peripheral and neuro vascular system, and 2) the removal of thrombus from the neuro vasculature using continuous aspiration. 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, Tuohy Borst Valve with Sideport, and Peel Away Introducer. The Rotating Hemostatic Valve (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. When used as part of the aspiration system, the AXS Catalyst Distal Access Catheter requires a minimum vacuum pressure of -68 kPa [-20.08 in Hg] from an external device (Medela Dominant Flex Pump). The aspiration accessories are the Medela Dominant Flex Pump with Suction Jar, AXS Universal Aspiration Tubing, and AXS Universal Liner Set. Accessory details are provided in **Section 012**. A picture of the aspiration system which consists of the AXS Catalyst Distal Access Catheter, Medela Dominant Flex Pump with Suction Jar, and accessories is provided below in **Section 011, Figure 1**.

(b)(4)

Bench and Animal testing utilizing the Medela Dominant Flex Pump was conducted to successfully demonstrate aspiration and is provided in **Sections 019 and 020**. The AXS Catalyst Distal Access Catheter is available in the following configurations outlined in **Section 011, Table 3**.

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(b)(4)

Operating Principle

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 aspiration source, 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 Universal Aspiration Tubing, and the AXS Universal Liner Set are disposed of per the institution's procedures. The Medela Dominant Flex Pump and Suction Jar are cleaned per the instructions provided with the pump.

The instructions for the Medela Dominant Flex Pump with Suction Jar, AXS Universal Liner Set, and the AXS Universal Aspiration Tubing can be found in the associated cleared Medela AG 510(k) K170329. For the purpose of the AXS Catalyst Distal Access Catheter, the Medela Dominant Flex Pump is the external aspiration source. The AXS Universal Liner Set and the AXS Universal Aspiration Tubing are accessories to the pump.

Packaging

Each AXS Catalyst Distal Access Catheter comes packaged inside a packaging hoop; the packaging hoop is placed on a packaging hoop card along with device accessories (a Rotating Hemostatic Valve, Tuohy Borst Valve with sideport, and two (2) peel away introducers); the packaging hoop card is then placed within a 9.13 inch x 11.47 inch pouch. The pouch is sealed and then placed inside a shelf carton along with the Directions for Use (DFU). The AXS Catalyst Distal Access Catheter is provided sterile in a single pack (unit per package) only. Additional information regarding the AXS Catalyst Distal Access Catheter packaging is provided in **Section 012** and **Section 015**.

The Medela AG products are packaged separately and details may be found in K130123, K150134 and K170329.

Intended Use / Indications for Use

Cleared 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.

Proposed additional Indication for Use

The AXS Catalyst Distal Access Catheter is indicated for use in the revascularization of patients with acute ischemic stroke secondary to intracranial large vessel occlusive disease (within 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 therapy are candidates for treatment.

Predicate Device Information

The Subject Device and the Predicate Device are identified below in **Section 011, Table 4**.

Section 011, Table 4: Identification of Subject, Primary Predicate and Reference Predicate		
Subject Device	Primary Predicate Device	Reference Predicate Device
Catheter		
AXS Catalyst Distal Access Catheter	Penumbra Reperfusion Catheter	AXS Catalyst Distal Access Catheter
TBD	K090752	K151667
Aspiration Accessories		
• Medela AG Dominant Flex Pump with Suction Jar • Medela AG AXS Universal Aspiration Tubing • Medela AG AXS Universal Liner Set	• Penumbra Max Pump • Penumbra Hi-Flo Aspiration Tubing • Penumbra MAX Canister	N/A
K170329	K160449	N/A

The **Reference Predicate** device is the previously cleared version of the AXS Catheter (K151667). The design, technology, engineering, materials, specifications, sterilization, biocompatibility, and packaging remain the same. The previously cleared testing results remain valid. Since clearance of K151667, the shelf-life (b)(4) two years under the previously cleared accelerated testing protocol.

The **Primary Predicate** device is the Penumbra Reperfusion Catheter cleared under K090752, of which 5MAX ACE¹ and 5MAX are the equivalent devices to compare to the Subject Device.

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¹ The Penumbra ACE60 and Penumbra 5MAX ACE are the same catheter. ACE60 is the trade name and 5MAXACE132 is the catalog number.

http://www.penumbrainc.com/wp-content/uploads/2016/12/10667A_ACE68_Science-of-Aspiration_Brochure_USA.pdf

(b)(4)

The Primary Predicate, the Penumbra Reperfusion Catheter with Aspiration Accessories, has an equivalent fit, form, and function when compared to the AXS Catalyst Catheter with Aspiration Accessories, and has the desired additional indication for use with the associated NRY product code.

A visual examination of the device and packaging identifies a device that is a single lumen, reinforced, variable stiffness shaft catheter designed for use in facilitating the insertion and guidance of an occlusion catheter, infusion catheter or other appropriate microcatheter into a selected blood vessel. The catheters include a radiopaque marker on the distal end for angiographic visualization and a luer hub on the proximal end allowing attachments for flushing and aspiration. The catheter shaft has a hydrophilic coating to reduce friction during use. A rotating hemostatic valve with side-arm adapter is provided with each catheter. The Catheter is provided sterile for single use.

The reference predicate 510(k) submission **K151667** is referenced for the verification and validation testing conducted which remains in effect for the subject device. The Penumbra 510(k) submission **K090752** is referenced in this submission for the intended use / indications for use with the ability to interface with a pump as the external source of vacuum with a minimum vacuum pressure for aspiration of -68 kPa [-20.08 in Hg].

Modifications from Reference Predicate Device

(b)(4)

A comparison of the product features of the Subject Device compared to both the Primary and Reference Predicates is provided in **Section 013**.

(b)(4)

Risk Assessment

Risk assessment of the AXS Catalyst Distal Access Catheter when used as part of the aspiration system has been conducted in accordance with EN ISO 14971. Stryker Neurovascular has determined that an additional warning is needed for the DFU to address an identified risk to users. Although a new warning was added, no new adverse events were identified. **Section 014** provides proposed labeling with the new warning.

Performance Data - Bench Testing

As the Subject Device and Primary Predicate device are physically equivalent, all previously submitted performance testing data is still applicable. Additional testing was performed to substantiate the additional indication for use when compared to the Primary Predicate device as outlined in **Section 011, Table 5** below. Full details are provided in **Sections 019 and 020**.

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Section 011, Table 7: Overview of Design Verification Testing Results

(b)(4)

Section 011, Table 7: Overview of Design Verification Testing Results

(b)(4)

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Performance Testing - Animal

Two (2) In-Vivo Acute and Chronic Safety Evaluations of the AXS Catalyst Distal Access Catheter (subject device) combined with Direct Aspiration from a pump (Medela Dominant Flex Surgical Suction Pump) were conducted in a porcine vascular model. (b)(4)

(b)(4)

The animal studies were conducted in compliance with applicable requirements in the GLP regulation (21 CFR Part 58). An overview of the animal studies test method is provided in **Section 011, Table 8** below. The associated report can be found in **Section 020**.

(b)(4)

(b)(4)

Clinical Information

Clinical information obtained from published articles for similar catheters including the Primary Predicate is provided in **Section 021**. The analysis of published clinical evidence demonstrates the requested indication, with the associated product code, is appropriate for the Subject Device given the equivalent device design form, fit, and function when compared to the Primary Predicate Device.

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 and were cleared as part of K151667. Real time Shelf Life Testing is ongoing and was described within the Reference predicate submission which cleared under K151667. An overview is provided in **Section 015**.

Sterilization

There were no changes to the Sterilization processes. Testing results were provided as part of the reference predicate submission for K151667. An overview is provided in **Section 015**.

Biocompatibility

The materials for producing the product remain the same as the reference predicate. Testing results were provided as part of the reference predicate submission K151667. An overview is provided in **Section 016**.

Conclusion

Stryker Neurovascular has demonstrated the subject AXS Catalyst Distal Access Catheter when used as part of the aspiration system is substantially equivalent to the Primary Predicate Device and the Reference Predicate Device based on intended use, materials, design, and the same fundamental operating principles. The conclusions drawn from risk assessment, the animal, bench testing conducted using the subject device compared to the Primary Predicate, and a review of available real world evidence from published articles demonstrate that the device is suitable for the additional indication for use with the associated NRY Product Code. Additionally, non-clinical testing results and risk assessment also 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 Distal Access Catheter when used as part of the aspiration system is as safe, as effective, and performs as well as the legally marketed Primary and Reference Predicate devices.

Section 011 Executive Summary

Attachment 11A -

(b)(4)

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CONFIDENTIAL

Stryker Neurovascular
47900 Bayside
Parkway
Fremont, CA 94538

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Section 011 Executive Summary

Attachment 11B -

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Section 011 Executive Summary

Attachment 11C – Medela AG Letter of Authority

Attachment is individually paginated.

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Section 012 Device Description

The Device Description is provided on the following pages.

Section 012 Device Description

The aspiration system consists of the AXS Catalyst™ Distal Access Catheter and the aspiration accessories (Medela Dominant Flex Pump with Suction Jar, AXS Universal Aspiration Tubing, and the AXS Universal Liner Set).

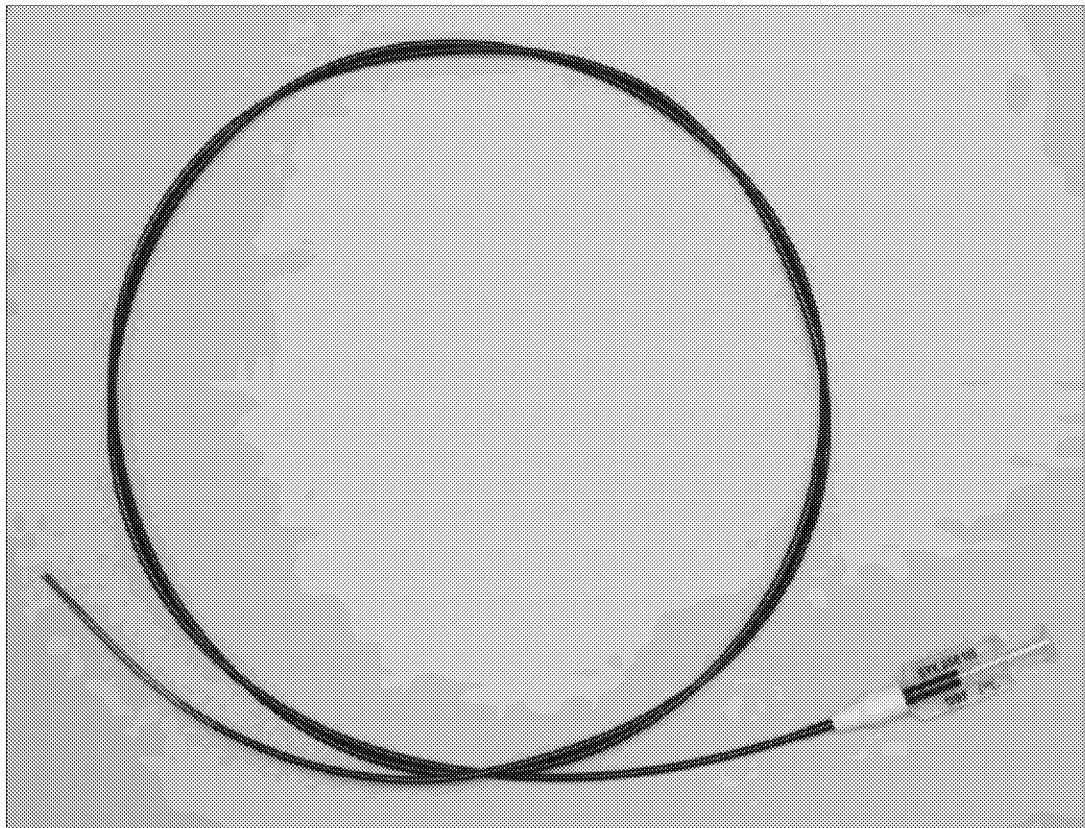
The subject device, AXS Catalyst™ Distal Access Catheter, is identical to the reference predicate which was cleared under **K151667**. A representative image of the aspiration system is provided in **Section 012, Figure 1**.

(b)(4)

Description of Subject Device

The AXS Catalyst™ Distal Access Catheter is a sterile single use, single lumen, variable stiffness catheter designed for use in 1) facilitating the insertion and guidance of appropriately sized interventional devices into the peripheral and neuro vascular system, and 2) the removal of

thrombus from the neuro vasculature using continuous aspiration. 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. A representative image of the catheter is provided in **Section 012, Figure 2** . 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.



Section 012, Figure 2: Representative Picture of the AXS Catalyst™ Distal Access Catheter

Subject Device Configurations

The AXS Catalyst Distal Access Catheter is available in the configurations outlined in **Section 012, Table 1: AXS Catalyst Catheter Configurations.**

(b)(4)

Section 012, Figure 4; and Section 012, Figure 5.

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(b)(4)



Section 012, Figure 13: Dominant Flex Pump with Suction Jar, AXS Universal Aspiration Tubing, AXS Universal Liner Set (Clot Finder not shown)

(b)(4)

Medela Dominant Flex Suction Jar

(b)(4)

AXS Universal Aspiration Tubing

Pump tubing is used for transport of body fluids from a suction catheter into a collection canister or to transfer the vacuum from the pump to the treatment site. The AXS Universal Aspiration Tubing is depicted in **Section 012, Figure 14**.

(b)(4)

Section 012, Figure 14: AXS Universal Aspiration Tubing

AXS Universal Liner Set

The AXS Universal Liners Set is 510(k) exempt and is depicted in **Section 012, Figure 15**. The AXS Universal Liner Set consists of non-sterile, disposable aspiration canister liners, and the Clot Finder. The Clot Finder is a plastic container with a built in porous plastic screen that is placed in-line between the aspiration tubing and the aspiration canister. It serves as a screen to catch clots as they are aspirated for inspection or analysis. The AXS Universal Liner Set is offered with or without a desiccant.

(b)(4)

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 guidewire. A Peel Away Sheath Introducer 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 Introducer 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 neuro vasculature using aspiration provided by an external aspiration source, 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, AXS Universal Aspiration Tubing, and AXS Universal Liner Set are disposed of per the institution's procedures. The Medela Dominant Flex Pump and Suction Jar are cleaned per the instructions provided with the Medela with the pump.

The Instructions for Use for the Medela Dominant Flex Pump with Suction Jar, AXS Universal Liner Set, and AXS Universal Aspiration Tubing can be found in the associated cleared Medela AG 510(k) K170329. For the purpose of the AXS Catalyst Distal Access Catheter, the Medela Dominant Flex Pump is the external aspiration source. The Medela Dominant Flex Suction Jar, AXS Universal Liner Set, and AXS Universal Aspiration Tubing are accessories to the pump.

Conditions of Use

The AXS Catalyst Distal Access Catheter when used as part of the aspiration system, should only be used by physicians trained in interventional endovascular procedures. Refer to the 'User Information' statement of the DFU provided in **Section 014, Attachment 14B**.

Anatomical Location of Use

For the purposes of this submission and the proposed additional indication for use, the AXS Catalyst Distal Access Catheter 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. Refer to the 'Intended Use/Indication for Use' statement of the DFU provided in **Section 014, Attachment 14B**.

User Interface

User interface is addressed in the Preparation for Use and Directions for Use sections of the DFU provided in **Section 014, Attachment 14B**, which describes the steps to follow for the procedure and describes the appropriate surgical technique.

Device Interactions

Interactions between the AXS Catalyst Distal Access Catheter and the accessories are described in Operational Instructions, Preparations for Use, and Directions for Use sections of

the DFU provided in **Section 014, Attachment 14B**. In particular, for the purpose of the submission, the Aspiration Procedure section for Indication 2 describes the interactions between the devices.

Device Interaction with Patient

For the purpose of this submission and the proposed additional indication for use, the AXS Catalyst Distal Access Catheter 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. Refer to the Intended Use/Indication for Use section of the DFU provided in **Section 014, Attachment 14B**.

Materials

The subject device and the reference predicate device cleared under **K151667** are identical with the exception of the additional indication for use (with the associated addition of the product code NRY), the expanded two-year shelf-life, and the labeling changes. The materials have not changed. Information pertinent to materials, additives, and colorants were provided and cleared with **K151667**. All catheter configurations (AXS Catalyst 6 Catheter and AXS Catalyst 5 Catheter) contain the same materials, with one additional co-extrusion part in the AXS Catalyst 6 Catheter which provides for additional support in the proximal shaft.

For reference, the materials are provided in **Section 012, Table 5**.

Patient Contact

As stated above, the materials have not changed from the previous **K151667** clearance. The information provided in **Section 012, Table 5** describes the patient contact for reference purposes only.

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Description of the Coating Material

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(b)(4)

(b)(4)

Coating Process

(b)(4)

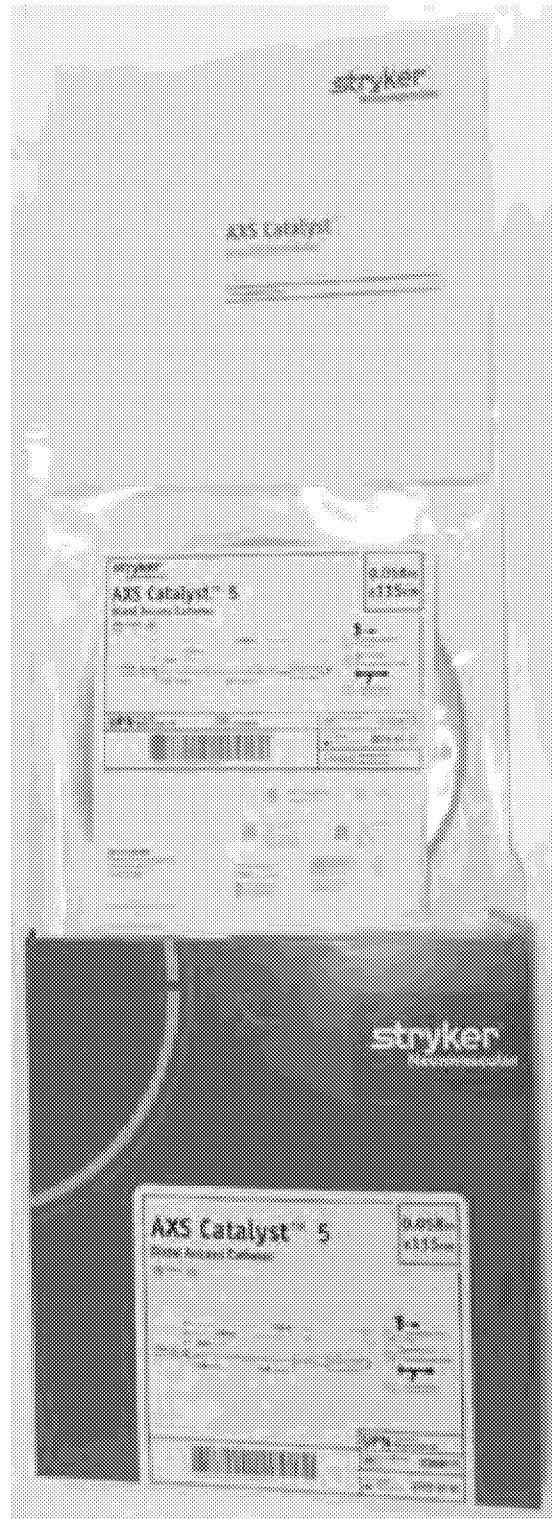
(b)(4)

AXS Catalyst Distal Access Catheter Packaging Configuration

(b)(4)



Section 012, Figure 17: Accessories on Packaging Hoop Card



Section 012, Figure 18: Representative Subject Device Packaged in Pouch with DFU and Placed in Carton
(Note: the electronic Directions for Use Page is omitted from image)

(b)(4)

Aspiration Accessories Packaging

The Medela AG products are packaged separately and details may be found in K130123, K150134 and K170329.

Model Numbers

The model numbers for the proposed subject device and accessories are listed in
Section 012, Table 12.

(b)(4)

Section 012 Device Description

Attachment 12A – Medela AG Right to Reference Letter

Attachment is individually paginated.



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6341 Baar
Switzerland
Phone +41 (0)41 562 51 51
Fax +41 (0)41 562 51 00
info@medela.ch
www.medela.com

Letter of Authorization

Baar, 07. November 2017

To Whom It May Concern

(b)(4)

07.12.2017
Date

07.12.2017
Date

Section 013 Substantial Equivalence Discussion

The Substantial Equivalence Discussion is provided in the following pages.

Section 013 Substantial Equivalence Discussion

Predicate Device Information

The Subject Device and the Predicate Devices are identified in **Section 013, Table 1** below.

(b)(4)

Purpose of the Submission:

The purpose of this notification is to 1) add an indication for use for the AXS Catalyst™ Distal Access Catheter to include aspiration (with the associated NRY Product Code) when used as part of the aspiration system, which consists of the AXS Catalyst™ Distal Access Catheter and the aspiration accessories, and 2) update the associated labeling to add a warning to the labeling and additional operating instructions to reflect the additional indication for aspiration. The aspiration system consists of the AXS Catalyst™ Distal Access Catheter and the aspiration accessories (Medela Dominant Flex Pump with Suction Jar, AXS Universal Aspiration Tubing, and the AXS Universal Liner Set). The subject device, AXS Catalyst™ Distal Access Catheter, is identical to the reference predicate which was cleared under **K151667**.

As part of this submission, the AXS Catalyst Catheters have been shown to be safe and effective at aspirating clots using an aspiration system that provides at least -68 kPa [-20.08 in HG]. (b)(4)

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(b)(4)

The Dominant Flex Pump and accessories, the AXS Universal Aspiration Tubing, and AXS Universal Liner Set, were used for testing to support this 510(k). The Dominant Flex Pump with Suction Jar, AXS Universal Aspiration Tubing, and AXS Universal Liner Set are submitted in this 510(k) as part of the AXS Catalyst Distal Access Catheter Aspiration System.

(b)(4)

There were no changes made to the Subject Device when compared to the previously cleared **K151667** (herein referred to as the Reference Predicate). The design, technology, engineering, materials, specifications, sterilization, biocompatibility, and packaging remain the same. The previously cleared testing results remain valid. Since

clearance of K151667, the shelf-life (b)(4) to two years under the previously cleared testing protocol.

(b)(4)

The Primary Predicate, the Penumbra Reperfusion Catheter with Aspiration Accessories, has an equivalent or similar fit, form, and function when compared to the AXS Catalyst Catheter with Aspiration Accessories, and has the desired additional indication for use with the associated NRY product code.

The subject and predicate devices are similar in design as follows:

- Devices are supplied as sterile, single-use devices.
- Devices use the same or similar materials (i.e. polymers and metals).
- Devices may be introduced through a guide catheter or sheath into the neurovasculature.
- Devices are designed to track within an introducer sheath or guide catheter in the neurovasculature.

¹ The Penumbra ACE60 and Penumbra 5MAX ACE are the same catheter. ACE60 is the trade name and 5MAXACE132/5MAXACE132 KIT is the catalog number.
http://www.penumbrainc.com/wp-content/uploads/2016/12/10667A_ACE68_Science-of-Aspiration_Brochure_USA.pdf

- Devices have the same or similar lengths
- Devices have the same or similar outer diameters
- Devices are comprised of a single lumen catheter with a luer hub on the proximal end allowing attachments for flushing and aspiration

And, proposed:

- Devices may be used as a conduit for aspiration to remove a thrombus from the occluded neurovascular vessel when connected to an aspiration source (such as a pump).

The Subject Device Aspiration System which consists of the AXS Catalyst Distal Access Catheter, Medela Dominant Flex Pump with Suction Jar, AXS Universal Tubing, and AXS Universal Liner Set was compared to the Primary Predicate Aspiration System which consists of the Penumbra Reperfusion Catheter (5MAX ACE or 5MAX or ACE60), Penumbra MAX Pump, Penumbra MAX Canister, and Penumbra Hi-Flow Aspiration Tubing. Comparison system testing of the AXS Catalyst Distal Access Catheter Aspiration System provided sufficient evidence to support a claim of substantial equivalence to the Penumbra Aspiration System with Penumbra Reperfusion Catheter.

The table below **Section 013, Table 2** includes a comparison of the submission's Subject Device, the Primary Predicate Device (Penumbra Reperfusion Catheter) which has the desired additional indication for use, and the Reference Predicate Device (the previously cleared version of the AXS Catalyst).

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Summary of Bench and Animal Testing

Additional testing was performed to substantiate the additional indication claim when compared to the Primary Predicate device as outlined in **Section 013, Table 3** below. As the Subject Device and Reference Predicate device are physically identical, all previously submitted performance testing data outlined in **Section 013, Table 4** is still applicable. Full details are provided in **Sections 019 and 020**.

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Clinical Information

Clinical information obtained from published articles for similar catheters including the Primary Predicate is provided in **Section 021**. The analysis of published clinical evidence demonstrates the requested indication, with the associated product code, is appropriate for the Subject Device when used as part of an aspiration system given the

equivalent device design form, fit, and function when compared to the Primary Predicate Device and Aspiration System.

Substantial Equivalence Conclusion

Stryker Neurovascular has demonstrated the subject AXS Catalyst Distal Access Catheter when used as part of an aspiration system is substantially equivalent to the Primary Predicate Device and Aspiration System and the Reference Predicate Device based on intended use, materials, design, and the same fundamental operating principles. The conclusions drawn from risk assessment, the animal and bench testing conducted using the subject device compared to the Primary Predicate, and a review of available real world evidence from published articles demonstrate that the device is suitable for the additional indication for use with the associated NRY Product Code, and 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 Distal Access Catheter when used as part of the aspiration system is as safe, as effective, and performs as well as the legally marketed Primary and Reference Predicate devices.

Section 014 Proposed Labeling

The proposed labeling is provided on the following pages.

Section 014 Proposed Labeling

Labeling of the subject device consists of the following packaging components:

Packaging Component	Part Number
Directions for Use	(b)(4)
Carton Label Spec	
Pouch Label Spec	
Preprinted Carton	
Preprinted Pouch	
Packaging Hoop Card	(b)(4)
Closure Strip	

(b)(4)

A copy of the draft Stryker and Medela AG co-branded labeling for the AXS Universal Accessories are provided in the following attachments.

Location	Description
(b)(4)	

Section 014 Proposed Labeling

Attachment 14A – Redline Copy of DFU, (b)(4)

Attachment is individually paginated.

(b)(4)

(b)(4)

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Section 014 Proposed Labeling

Attachment 14B – Clean Copy of DFU, (b)(4)

Attachment is individually paginated.

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(b)(4)

Section 014 Proposed Labeling

Attachment 14C – AXS Universal Aspiration Tubing

Attachment is individually paginated.

(b)(4)

(b)(4)


AXS Universal™
 Aspiration Tubing

300cm
 (118.11in)

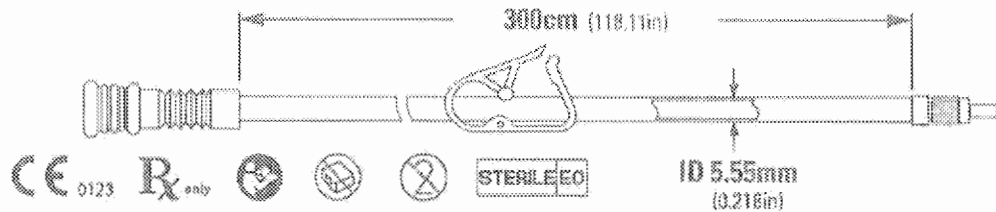
REF 077.0193
 2022-03-15

AXS Universal™		Aspiration Tubing		300cm (118.11in)		
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			LOT	123456		
		AXS Universal™ Aspiration Tubing 300cm (118.11in)	REF	077.0193	LOT	123456
		AXS Universal™ Aspiration Tubing 300cm (118.11in)	 019370123456789			
		REF 077.0193 LOT 123456	 17323456789123456			
Distributed by Stryker Neurovascular 47900 Bayside Parkway Fremont, CA 94538						
REF 077.0193		LOT 123456		 2022-03-15		

(b)(4)

stryker**medela****AXS Universal™****Aspiration Tubing****300cm
(118.11in)**PCS
1

Aspiration Tubing, Tubo de aspiración, Tubulure d'aspiration, Aspirationschlauch, Tubo di aspirazione, Aspirationslang,
Aspirationslange, Σωληφόνη οσφύγιση, Tubo de aspiração, Aspirationslang, Aspirációs csővezeték, Aspiracní hadička,
Rurka do aspiracji, Aspirasjonslange, Aspirasyon Hurlumu, trauletku

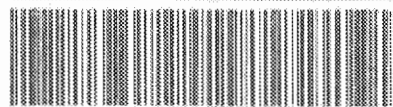


CE 0123

Rx only



STERILE EO

ID 5.55mm
(0.218in)

01107012307052710(17)220314(10)123456

REF

077.0193

Use By
(YYYY-MM-DD)

2022-03-14



Medela AG
Lättichstrasse 4b
6341 Baar, Switzerland
www.medela.com



AXS Universal™
Aspiration Tubing
300cm (118.11in)

REF

077.0193

LOT

123456



AXS Universal™
Aspiration Tubing
300cm (118.11in)

REF 077.0193 LOT 123456



AXS Universal™
Aspiration Tubing
300cm (118.11in)

REF 077.0193 LOT 123456

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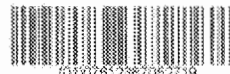
AXS Universal™
Aspiration Tubing
300cm (118.11in)

REF

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LOT

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LABEL STOCK# N00000001-01

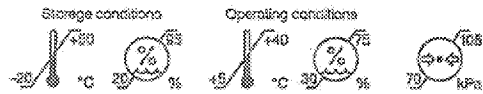
stryker | **medela** 

REF 077.0193

pcs
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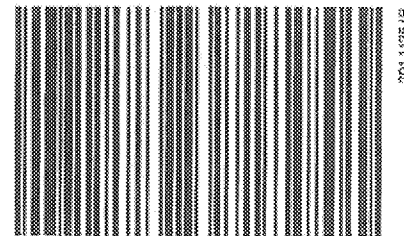
AXS Universal™ Aspiration Tubing

EN Aspiration tubing / ES Tubo de aspiración /
FR Tubulure d'aspiration / DE Aspirationschlauch /
IT Tubo di aspirazione



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LOT



(01)07612367053921

Overpack / Please Unpack



GTIN: (01) XXXXXXXXXXXXXXX
LOT: (10) XXXXXX
EXP: (17) YYMMDD

Section 014 Proposed Labeling

Attachment 14D – AXS Universal Liner Set

Attachment is individually paginated.

(b)(4)

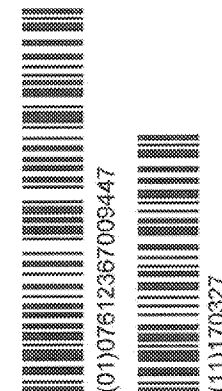
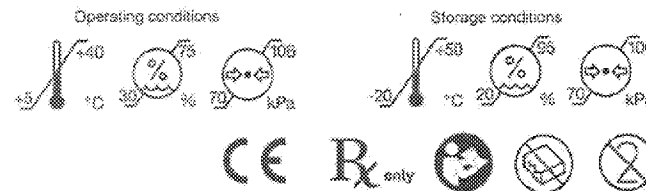
stryker | medela 

REF 077.0194

pcs
3

AXS Universal™ Liner Set

EN: Liner Set / ES: Conjunto de funda / FR: Kit de poche / DE: Beutel-Set /
IT: Set di raccolta / NL: Set met binnenzakken / DA: Posesæt /
EL: Σειτ εσωτερικής επένδυσης / PT: Conjunto de recolha / SV: Påssats /
HU: Béléskészlet / CS: Sada vložky / PL: Zestaw wkładki / NO: Posesett /
TR: Poşet Seti / FI: Imupussi ja -purkki



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 2017-03-27



GTIN (01) 07612367009447
MFG: (11) 170327



101633332

Stryker Neurovascular

Premarket Notification Trademark 51940

AXS Universal™

Liner Set



077.0194

under FOIA Request 2023-10505; Released by CDRH on 06-21-2024

AXS-Catalyst

Distal Access Catheter

stryker | medela

AXS Universal™ Liner Set

EN: Liner Set / ES: Conjunto de funda /
 FR: Kit de poche / DE: Beutel-Set /
 IT: Set di raccolta

Overpack / Please Unpack

Operating conditions

Storage conditions

CE R_x only

2017-04-25

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 Lättichstr. 4b
 6341 Baar
 Switzerland
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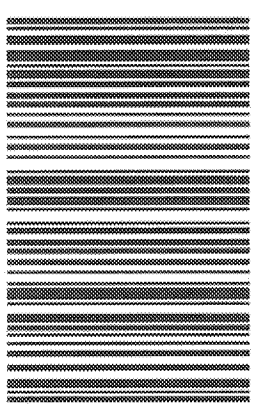
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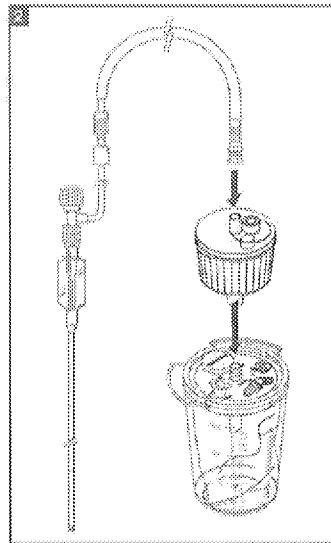
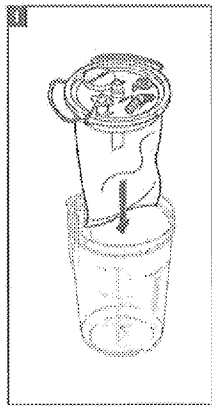
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18 pcs

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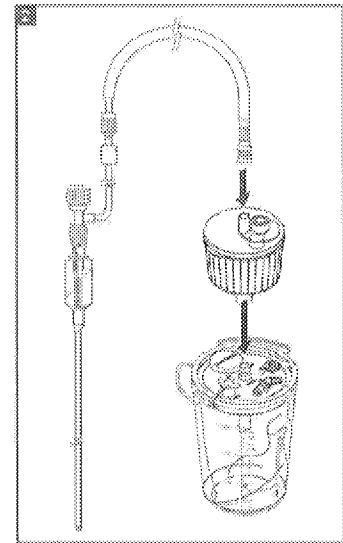
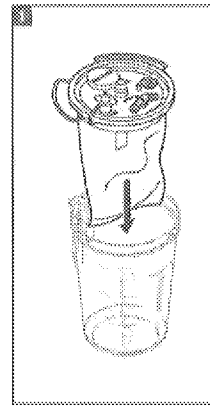
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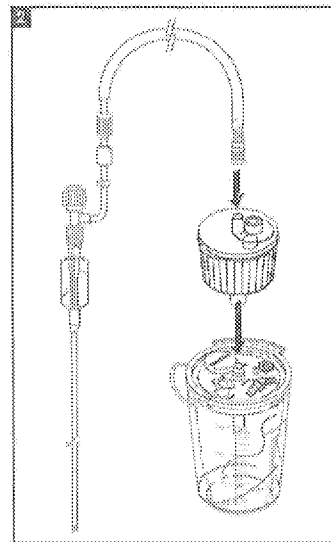
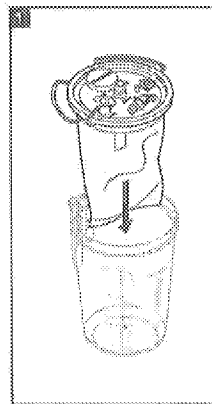
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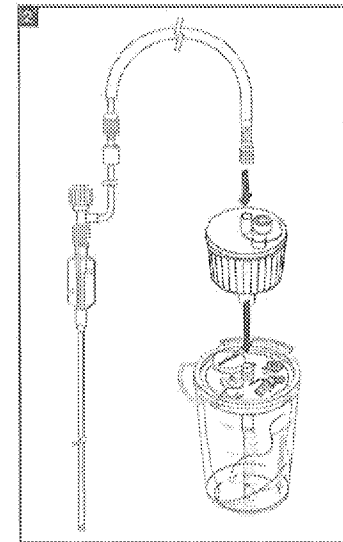
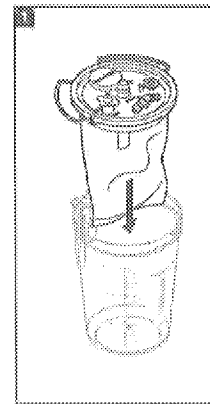
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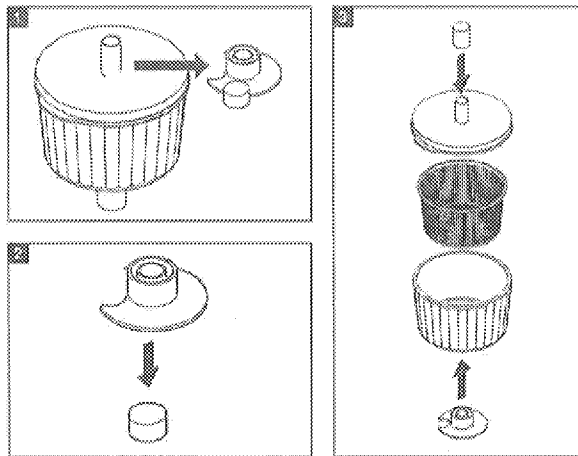
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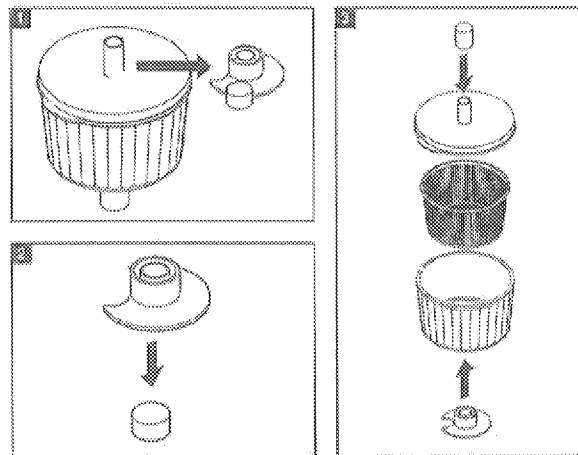


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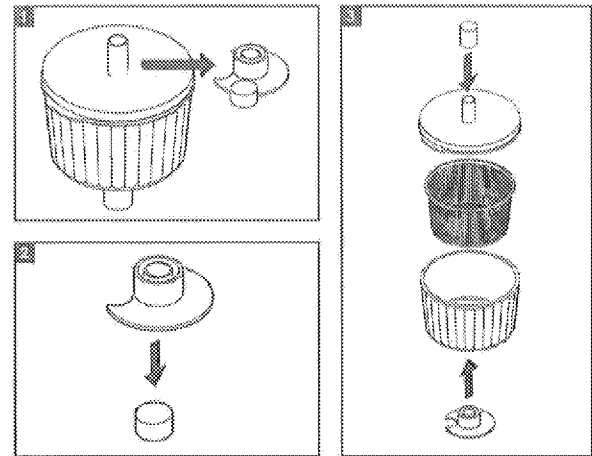


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REF 077.0194

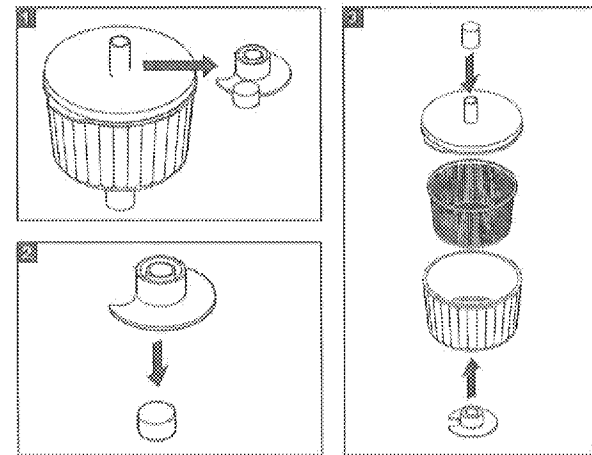


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Section 014 Proposed Labeling

Attachment 14E – AXS Universal Liner Set with Dessicant

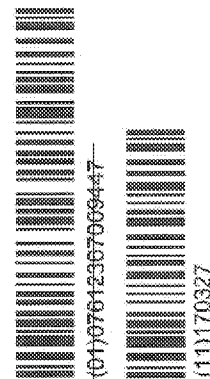
Attachment is individually paginated.

stryker | medela

REF 101035340 pcs
3

AXS Universal™ Liner Set with Desiccant

EN: Liner Set / ES: Conjunto de funda- / FR: Kit de poche / DE: Beutel-Set /
IT: Set di raccolta / NL: Set met twee zakken / DA: Posesæt /
EL: Σet σωτρε / PT: Conjunto de recolha / SV: Pässats /
HU: Béléskészlet / SK: Sada vložky / PL: Zestaw wkładki / NO: Posesett /
TR: Poşet Seti / FI: Imupussi ja -purkki



101035340

Medela AG
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6341 Baar
Switzerland
www.medela.com

Distributed by
Stryker Neurovascular
47500 Bayside Parkway
Fremont, CA 94538

2017-03-27



GTIN (01) 07612367009447
MFG (11) 170327

Section 015 Sterilization and Shelf Life

The Sterilization and Shelf Life information is provided on the following pages.

Section 015 Sterilization and Shelf-Life

The sterilization is unchanged from the reference predicate clearance of the AXS Catalyst Distal Access Catheter. Associated testing documentation was provided and cleared as part of K151667. The primary predicate also undergoes EO sterilization with an SAL of 10^{-6} .

The details for the subject and reference predicate device are provided below.

AXS Catalyst Distal Access Catheter (packaged with Rotating Hemostatic Valve, Tuohy Borst Valve, and Peel Away Introducer Sheath)

Sterilization Site

Company:
Street:
City:
County, State, Zip code:
Country:

(b)(4)

Sterilization Cycle

The AXS Catalyst Distal Access Catheter and all packaged accessories (including the Rotating Hemostatic Valve, the Tuohy Borst Valve and the Peel Away Introducer Sheaths) 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 Sheaths) are provided sterile to a sterility assurance level (SAL) of 10^{-6} , and are for single use only.

Sterility Assurance Validation

(b)(4)

(b)(4)

EO and ECH Limits

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

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

Pyrogenicity

(b)(4)

(b)(4)

(b)(4)

(b)(4)

Shelf Life - Product

Shelf life periods are initially established via accelerated aging tests which are then confirmed by real time shelf life testing. Testing data to support shelf life of the subject device was cleared as part of K151667.

(b)(4)

(b)(4)

(b)(4)

Based on the successful completion of the Shelf Life testing listed in **Section 015, Table 2**, the subject device, AXS Catalyst Distal Access Catheter, has met all of the pre-specified requirements. Therefore, the AXS Catalyst Distal Access Catheters is currently labeled with a shelf life of two years.

The Medela Dominant Flex Pump has a shelf life of (b)(4). The AXS Universal Aspiration Tubing has a shelf life of (b)(4). The AXS Universal Liner Set has a shelf life of (b)(4). For additional information regarding the shelf life of the aspiration accessories

manufactured by Medela, please refer to the associated 510(k): K130123, K150134 and K170329.

Section 015 Sterilization and Shelf Life

Attachment 15A – (b)(4) Packaging Technical Report, Sterile Barrier Microbial Barrier

Attachment is individually paginated.

(b)(4)

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(b)(4)

(b)(4)

Microbial Barrier Testing for Non – Porous Materials

Material:

(b)(4)

Date: 31 – May – 2013

ISO 11607 states that impermeable materials for sterile barrier systems shall be tested for air permeance in accordance with ISO 5636-5.

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

Section 015 Sterilization and Shelf Life

Attachment 15B – (b)(4) AXS Catalyst Catheter Packaging Design Verification and Aging Report

Attachment is individually paginated.

Stryker Neurovascular Design Verification Report

Document Title: AXS Catalyst Catheter Packaging Design Verification and Aging Report

Document Number (b)(4)

(b)(4)

Project Name and #

Author/Contributors

Approvals

(b)(4)

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(b)(4)

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(b)(4)

(b)(4)

STRYKER NEUROVASCULAR
REAL TIME AGING, DYE PENETRATION, GROSS LEAK DETECTION (BUBBLE),
AND SEAL STRENGTH (PEEL) TESTING
of the Lotus

Report No. (b)(4)
Proposal No. (b)(4)

Customer Information

Stryker Neurovascular

(b)(4)

Laboratory Information

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

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APPENDIX II

REAL TIME AGING CONTROL DATA

(b)(4)

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(b)(4)

APPENDIX IV

GROSS LEAK DETECTION (BUBBLE) TEST DATA

(b)(4)

Section 016 Biocompatibility

Biocompatibility information is provided on the following pages.

Section 016 Biocompatibility

Stryker Neurovascular took the FDA issued guidance Pre-Clinical and Clinical Studies for Neurothrombectomy Devices into account when submitting the Subject Device and its performance evaluation data. The guidance document outlines requirements in three major areas of investigation: Biocompatibility, Pre-clinical Testing (including bench and animal testing), and Clinical Studies. This section of the 510(k) will address biocompatibility.

The change to the Subject Device is to the indications, labeling and the associated product code. The Biocompatibility profile has not changed from the Reference Predicate Device, and the associated Biocompatibility testing remains valid. The results were provided and cleared as part of K151667. All biocompatibility testing complied with ISO-10993, as is recommended by the FDA. An overview of the previously submitted and cleared Biocompatibility information is provided below for reference purposes.

Overview

The subject device, AXS Catalyst Distal Access Catheters has been classified according to EN ISO 10993-1, *Biological Evaluation of Medical Devices - Part 1: Evaluation and Testing* as follows:

(b)(4)

(b)(4)

(b)(4) The full biocompatibility report, (b)(4) was provided and cleared as part of K151667. (b)(4) was previously provided in K151667, Attachment E-11. The overview is provided in Section 016, Table 1 below for reference.

Section 016, Table 1: Overview of Biocompatibility Testing Cleared as part of K151667				
Test Performed / Applicable ISO 10993 Part No.	Test Lab Report No.	Extract/Conditions ¹	Test Article	Results (Pass/Fail/Other)
MEM Elution Cytotoxicity/Part 5	(b)(4)	(b)(4)	(b)(4)	Pass. No cytotoxicity or cell lysis; (b)(4)
Guinea Pig Maximization Sensitization/Part 10				Pass. No evidence of sensitization
Intracutaneous Reactivity/Part 10				Pass. (b)(4)
Acute Systemic Injection/Part 11				Pass. No mortality or evidence of systemic toxicity
Rabbit Pyrogen / Part 11				Pass Nonpyrogenic; (b)(4)
Hemolysis Extract/Direct Contact Method/Part 4				Pass. Test article is considered non-hemolytic.

(b)(4)

Section 016, Table 1: Overview of Biocompatibility Testing Cleared as part of K151667				
Test Performed / Applicable ISO 10993 Part No.	Test Lab Report No.	Extract/Conditions ¹	Test Article	Results (Pass/Fail/Other)
Partial Thromboplastin /Part 4	(b)(4)	(b)(4)	(b)(4)	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.
Complement Activation (SC5b-9) /Part 4				Pass. Concentration of SC5b-9 in the test articles were not statistically higher than the negative control. The test articles are not considered to be potential activators of the complement system.
Complement Activation (C3a) /Part 4				Pass. Concentration of C3a in the test articles were not statistically higher than the negative control. The test articles are not considered to be a potential activator of the complement system.

Section 016, Table 1: Overview of Biocompatibility Testing Cleared as part of K151667				
Test Performed / Applicable ISO 10993 Part No.	Test Lab Report No.	Extract/Conditions ¹	Test Article	Results (Pass/Fail/Other)
In Vitro Hemocompatibility / Part 4	(b)(4)			Pass. 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%
(b)(4)				

(b)(4)

Conclusion

Based on the test results summarized above, the subject device, AXS Catalyst Distal Access Catheters meets biological safety requirements per ISO 10993-1 for externally communicating medical devices with circulating blood contact for less than 24 hours.

The Medela Dominant Flex Pump and associated accessories are cleared under 510(k): K130123, K150134 and K170329. Please refer to the Medela AG 510(k)s for associated biocompatibility information.

Section 017 Software

Software information is provided on the following pages.

Section 017 Software

Not applicable. The AXS Catalyst Distal Access Catheter does not incorporate or utilize software or firmware.

Section 018 Electromagnetic Compatibility and Safety

Information regarding Electromagnetic Compatibility and Safety is provided on the following pages.

Section 018 Electromagnetic Compatibility and Electrical Safety

Not applicable. The AXS Catalyst Distal Access Catheter does not require Electromagnetic Compatibility or an Electrical Safety Evaluation as the device does not include technology of this type.

Dear Ms. Williams,

Enclosed are the responses to FDA's Interactive Request #1 regarding the 510(k) Submission K173841. The requested information is contained within the attached pdf file.

Please feel free to call me or send email with any additional requests.

Best regards,

Angelica Beckmann
Director Regulatory Affairs
Stryker Neurovascular
47900 Bayside Pkwy
Fremont, CA 94538
(b)(6) Mobile
angelica.beckmann@stryker.com

From: Williams, Dhanya K [mailto:Dhanya.Kumar@fda.hhs.gov]
Sent: Wednesday, March 7, 2018 6:02 AM
To: Beckmann, Angelica <angelica.beckmann@stryker.com>
Cc: Allison, John <John.Allison@stryker.com>; Mateus, Jennifer <Jennifer.Mateus@stryker.com>; K173841@docs.fda.gov; Williams, Dhanya K <Dhanya.Kumar@fda.hhs.gov>
Subject: K173841 - Interactive request #1 - Updated (b)(4)

Hello Ms. Beckmann,

Thank you for your email. As Ms. Anderson noted, I am the lead reviewer for your submission, K173841, and we are still in the process of reviewing your deficiency responses. I will be in touch with you in the next day or two regarding any additional items that need to be addressed as we continue our review, however in the meantime, please address the following:

(b)(4)

Thank you,

Dhanya Williams, M.S.
Biologist/Scientific Reviewer
Center for Devices and Radiological Health (CDRH)
Office of Device Evaluation (ODE)
U.S. Food and Drug Administration

Tel: 301-796-6498
dhanya.williams@fda.hhs.gov

 cid:image001.png@01D1C57E2EA032AA

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From: Anderson, Leigh
Sent: Wednesday, March 07, 2018 7:30 AM
To: 'Beckmann, Angelica' <angelica.beckmann@stryker.com>
Cc: Allison, John <John.Allison@stryker.com>; Mateus, Jennifer <Jennifer.Mateus@stryker.com>; Zheng, Xiaolin <Xiaolin.Zheng@fda.hhs.gov>; Williams, Dhanya K <Dhanya.Kumar@fda.hhs.gov>
Subject: RE: K173841-A1 - Updated 

Dear Ms. Beckmann,

Thank you for your email.

Ms. Dhanya Williams is the Lead Reviewer for K173841, and I have forwarded the email to her, as well as copied her on this reply. Ms. Williams can assist with questions specific to K173841 and review of the submission.

Regards,

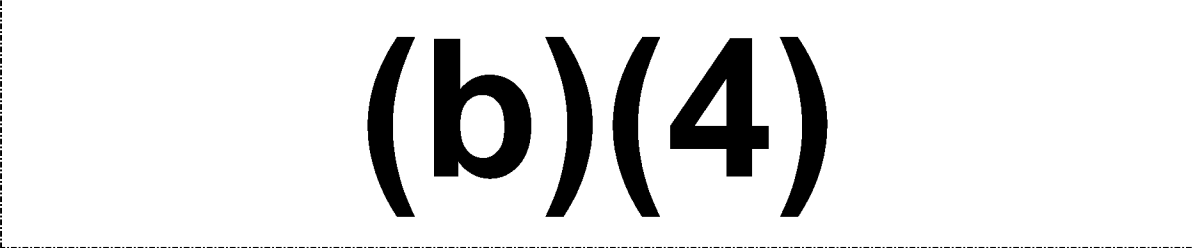
Leigh Anderson
Biomedical Engineer
Neurointerventional Devices Branch (NIDB)
Division of Neurological and Physical Medicine Devices (DNPMD)
Center for Devices and Radiological Health (CDRH)
Office of Device Evaluation (ODE)
U.S. Food and Drug Administration
Tel: 301-796-5613
leigh.anderson@fda.hhs.gov

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Sent: Tuesday, March 06, 2018 6:04 PM
To: Anderson, Leigh <Leigh.Anderson@fda.hhs.gov>
Cc: Allison, John <John.Allison@stryker.com>; Mateus, Jennifer <Jennifer.Mateus@stryker.com>; Zheng, Xiaolin <Xiaolin.Zheng@fda.hhs.gov>
Subject: K173841-A1 - Updated 
Importance: High

Dear Ms. Anderson,
I hope this e-mail finds you well.



(b)(4)

I would also like to understand the next steps for the interactive review of K173481.

Kind regards,

Angelica Beckmann
Director Regulatory Affairs
Stryker Neurovascular
47900 Bayside Pkwy
Fremont, CA 94538
510-413-2900 Office
(b)(6) Mobile
angelica.beckmann@stryker.com

Dear Ms. Williams,

Thank you for your e-mail.

Enclosed are the responses to FDA's Interactive Request regarding additional information needed. The requested information is contained within the attached pdf file.

Please feel free to call me or send email with any additional requests.

Best regards,

Angelica Beckmann

Director Regulatory Affairs

Stryker Neurovascular

47900 Bayside Pkwy

Fremont, CA 94538

(b)(6) Mobile

angelica.beckmann@stryker.com<mailto:angelica.beckmann@stryker.com>

From: Williams, Dhanya K [mailto:Dhanya.Kumar@fda.hhs.gov]

Sent: Monday, March 12, 2018 11:24 AM

To: Beckmann, Angelica <angelica.beckmann@stryker.com>

Cc: K173841@docs.fda.gov; Williams, Dhanya K <Dhanya.Kumar@fda.hhs.gov>

Subject: K173841 - Interactive request #2 - (b)(4)

Importance: High

Hello Ms. Beckmann,

We are nearing the completion of our review, however after (b)(4)
(b)(4) "Response to FDA Interactive Request #1 Rev 2 (002)" that you provided interactively on 3/8/18, we have identified two items that need to be addressed:

(b)(4)

(b)(4)

Please feel free to email me or call me at 301-796-6498 if you need any clarification.

(b)(4)

Thank you,

Dhanya Williams, M.S.

Biologist/Scientific Reviewer

Center for Devices and Radiological Health (CDRH)

Office of Device Evaluation (ODE)

U.S. Food and Drug Administration

Tel: 301-796-6498

dhanya.williams@fda.hhs.gov<mailto:dhanya.williams@fda.hhs.gov>

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[cid:image002.jpg@01D1C57E.DFA022A0]<<https://www.facebook.com/FDA>>

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[cid:image004.jpg@01D1C57E.DFA022A0]<<http://www.youtube.com/user/USFoodandDrugAdmin>>

[cid:image005.jpg@01D1C57E.DFA022A0]<<http://www.flickr.com/photos/fdaphotos/>>

[cid:image006.jpg@01D1C57E.DFA022A0]

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Memorandum

Engineering Review

Date:	January 26, 2018
To:	Dhanya Williams
From:	Matthew R. Fusco, MD Staff Fellow, DNPMD/NIDB
Reviewer Electronic Signature:	Matthew Fusco -S Digitally signed by Matthew Fusco -S DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, cn=Matthew Fusco -S, 0.9.2342.19200300.100.1.1=2001924937 Date: 2018.02.19 16:28:12 -06'00'
Subject:	K173841
Applicant:	Stryker
Device:	AXS Catalyst Distal Access Catheter 058 x 115cm, 058 x 132cm, 060 x 132cm

(b)(5)

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(b)(5)

Ms. Williams,
Thank you for your e-mail.
I will be available for a phone call at 12:30 pm (EST).
Should I call your desk phone number?

Regards

Angelica

From: Williams, Dhanya K [mailto:Dhanya.Kumar@fda.hhs.gov]
Sent: Wednesday, March 7, 2018 6:02 AM
To: Beckmann, Angelica <angelica.beckmann@stryker.com>
Cc: Allison, John <John.Allison@stryker.com>; Mateus, Jennifer <Jennifer.Mateus@stryker.com>; K173841@docs.fda.gov; Williams, Dhanya K <Dhanya.Kumar@fda.hhs.gov>
Subject: K173841 - Interactive request #1 - Updated [(b)(4)]

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Dhanya Williams, M.S.
Biologist/Scientific Reviewer
Center for Devices and Radiological Health (CDRH)
Office of Device Evaluation (ODE)
U.S. Food and Drug Administration
Tel: 301-796-6498
dhanya.williams@fda.hhs.gov

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Regards,

Leigh Anderson
Biomedical Engineer
Neurointerventional Devices Branch (NIDB)
Division of Neurological and Physical Medicine Devices (DNPMD)
Center for Devices and Radiological Health (CDRH)
Office of Device Evaluation (ODE)
U.S. Food and Drug Administration
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leigh.anderson@fda.hhs.gov

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Cc: Allison, John <John.Allison@stryker.com>; Mateus, Jennifer <Jennifer.Mateus@stryker.com>; Zheng, Xiaolin <Xiaolin.Zheng@fda.hhs.gov>
Subject: K173841-A1 - Updated (b)(4)
Importance: High

Dear Ms. Anderson,
I hope this e-mail finds you well.

(b)(4)

(b)(4)

I would also like to understand the next steps for the interactive review of K173481.

Kind regards,

Angelica Beckmann
Director Regulatory Affairs
Stryker Neurovascular
47900 Bayside Pkwy
Fremont, CA 94538
510-413-2900 Office
(b)(6) Mobile
angelica.beckmann@stryker.com



Contains Nonbinding Recommendations

Print Form

Acceptance Checklist for Traditional 510(k)s

(Should be completed within 15 days of DCC receipt)

The following information is not intended to serve as a comprehensive review.
FDA recommends that the submitter include this completed checklist as part of the submission.

510(k) #: K173841

Date Received by DCC: Dec 18, 2017

Lead Reviewer: Dhanya Williams

Branch: NIDB

Division: DNPMD

Center/Office: CDRH/ODE

Note: If an element is left blank on the checklist, it does not mean the checklist is incomplete; it means the reviewer did not assess the element during the RTA review and that the element will be assessed during substantive review.

IMPORTANT - Many checklist elements include additional details regarding information to address the element that can be seen by hovering over the element (Example - Element 4 in Section A of the checklist).

Preliminary Questions

Answers in the shaded blocks indicate consultation with a Center advisor is needed. (Boxes checked in this section represent FDAs preliminary assessment of these questions at the time of administrative review.)

Yes No N/A

1) Is the product a device (per section 201(h) of the FD&C Act) or a combination product (per 21 CFR 3.2(e)) with a device constituent part subject to review in a 510(k)?

If it appears not to be a device (per section 201(h) of the FD&C Act) or such a combination product, or you are unsure, consult with the CDRH Jurisdictional Officer or the CBER Product Jurisdiction Liaison to determine the appropriate action, and inform division management. *Provide a summary of the Jurisdictional Officer's/Liaison's determination.* If the product does not appear to be a device or such a combination product, mark "No."

X

Comments:

2. Is the submission with the appropriate Center?

If the product is a device or a combination product with a device constituent part, is it subject to review by the Center in which the submission was received? If you believe the submission is not with the appropriate Center or you are unsure, consult with the CDRH Jurisdictional Officer or CBER Product Jurisdiction Liaison to determine the appropriate action and inform your division management. *Provide a summary of the Jurisdictional Officer's/Liaison's determination.* If submission should not be reviewed by your Center mark "No."

X

Comments:

3) If a Request for Designation (RFD) was submitted for the device or combination product with a device constituent part and assigned to your center, identify the RFD # and confirm the following: a) Is the device or combination product the same (e.g., design, formulation) as that presented in the RFD submission? b) Are the indications for use for the device or combination product identified in the 510(k) the same as those identified in the RFD submission?

If you believe the product or the indications presented in the 510(k) have changed from the RFD, or you are unsure, consult with the CDRH Jurisdictional Officer or the CBER Product Jurisdiction Liaison to determine the appropriate action and inform your division management. *Provide summary of Jurisdictional Officer's/Liaison's determination.*

If the answer to either question above is no, mark "No." If there was no RFD, mark "N/A."

X

Comments:

4) Is this device type eligible for a 510(k) submission? Records processed under FOIA Request 2023-10505; Released by CDRH on 06-21-2024 If a 510(k) does not appear to be appropriate (e.g., Class III type and PMA required, or Class I or II type and 510(k)-exempt), you should consult with the CDRH 510(k) Program Director or appropriate CBER staff during the acceptance review. If 510(k) is not the appropriate regulatory submission, mark "No."	×		
Comments:			
5) Is there a pending PMA for the same device with the same indications for use? If yes, consult division management and the CDRH 510(k) Program Director or appropriate CBER staff to determine the appropriate action.		×	
Comments:			
6) If clinical studies have been submitted, is the submitter the subject of an Application Integrity Policy (AIP)? If yes, consult with the CDRH Office of Compliance/Division of Bioresearch Monitoring (OC/DBM) or CBER Office of Compliance and Biologics Quality/Division of Inspections and Surveillance/Bioresearch Monitoring Branch (OCBQ/DIS/BMB) to determine the appropriate action. Check on web at http://www.fda.gov/ICECI/EnforcementActions/ApplicationIntegrityPolicy/ucm134453.htm If no clinical studies have been submitted, mark "N/A."		×	
Comments:			

- If the answer to 1 or 2 appears to be "No," then stop review of the 510(k) and issue the "Original Jurisdictional Product" letter.
- If the answer to 3a or 3b appears to be "No," then stop the review and contact the CDRH Jurisdictional Officer or CBER Office of Jurisdiction Liaison.
- If the answer to 4 is "No," the lead reviewer should consult division management and other Center resources to determine the appropriate action.
- If the answer to 5 is "Yes," then stop review of the 510(k), contact the CDRH 510(k) Staff and PMA Staff, or appropriate CBER staff.
- If the answer to 6 is "Yes," then contact CDRH/OC/DBM or CBER/OCBQ/DIS/BMB, provide a summary of the discussion with DBM or BMB Staff, and indicate their recommendation/action.

*Submitters including the checklist with their submission should identify the page numbers where requested information located. Use the comments section for an element if additional space is needed to identify the location of supporting information.	Yes	No	*Page #
1) Submission contains a Table of Contents	X		
2) Each section is labeled (e.g., headings or tabs designating Device Description section, Labeling section, etc.)	X		
3) All pages of the submission are numbered.	X		
4) Type of 510(k) is identified (i.e., Traditional, Abbreviated, or Special).	X		

Comments:

Elements of a Complete Submission (RTA Items)
(21 CFR 807.87 unless otherwise indicated)

Submission should be designated RTA if not addressed.

- Any "No" answer will result in a "Refuse to Accept" decision; however, FDA staff has discretion to determine whether missing items are needed to ensure that the submission is administratively complete to allow the submission to be accepted or to request missing checklist items interactively from submitters during RTA review.
- Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission.

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.					
Records processed under FOIA Request 2023-10505; Released by CDRH on 06-21-2024					
	Yes	No	N/A	Comment	*Page #
*Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.					
A. Administrative					
1) All content used to support the submission is written in English (including translations of test reports, literature articles, etc.)	×				
2) Submission identifies the following (FDA recommends use of the CDRH Premarket Review Submission Cover Sheet form [Form 3514]):					
a) Device trade/proprietary name	×				
b) Device class and panel or Classification regulation or Statement that device has not been classified with rationale for that conclusion	×				
3) Submission contains an Indication for Use Statement with Rx and/or OTC designated (see also 21 CFR 801.109, and FDA's guidance "Alternative to Certain Prescription Devices Labeling Requirements.") See recommended format, (http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM360431.pdf).	×				
4) Submission contains a 510(k) Summary or 510(k) Statement.	×				
5) Submission contains a Truthful and Accuracy Statement per 21 CFR 807.87(k) See recommended format, (http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm142707.htm).	×				
6) Submission is a Class III 510(k) device.			×		
7) Submission contains clinical data			×		
8) The submission identifies prior submissions for the same device included in the current submission (e.g., submission numbers for a prior not substantially equivalent [NSE] determination, prior deleted or withdrawn 510(k), Pre-Submission, IDE, PMA, etc.). OR States that there were no prior submissions for the subject device.	×				
a) If there were prior submissions, the submitter has identified where in the current submission any issues related to a determination of substantial equivalence from prior submissions for this device are addressed.	×				
B. Device Description					
9) The device has a device-specific guidance document, special controls document, and/or requirements in a device-specific regulation regarding device description that is applicable to the subject device.			×		
10) Descriptive information is present and consistent within the submission (e.g., the device description section is consistent with the device description in the labeling).	×			×	
(b)(4)					

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. Records processed under FOIA Request 2023-10505; Released by CDRH on 06-21-2024					
*Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.					
	Yes	No	N/A	Comment	*Page #
11) The submission includes descriptive information for the device, including the following:					
a) A description of the principle of operation or mechanism of action for achieving the intended effect.	×				
b) A description of proposed conditions of use, such as surgical technique for implants; anatomical location of use; user interface; how the device interacts with other devices; and/or how the device interacts with the patient.	×				
c) A list and description of each device for which clearance is requested.	×				
d) Submission contains representative engineering drawing(s), schematics, illustrations, photos and/or figures of the device. OR Submission includes a statement that engineering drawings, schematics, etc. are not applicable to the device (e.g., device is a reagent and figures are not pertinent to describe the device).	×				
12) Device is intended to be marketed with multiple components, accessories, and/or as part of a system.	×				
a) Submission includes a list of all components and accessories to be marketed with the subject device.	×				
b) Submission includes a description (as detailed in item 11(a), 11(b) and 11(d) above) of each component or accessory.	×				
c) A 510(k) number is provided for each component or accessory that received a prior 510(k) clearance AND A statement is provided that identifies components or accessories that have not received prior 510(k) clearance.	×				
C. Substantial Equivalence Discussion					
13) Submitter has identified a predicate device(s), including the following information:					
a) Predicate device identifier provided (e.g., 510(k) number, de novo number, reclassified PMA number, regulation number if exempt or statement that the predicate is a preamendment device). For predicates that are preamendments devices, information is provided to document preamendments status. <i>Information regarding documenting preamendment status is available online. (http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/MedicalDeviceQualityandCompliance/ucm379552.htm).</i>	×				
b) The identified predicate(s) is consistent throughout the submission (e.g., the predicate(s) identified in the Substantial Equivalence section is the same as that listed in the 510(k) Summary (if applicable) and that used in comparative performance testing).	×				
14) Submission includes a comparison of the following for the predicate(s) and subject device and a discussion why any differences between the subject and predicate(s) do not impact safety and effectiveness [see section 513(i)(1)(A) of the FD&C Act and 21 CFR 807.87(f)] See " The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)] " guidance document for more information on comparing intended use and technological characteristics.					

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.					
Records processed under FOIA Request 2023-10505; Released by CDRH on 06-21-2024					
	Yes	No	N/A	Comment	*Page #
*Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.					
a) Indications for Use	×				
b) Technology, including features, materials, and principles of operation	×				
D. Proposed Labeling (see also 21 CFR part 801 and 809 as applicable)					
15) Submission includes proposed package labels and labeling (e.g., instructions for use, package insert, operator's manual).	×				
a) Indications for use are stated in labeling and are identical to Indications for Use form and 510(k) Summary (if 510(k) Summary provided).	×				
b) Labeling includes: - Statements of conditions, purposes or uses for which the device is intended (e.g., hazards, warnings, precautions, contraindications) (21 CFR 801.5) AND - Includes adequate directions for use (see 21 CFR 801.5) OR - Submission states that device qualifies for exemption per 21 CFR 801 Subpart D	×				
16) Labeling includes name and place of business of the manufacturer, packer, or distributor (21 CFR 801.1).	×				
17) Labeling includes the prescription statement [see 21 CFR 801.109(b)(1)] or Rx Only symbol (see also Section 502(a) of the FD&C Act and FDA's guidance "Alternative to Certain Prescription Device Labeling Requirements").	×				
18) The device has a device-specific guidance document, special controls document, and/or requirements in a device-specific regulation regarding labeling that is applicable to the subject device.			×		
19) If the device is an in vitro diagnostic device, provided labeling includes all applicable information required per 21 CFR 809.10.			×		
E. Sterilization					
If an <i>in vitro</i> diagnostic (IVD) device and sterilization is not applicable, select "N/A." The criteria in this section will be omitted from the checklist if "N/A" is selected.					
Submission states that the device, and/or accessories, and/or components are: (one of the below must be checked)					
☒ Provided sterile, intended to be single-use					
☐ Requires processing during its use-life					
☐ Non-sterile when used (and no processing required)					
Information regarding the sterility status of the device is not provided. (If this box is checked, please also check one of the two boxes below.)					
☐ Sterility status not needed for this device (e.g., software-only device)					
☐ Sterility status needed or need unclear					
This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination. Please refer to the guidance document titled " Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling " for additional information.					

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. Records processed under FOIA Request 2023-10505; Released by CDRH on 06-21-2024					
*Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.					
	Yes	No	N/A	Comment	*Page #
20) Assessment of the need for cleaning and subsequent disinfection or sterilization information					
a) Identification of device, and/or accessories, and/or components that are provided sterile.	×				
b) Identification of device, and/or accessories, and/or components that are end user sterilized or disinfected.	×				
c) Identification of device, and/or accessories, and/or components that are reusable.	×				
21) If the device, and/or accessory, and/or a component is provided sterile:					
a) Sterilization method is stated for each component (including dose for radiation sterilization).	×				
b) A description of method to validate the sterilization parameters is provided for each proposed sterilization method (e.g., half-cycle method and full citation of FDA-recognized standard, including date).	×				
c) For devices sterilized using chemical sterilants such as ethylene oxide (EO) and hydrogen peroxide, submission states maximum levels of sterilant residuals remaining on the device and sterilant residual limits.	×				
d) Sterility Assurance Level (SAL) is stated.	×				
e) Submission includes description of packaging.	×				
f) For products labeled "non-pyrogenic," a description of the method used to make the determination stated (e.g., limulus amebocyte lysate [LAL]).	×				
22) If the device, and/or accessory, and/or a component is reusable or end user sterilized or disinfected:					
a) Cleaning method is provided in labeling for each device, and/or accessory, and/or component.	×				
b) Disinfection method is provided in labeling for each device, and/or accessory, and/or component.	×				
c) Sterilization method is provided in labeling for each device and/or accessory, and/or component.			×		
d) Device types in this submission are listed in Appendix E of the FDA's guidance <u>"Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling."</u>			×		
i) If device types in this submission are included in Appendix E of the reprocessing guidance, the submission includes protocols and test reports for validating the reprocessing instructions.			×		
23) The device has a device-specific guidance document, special controls document, and/or requirement in a device-specific regulation regarding sterility and/or reprocessing that is applicable to the subject device.			×		
F. Shelf Life					
24) Proposed shelf life/expiration date stated OR Statement that shelf-life is not applicable because of low likelihood of time-dependent product degradation	×				

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. Records processed under FOIA Request 2023-10505; Released by CDRH on 06-21-2024					
	Yes	No	N/A	Comment	*Page #
*Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.					
25) For a sterile device, submission includes summary of methods used to establish that device packaging will maintain a sterile barrier for the entirety of the proposed shelf life.	✗				
26) Submission includes summary of methods used to establish that device performance is maintained for the entirety of the proposed shelf-life (e.g., mechanical properties, coating integrity, pH, osmolality, etc.). OR Statement why performance data is not needed to establish maintenance of device performance characteristics over the shelf-life period.	✗				
G. Biocompatibility					
If an vitro diagnostic (IVD) device, select "N/A." The criteria in this section will be omitted from the checklist if "N/A" is selected.					
Submission states that there: (one of the below must be checked)					
✗ Are direct or indirect patient-contacting components.					
Are no direct or indirect patient-contacting components.					
Information regarding patient contact status of the device is not provided (if this box checked, please also check one of the two boxes below).					
	Patient contact information not needed for this device (e.g., software-only device)				
	Patient contact information needed or need unclear				
This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination.					
27) Submission includes a list identifying each of patient-contacting device component (e.g., implant, delivery catheter) and associated materials of construction for each component, including identification of color additives, if present.	✗				
28) Submission identifies contact classification (e.g., surface-contacting, less than 24 hour duration) for each patient-contacting device component (e.g., implant, delivery catheter)	✗				
29) Biocompatibility assessment of patient-contacting components Submission includes: Test protocol (including identification and description of test article), methods, pass/fail criteria, and results provided for each completed test. OR A statement that biocompatibility testing is not needed with a rationale (e.g., materials and manufacturing/processing are identical to the predicate).	✗				
H. Software					
Submission states that the device: (one of the below must be checked)					
Does contain software/firmware					
✗ Does not contain software/firmware					
Information on whether device contains software/firmware is not provided. (If this box is checked, please also check one of the two boxes below.)					
	Software/firmware information not needed for this device (e.g., surgical suture, condom)				

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.		Yes	No	N/A	Comment	*Page #
*Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.						
Software/firmware information is needed or need unclear						
This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination.						
I. Electrical Safety and EMC						
Electrical Safety					×	
Submission states that the device: (one of the below must be checked)						
Does require electrical safety evaluation						
☒ Does not require electrical safety evaluation						
Information on whether device requires electrical safety evaluation is not provided. (If this box is checked, please also check one of the two boxes below.)						
Electrical safety information not needed for this device (e.g., surgical suture, condom)						
Electrical safety information is needed or need unclear						
This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination.						
(b)(4)						
EMC					×	
Submission states that the device: (one of the below must be checked)						
Does require EMC evaluation						
☒ Does not require EMC evaluation						
Information on whether device requires EMC evaluation is not provided. (If this box is checked, please also check one of the two boxes below.)						
EMC information not needed for this device (e.g., surgical suture, condom)						
EMC information is needed or need unclear						
This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination.						
(b)(4)						
J. Performance Data - General						
If an in vitro diagnostic (IVD) device, select "N/A." The criteria in this section will be omitted from checklist if "N/A" is selected. Performance data criteria relating to IVD devices is addressed in Section K.						
34) Full test report is provided for each completed test. A full test report includes: objective of the test, description of the test methods and procedures, study endpoint(s), pre-defined pass/fail criteria, results summary, conclusions.		×				
a) Submission includes an explanation of how the data generated from each test report supports a finding of substantial equivalence (e.g., comparison to predicate device testing, dimensional analysis, etc.).		×				

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed.					
Records processed under FOIA Request 2023-10505; Released by CDRH on 06-21-2024					
*Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.	Yes	No	N/A	Comment	*Page #
35) The device has a device-specific guidance document, special controls document, and/or requirements in a device-specific regulation regarding performance data that is applicable to the subject device.	×				
a) The submission addresses performance data recommendations outlined in the device-specific guidance. OR The submission provides an alternative approach intended to address the applicable statutory and/or regulatory criteria.	×				
b) The submission includes performance data that addresses relevant mitigation measures set forth in a special controls document or device-specific regulation applicable to the device. OR The submission uses alternative mitigation measures and provides rationale why the alternative measures provide an equivalent assurance of safety and effectiveness.	×				
36) If literature is referenced in the submission, submission includes:					
a) Legible reprints or a summary of each article.	×				
b) Discussion of how each article is applicable to support the substantial equivalence of the subject device to the predicate.	×				
37) For each completed animal study, the submission provides the following:					
a) Submission includes a study protocol which includes all elements as outlined in <u>21 CFR 58.120</u> .	×				
b) Submission includes final study report which includes all elements outlined in <u>21 CFR 58.185</u> .	×				
c) Submission contains a statement that the study was conducted in compliance with applicable requirements in the GLP regulation (<u>21 CFR Part 58</u>), or, if the study was not conducted in compliance with the GLP regulation, the submission explains why the noncompliance would not impact the validity of the study data provided to support a substantial equivalence determination.	×				
K. Performance Characteristics - In Vitro Diagnostic Devices Only (Also see <u>21 CFR 809.10(b)(12)</u>)					
Submission states that the device: (one of the below must be checked)					
is an in vitro diagnostic device.					
× is not an in vitro diagnostic device.					
If "is not" is selected, the performance data-related criteria below are omitted from the checklist.					

If Accept, notify applicant.

If Refuse to Accept, notify applicant electronically and include a copy of this checklist.

Digital Signature Concurrence Table	
Reviewer Sign-Off	Dhanya K. Williams -S 2018.01.02 11:36:09 -05'00'
Branch Chief Sign-Off (digital signature optional)*	
Division Sign-Off (digital signature optional)*	
* Branch and Division review of checklist and concurrence with decision required. Branch and Division digital signature optional.	

K173841

Stryker Neurovascular
Premarket Notification, Traditional 510(k)

FDA/CDRH/DCC

AXS Catalyst Distal Access Catheter

DEC 18 2017

stryker

RECEIVED

December 14, 2017

U.S. Food and Drug Administration
Center for Devices and Radiological Health (CDRH)
Document Mail Center – WO66-G609
10903 New Hampshire Avenue
Silver Spring, Maryland 20993-0002

Re: Traditional 510(k) Submission
Stryker Neurovascular's AXS Catalyst™ Distal Access Catheter

Regulation Number:	21 CFR 870.1250
Trade Name or Proprietary Name:	AXS Catalyst™ Distal Access Catheter
Common Name or Classification Name:	Percutaneous Catheter
Regulation Class:	Class II
Product Code:	DQY, and proposed addition of NRY

To Whom It May Concern:

Pursuant to Section 510(k) of the Federal Food, Drug and Cosmetic Act, and in conformance with 21 CFR 807, Stryker Neurovascular hereby submits this Traditional 510(k) requesting review and clearance of an additional indication for use for the subject device as well as a request for an additional product code, NRY.

(b)(4)

This notification adds an indication for use for the AXS Catalyst™ Distal Access Catheter to include aspiration (with the associated NRY Product Code) when used as part of the aspiration system, and to add a warning to the labeling and additional operating

129



instructions to reflect the additional indication for aspiration. The aspiration system consists of the AXS Catalyst™ Distal Access Catheter and the aspiration accessories (Medela Dominant Flex Pump with Suction Jar, AXS Universal Aspiration Tubing, and AXS Universal Liner Set).

Substantial equivalence is claimed to the Penumbra Aspiration System which consists of the Penumbra Pump MAX, Penumbra Reperfusion Catheter, and Penumbra Aspiration Tubing (K160449) as a primary predicate and the AXS Catalyst™ Distal Access Catheter (K151667) as a reference predicate.

The AXS Catalyst™ Distal Access Catheter product family is comprised of the following intermediate catheter subtypes:

- AXS Catalyst™ 5 Distal Access Catheter
- AXS Catalyst™ 6 Distal Access Catheter

There are no changes to the design of the catheter, and testing was conducted for the purpose of supporting the additional indication for use and the addition of the new Product Code NRY.

As part of this submission, the AXS Catalyst Catheters have been shown to be safe and effective at aspirating clots using aspiration systems that provide at least -68 kPa [-20.08 in HG]. (b)(4)

(b)(4)

(b)(4)

The AXS Catalyst Distal Access Catheter when used as part of the aspiration system has the following similarities to the predicate devices cleared under the above listed premarket notifications:

- Similar intended use/indications for use
- Same or similar materials
- Same or similar design
- Same or similar operating principles

Stryker Neurovascular
Premarket Notification, Traditional 510(k)

AXS Catalyst Distal Access Catheter

stryker

Successful non-clinical testing results support that the additional indication for use with the corresponding product code is appropriate. Additionally, the testing results demonstrated that the AXS Catalyst Distal Access Catheter when used as part of the aspiration system is as safe and effective as the predicate devices.

Risk assessments have been reviewed in accordance with EN ISO 14971. The conclusions drawn from risk assessments, bench testing, and animal testing as well as a review of publicly available clinical evidence for the primary predicate is that the AXS Catalyst Distal Access Catheters when used as part of the aspiration system are substantially equivalent to the predicate devices. The device performs as designed, is suitable for the additional indication for use, and the benefits of the device outweigh any residual risks when used in accordance with device instructions for Use.

Stryker Neurovascular considers its intent to market this proposed device as confidential commercial information and requests that it be treated as such by FDA. Stryker has taken precautions to protect the confidentiality of the intent to market these devices and understands that the submission to the government of false information is prohibited by 18 U.S.C. 1001 and 21 U.S.C. 331 (q).

Two copies of this submission are being provided; one paper copy and one electronic copy. The electronic copy of the submission is included on the provided electronic drive. The electronic copy is an exact duplicate of the paper copy with the exception of a duplicate of the Company Cover Letter placed at the beginning of the submission.

Thank you in advance for your consideration of our notification. If there are questions, please feel free to contact me at the email address or number listed below.

Sincerely,

(b)(6)

✓ Angelica Beckmann
Director, Regulatory Affairs
Stryker Neurovascular
47900 Bayside Parkway
Fremont, California 94538
510-413-2900
angelica.beckmann@stryker.com

Thank you Ms. Williams,

I will check the Stryker team availability and let you know.

Best regards

Angelica

-----Original Appointment-----

From: Williams, Dhanya K [mailto:Dhanya.Kumar@fda.hhs.gov]

Sent: Wednesday, March 7, 2018 7:44 AM

To: Zheng, Xiaolin; Beckmann, Angelica; Allison, John; Mateus, Jennifer;
K173841@docs.fda.gov

Subject: K173841 - Updates to (b)(4)

When: Wednesday, March 7, 2018 12:30 PM-1:00 PM (UTC-05:00) Eastern Time (US & Canada).

Where: Webex

Hello all,

I am setting up this brief call with your team and NIDB branch chief Dr. Xiaolin Zheng to discuss your AXS Catalyst (K173841) submission in regards to the (b)(4)

(b)(4)

Right now I have set this call up for 12:30pm EST, however please let me know if you would like me to reschedule for 1:30pm EST instead.

Thank you,

Dhanya Williams

Tel: 301-796-6498

WEBEX Info:

-- Do not delete or change any of the following text. --

(b)(4)

(b)(4)

IMPORTANT NOTICE: Please note that this WebEx service allows audio and other information sent during the session to be recorded, which may be discoverable in a legal matter. By joining this session, you automatically consent to such recordings. If you do not consent to being recorded, discuss your concerns with the host or do not join the session.

Organizer: Williams, Dhanya K : Dhanya.Kumar@fda.hhs.gov
Subject: K173841 - Updates to (b)(4)
Location: Webex
Start Time: 2018-03-07T12:30:00-05:00
End Time: 2018-03-07T13:00:00-05:00
Attendees: Zheng, Xiaolin : Xiaolin.Zheng@fda.hhs.gov, Beckmann, Angelica : angelica.beckmann@stryker.com, Allison, John : John.Allison@stryker.com, Mateus, Jennifer, Jennifer.Mateus@stryker.com, K173841@docs.fda.gov : K173841@docs.fda.gov

(b)(4)

Hello all,

I am setting up this brief call with your team and NIDB branch chief Dr. Xiaolin Zheng to discuss your AXS Catalyst (K173841) submission in regards to the (b)(4)

(b)(4)

Right now I have set this call up for 12:30pm EST, however please let me know if you would like me to reschedule for 1:30pm EST instead.

Thank you,
Dhanya Williams
Tel: 301-796-6498

WEBEX Info:

-- Do not delete or change any of the following text. --

(b)(4)

(b)(4)

Ms. Williams,

Thank you for your quick response.

Best regards,

Angelica Beckmann

Director Regulatory Affairs

Stryker Neurovascular

47900 Bayside Pkwy

Fremont, CA 94538

510-413-2900 Office

(b)(6) Mobile

angelica.beckmann@stryker.com<mailto:angelica.beckmann@stryker.com>

From: Williams, Dhanya K [mailto:Dhanya.Kumar@fda.hhs.gov]

Sent: Thursday, March 8, 2018 9:00 PM

To: Beckmann, Angelica <angelica.beckmann@stryker.com>

Cc: Mateus, Jennifer <Jennifer.Mateus@stryker.com>; K173841@docs.fda.gov; Zheng, Xiaolin <Xiaolin.Zheng@fda.hhs.gov>; Allison, John <John.Allison@stryker.com>; Williams, Dhanya K <Dhanya.Kumar@fda.hhs.gov>

Subject: RE: K173841-S001 - Interactive request #1 rev 2

Hello Ms. Beckmann,

We will (b)(4) you have provided and I will get back to you with any additional questions by close of business Monday.

Thank you,

Dhanya Williams, M.S.

Biologist/Scientific Reviewer

Center for Devices and Radiological Health (CDRH)

Office of Device Evaluation (ODE)

U.S. Food and Drug Administration

Tel: 301-796-6498

dhanya.williams@fda.hhs.gov<mailto:dhanya.williams@fda.hhs.gov>

[cid:image001.png@01D1C57E.DFA022A0]<http://www.fda.gov/>

[cid:image002.jpg@01D1C57E.DFA022A0]<https://www.facebook.com/FDA>

[cid:image003.jpg@01D1C57E.DFA022A0] <https://twitter.com/US_FDA>

[cid:image004.jpg@01D1C57E.DFA022A0] <http://www.youtube.com/user/USFoodandDrugAdmin>

[cid:image005.jpg@01D1C57E.DFA022A0] <http://www.flickr.com/photos/fdaphotos/>

[cid:image006.jpg@01D1C57E.DFA022A0]

<http://www.fda.gov/AboutFDA/ContactFDA/StayInformed/RSSFeeds/default.htm>

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From: Beckmann, Angelica [mailto:angelica.beckmann@stryker.com]

Sent: Thursday, March 08, 2018 11:52 PM

To: Williams, Dhanya K <Dhanya.Kumar@fda.hhs.gov<mailto:Dhanya.Kumar@fda.hhs.gov>>

Cc: Mateus, Jennifer <Jennifer.Mateus@stryker.com<mailto:Jennifer.Mateus@stryker.com>>; K173841@docs.fda.gov<mailto:K173841@docs.fda.gov>; Zheng, Xiaolin <Xiaolin.Zheng@fda.hhs.gov<mailto:Xiaolin.Zheng@fda.hhs.gov>>; Allison, John <John.Allison@stryker.com<mailto:John.Allison@stryker.com>>

Subject: K173841-S001 - Interactive request #1 rev 2

Dear Ms. Williams,

(b)(4)

Please feel free to call me or send email with any additional requests.

Best regards,

Angelica Beckmann

Director Regulatory Affairs

Stryker Neurovascular

47900 Bayside Pkwy

Fremont, CA 94538

(b)(6)

Mobile

angelica.beckmann@stryker.com<mailto:angelica.beckmann@stryker.com>

Ms. Williams,

Thank you for your e-mail.

I will be available for a phone call at 12:30 pm (EST).

Should I call your desk phone number?

Regards

Angelica

From: Williams, Dhanya K [mailto:Dhanya.Kumar@fda.hhs.gov]

Sent: Wednesday, March 7, 2018 6:02 AM

To: Beckmann, Angelica <angelica.beckmann@stryker.com>

Cc: Allison, John <John.Allison@stryker.com>; Mateus, Jennifer <Jennifer.Mateus@stryker.com>; K173841@docs.fda.gov; Williams, Dhanya K <Dhanya.Kumar@fda.hhs.gov>

Subject: K173841 - Interactive request #1 - Updated (b)(4)

Hello Ms. Beckmann,

Thank you for your email. As Ms. Anderson noted, I am the lead reviewer for your submission, K173841, and we are still in the process of reviewing your deficiency responses. I will be in touch with you in the next day or two regarding any additional items that need to be addressed as we continue our review, however in the meantime, please address the following:

(b)(4)

(b)(4)

Thank you,

Dhanya Williams, M.S.

Biologist/Scientific Reviewer

Center for Devices and Radiological Health (CDRH)

Office of Device Evaluation (ODE)

U.S. Food and Drug Administration

Tel: 301-796-6498

dhanya.williams@fda.hhs.gov<mailto:dhanya.williams@fda.hhs.gov>

[cid:image001.png@01D1C57E.DFA022A0]<http://www.fda.gov/>

[cid:image002.jpg@01D1C57E.DFA022A0]<https://www.facebook.com/FDA>

[cid:image003.jpg@01D1C57E.DFA022A0]<https://twitter.com/US_FDA>

[cid:image004.jpg@01D1C57E.DFA022A0]<http://www.youtube.com/user/USFoodandDrugAdmin>

[cid:image005.jpg@01D1C57E.DFA022A0]<http://www.flickr.com/photos/fdaphotos/>

[cid:image006.jpg@01D1C57E.DFA022A0]

<http://www.fda.gov/AboutFDA/ContactFDA/StayInformed/RSSFeeds/default.htm>

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From: Anderson, Leigh

Sent: Wednesday, March 07, 2018 7:30 AM

To: 'Beckmann, Angelica'

<angelica.beckmann@stryker.com<mailto:angelica.beckmann@stryker.com>>

Cc: Allison, John <John.Allison@stryker.com<mailto:John.Allison@stryker.com>>; Mateus, Jennifer <Jennifer.Mateus@stryker.com<mailto:Jennifer.Mateus@stryker.com>>; Zheng, Xiaolin <Xiaolin.Zheng@fda.hhs.gov<mailto:Xiaolin.Zheng@fda.hhs.gov>>; Williams, Dhanya K <Dhanya.Kumar@fda.hhs.gov<mailto:Dhanya.Kumar@fda.hhs.gov>>

Subject: RE: K173841-A1 - Updated (b)(4)

Dear Ms. Beckmann,

Thank you for your email.

Ms. Dhanya Williams is the Lead Reviewer for K173841, and I have forwarded the email to her, as well as copied her on this reply. Ms. Williams can assist with questions specific to K173841 and review of the submission.

Regards,

Leigh Anderson

Biomedical Engineer

Neurointerventional Devices Branch (NIDB)

Division of Neurological and Physical Medicine Devices (DNPMD)

Center for Devices and Radiological Health (CDRH)

Office of Device Evaluation (ODE)

U.S. Food and Drug Administration

Tel: 301-796-5613

leigh.anderson@fda.hhs.gov<<mailto:leigh.anderson@fda.hhs.gov>>

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From: Beckmann, Angelica [<mailto:angelica.beckmann@stryker.com>]

Sent: Tuesday, March 06, 2018 6:04 PM

To: Anderson, Leigh <Leigh.Anderson@fda.hhs.gov<<mailto:Leigh.Anderson@fda.hhs.gov>>>

Cc: Allison, John <John.Allison@stryker.com<<mailto:John.Allison@stryker.com>>>; Mateus, Jennifer <Jennifer.Mateus@stryker.com<<mailto:Jennifer.Mateus@stryker.com>>>; Zheng, Xiaolin <Xiaolin.Zheng@fda.hhs.gov<<mailto:Xiaolin.Zheng@fda.hhs.gov>>>

Subject: K173841-A1 - Updated [(b)(4)]

Importance: High

Dear Ms. Anderson,

I hope this e-mail finds you well.

(b)(4)

(b)(4)

(b)(4)

I would also like to understand the next steps for the interactive review of K173481.

Kind regards,

Angelica Beckmann

Director Regulatory Affairs

Stryker Neurovascular

47900 Bayside Pkwy

Fremont, CA 94538

510-413-2900 Office

(b)(6)

Mobile

angelica.beckmann@stryker.com<mailto:angelica.beckmann@stryker.com>

From: Beckmann, Angelica
To: Williams, Dhanya K
Cc: Mateus, Jennifer; K173841@docs.fda.gov; Zheng, Xiaolin; Allison, John
Subject: K173841-S001 - Interactive request #1 rev 2
Date: Thursday, March 08, 2018 11:52:51 PM
Attachments: K173841-S001 Response to FDA Interactive Request #1 Rev 2.pdf

Dear Ms. Williams,

(b)(4)

Please feel free to call me or send email with any additional requests.

Best regards,

Angelica Beckmann

Director Regulatory Affairs

Stryker Neurovascular

47900 Bayside Pkwy

Fremont, CA 94538

(b)(6) Mobile

angelica.beckmann@stryker.com

From: Beckmann, Angelica
To: Williams, Dhanya K
Cc: Allison, John; Mateus, Jennifer; K173841@docs.fda.gov; Ellis, Kristin (Contractor)
Subject: RE: K173841 - Interactive request #1 - Updated DFU
Date: Wednesday, March 07, 2018 11:41:34 PM
Attachments: image001.png
(b)(4)

Dear Ms. Williams,

(b)(4)

Best regards,

Angelica Beckmann

Director Regulatory Affairs

Stryker Neurovascular

47900 Bayside Pkwy

Fremont, CA 94538

510-413-2900 Office

(b)(6) Mobile

angelica.beckmann@stryker.com

From: Williams, Dhanya K [mailto:Dhanya.Kumar@fda.hhs.gov]
Sent: Wednesday, March 7, 2018 6:02 AM
To: Beckmann, Angelica <angelica.beckmann@stryker.com>
Cc: Allison, John <John.Allison@stryker.com>; Mateus, Jennifer <Jennifer.Mateus@stryker.com>; K173841@docs.fda.gov; Williams, Dhanya K <Dhanya.Kumar@fda.hhs.gov>
Subject: K173841 - Interactive request #1 - Updated (b)(4)

Hello Ms. Beckmann,

Thank you for your email. As Ms. Anderson noted, I am the lead reviewer for your submission, K173841, and we are still in the process of reviewing your deficiency responses. I will be in touch with you in the next day or two regarding any additional items that need to be addressed as we continue our review, however in the meantime, please address the following:

(b)(4)

(b)(4)

Thank you,

Dhanya Williams, M.S.
Biologist/Scientific Reviewer
Center for Devices and Radiological Health (CDRH)

Office of Device Evaluation (ODE)
U.S. Food and Drug Administration
Tel: 301-796-6498
dhanya.williams@fda.hhs.gov



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From: Anderson, Leigh
Sent: Wednesday, March 07, 2018 7:30 AM
To: 'Beckmann, Angelica' <angelica.beckmann@stryker.com>
Cc: Allison, John <John.Allison@stryker.com>; Mateus, Jennifer <Jennifer.Mateus@stryker.com>; Zheng, Xiaolin <Xiaolin.Zheng@fda.hhs.gov>; Williams, Dhanya K <Dhanya.Kumar@fda.hhs.gov>
Subject: RE: K173841-A1 - Updated (b)(4)

Dear Ms. Beckmann,

Thank you for your email.

Ms. Dhanya Williams is the Lead Reviewer for K173841, and I have forwarded the email to her, as well as copied her on this reply. Ms. Williams can assist with questions specific to K173841 and review of the submission.

Regards,

Leigh Anderson
Biomedical Engineer
Neurointerventional Devices Branch (NIDB)

Division of Neurological and Physical Medicine Devices (DNPMD)
Center for Devices and Radiological Health (CDRH)
Office of Device Evaluation (ODE)
U.S. Food and Drug Administration
Tel: 301-796-5613
leigh.anderson@fda.hhs.gov

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From: Beckmann, Angelica [<mailto:angelica.beckmann@stryker.com>]
Sent: Tuesday, March 06, 2018 6:04 PM
To: Anderson, Leigh <Leigh.Anderson@fda.hhs.gov>
Cc: Allison, John <John.Allison@stryker.com>; Mateus, Jennifer <Jennifer.Mateus@stryker.com>; Zheng, Xiaolin <Xiaolin.Zheng@fda.hhs.gov>
Subject: K173841-A1 - Updated (b)(4)
Importance: High

Dear Ms. Anderson,
I hope this e-mail finds you well.

(b)(4)

(b)(4)

I would also like to understand the next steps for the interactive review of K173481.

Kind regards,

Angelica Beckmann

Director Regulatory Affairs

Stryker Neurovascular

47900 Bayside Pkwy

Fremont, CA 94538

510-413-2900 Office

(b)(6) Mobile
angelica.beckmann@stryker.com



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(b)(4)

(b)(4)

From: Beckmann, Angelica
To: Williams, Dhanya K
Cc: Mateus, Jennifer; K173841@docs.fda.gov; Allison, John
Subject: RE: K173841 - Interactive request #1 - Updated (b)(4)
Date: Thursday, March 08, 2018 2:59:27 PM
Attachments: image007.png
K173841-S001 Response to FDA Interactive Request #1.pdf

Dear Ms. Williams,

Enclosed are the responses to FDA's Interactive Request #1 regarding the 510(k) Submission K173841. The requested information is contained within the attached pdf file.

Please feel free to call me or send email with any additional requests.

Best regards,

Angelica Beckmann

Director Regulatory Affairs

Stryker Neurovascular

47900 Bayside Pkwy

Fremont, CA 94538

(b)(6) Mobile

angelica.beckmann@stryker.com

From: Williams, Dhanya K [mailto:Dhanya.Kumar@fda.hhs.gov]
Sent: Wednesday, March 7, 2018 6:02 AM
To: Beckmann, Angelica <angelica.beckmann@stryker.com>
Cc: Allison, John <John.Allison@stryker.com>; Mateus, Jennifer <Jennifer.Mateus@stryker.com>; K173841@docs.fda.gov; Williams, Dhanya K <Dhanya.Kumar@fda.hhs.gov>
Subject: K173841 - Interactive request #1 - Updated (b)(4)

Hello Ms. Beckmann,

Thank you for your email. As Ms. Anderson noted, I am the lead reviewer for your submission, K173841, and we are still in the process of reviewing your deficiency responses. I will be in touch with you in the next day or two regarding any additional items that need to be addressed as we continue our review, however in the meantime, please address the following:

(b)(4)

(b)(4)

Thank you,

Dhanya Williams, M.S.
Biologist/Scientific Reviewer
Center for Devices and Radiological Health (CDRH)
Office of Device Evaluation (ODE)
U.S. Food and Drug Administration
Tel: 301-796-6498
dhanya.williams@fda.hhs.gov



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From: Anderson, Leigh

Sent: Wednesday, March 07, 2018 7:30 AM

To: 'Beckmann, Angelica' <angelica.beckmann@stryker.com>

Cc: Allison, John <John.Allison@stryker.com>; Mateus, Jennifer <Jennifer.Mateus@stryker.com>; Zheng, Xiaolin <Xiaolin.Zheng@fda.hhs.gov>; Williams, Dhanya K <Dhanya.Kumar@fda.hhs.gov>

Subject: RE: K173841-A1 - Updated (b)(4)

Dear Ms. Beckmann,

Thank you for your email.

Ms. Dhanya Williams is the Lead Reviewer for K173841, and I have forwarded the email to her, as well as copied her on this reply. Ms. Williams can assist with questions specific to K173841 and review of the submission.

Regards,

Leigh Anderson

Biomedical Engineer

Neurointerventional Devices Branch (NIDB)

Division of Neurological and Physical Medicine Devices (DNPMD)

Center for Devices and Radiological Health (CDRH)

Office of Device Evaluation (ODE)

U.S. Food and Drug Administration

Tel: 301-796-5613

leigh.anderson@fda.hhs.gov

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From: Beckmann, Angelica [<mailto:angelica.beckmann@stryker.com>]

Sent: Tuesday, March 06, 2018 6:04 PM

To: Anderson, Leigh <Leigh.Anderson@fda.hhs.gov>

Cc: Allison, John <John.Allison@stryker.com>; Mateus, Jennifer <Jennifer.Mateus@stryker.com>; Zheng, Xiaolin <Xiaolin.Zheng@fda.hhs.gov>

Subject: K173841-A1 - Updated[(b)(4)]

Importance: High

Dear Ms. Anderson,

I hope this e-mail finds you well.

(b)(4)

(b)(4)

I would also like to understand the next steps for the interactive review of K173481.

Kind regards,

Angelica Beckmann

Director Regulatory Affairs

Stryker Neurovascular

47900 Bayside Pkwy

Fremont, CA 94538

510-413-2900 Office

(b)(6) Mobile

angelica.beckmann@stryker.com

From: [Beckmann, Angelica](#)
To: [Williams, Dhanya K](#)
Cc: K173841@docs.fda.gov
Subject: RE: K173841 - Interactive request #2 - (b)(4)
Date: Tuesday, March 13, 2018 11:57:11 AM
Attachments: [image007.png](#)
[K173841-S001 Response to FDA Interactive Request#2.pdf](#)
Importance: High

Dear Ms. Williams,

Thank you for your e-mail.

Enclosed are the responses to FDA's Interactive Request regarding additional information needed. The requested information is contained within the attached pdf file.

Please feel free to call me or send email with any additional requests.

Best regards,

Angelica Beckmann

Director Regulatory Affairs

Stryker Neurovascular

47900 Bayside Pkwy

Fremont, CA 94538

(b)(6) Mobile

angelica.beckmann@stryker.com

From: Williams, Dhanya K [mailto:Dhanya.Kumar@fda.hhs.gov]
Sent: Monday, March 12, 2018 11:24 AM
To: Beckmann, Angelica <angelica.beckmann@stryker.com>
Cc: K173841@docs.fda.gov; Williams, Dhanya K <Dhanya.Kumar@fda.hhs.gov>
Subject: K173841 - Interactive request #2 - (b)(4)
Importance: High

Hello Ms. Beckmann,

We are nearing the completion of our review, however after reviewing your most recent version of labeling, "Response to FDA Interactive Request #1 Rev 2 (002)" that you provided interactively on 3/8/18, we have identified two items that need to be addressed:

(b)(4)

(b)(4)

Please feel free to email me or call me at 301-796-6498 if you need any clarification.

(b)(4)

Thank you,

Dhanya Williams, M.S.
Biologist/Scientific Reviewer
Center for Devices and Radiological Health (CDRH)
Office of Device Evaluation (ODE)
U.S. Food and Drug Administration
Tel: 301-796-6498
dhanya.williams@fda.hhs.gov



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Hello Ms. Beckmann,

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(b)(4)

Thank you,

Dhanya Williams, M.S.

Biologist/Scientific Reviewer

Center for Devices and Radiological Health (CDRH)

Office of Device Evaluation (ODE)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

U.S. Food and Drug Administration

Tel: 301-796-6498

dhanya.williams@fda.hhs.gov

[cid:image001.png@01D1C57E.DFA022A0]<<http://www.fda.gov/>>

[cid:image002.jpg@01D1C57E.DFA022A0]<<https://www.facebook.com/FDA>>

[cid:image003.jpg@01D1C57E.DFA022A0] <https://twitter.com/US_FDA>

[cid:image004.jpg@01D1C57E.DFA022A0] <<http://www.youtube.com/user/USFoodandDrugAdmin>>

[cid:image005.jpg@01D1C57E.DFA022A0] <<http://www.flickr.com/photos/fdaphotos/>>

[cid:image006.jpg@01D1C57E.DFA022A0]

<<http://www.fda.gov/AboutFDA/ContactFDA/StayInformed/RSSFeeds/default.htm>>

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Sent: Wednesday, March 07, 2018 7:30 AM

To: 'Beckmann, Angelica' <angelica.beckmann@stryker.com>

Cc: Allison, John <John.Allison@stryker.com>; Mateus, Jennifer <Jennifer.Mateus@stryker.com>; Zheng, Xiaolin <Xiaolin.Zheng@fda.hhs.gov>; Williams, Dhanya K <Dhanya.Kumar@fda.hhs.gov>

Subject: RE: K173841-A1 - Updated (b)(4)

Dear Ms. Beckmann,

Thank you for your email.

Ms. Dhanya Williams is the Lead Reviewer for K173841, and I have forwarded the email to her, as well as copied her on this reply. Ms. Williams can assist with questions specific to K173841 and review of the submission.

Regards,

Leigh Anderson

Biomedical Engineer

Neurointerventional Devices Branch (NIDB)

Division of Neurological and Physical Medicine Devices (DNPMD)

Center for Devices and Radiological Health (CDRH)

Office of Device Evaluation (ODE)

U.S. Food and Drug Administration

Tel: 301-796-5613

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From: Beckmann, Angelica [mailto:angelica.beckmann@stryker.com]

Sent: Tuesday, March 06, 2018 6:04 PM

To: Anderson, Leigh <Leigh.Anderson@fda.hhs.gov<mailto:Leigh.Anderson@fda.hhs.gov>>

Cc: Allison, John <John.Allison@stryker.com<mailto:John.Allison@stryker.com>>; Mateus, Jennifer <Jennifer.Mateus@stryker.com<mailto:Jennifer.Mateus@stryker.com>>; Zheng, Xiaolin <Xiaolin.Zheng@fda.hhs.gov<mailto:Xiaolin.Zheng@fda.hhs.gov>>

Subject: K173841-A1 - Updated (b)(4)

Importance: High

Dear Ms. Anderson,

I hope this e-mail finds you well.

(b)(4)

(b)(4)

I would also like to understand the next steps for the interactive review of K173481.

Kind regards,

Angelica Beckmann

Director Regulatory Affairs

Stryker Neurovascular

47900 Bayside Pkwy

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Fremont, CA 94538

510-413-2900 Office

(b)(6)

Mobile

angelica.beckmann@stryker.com<mailto:angelica.beckmann@stryker.com>

Hello Ms. Beckmann,

I recently sent you an email responding to your questions, with a couple of additional interactive requests and a time to set up a call later today. It may be possible that our emails crossed each other, but please let me know if you still haven't received it and I can resend.

Thank you,

Dhanya Williams, M.S.

Biologist/Scientific Reviewer

Center for Devices and Radiological Health (CDRH)

Office of Device Evaluation (ODE)

U.S. Food and Drug Administration

Tel: 301-796-6498

dhanya.williams@fda.hhs.gov

[cid:image001.png@01D1C57E.DFA022A0]<<http://www.fda.gov/>>

[cid:image002.jpg@01D1C57E.DFA022A0]<<https://www.facebook.com/FDA>>

[cid:image003.jpg@01D1C57E.DFA022A0] <https://twitter.com/US_FDA>

[cid:image004.jpg@01D1C57E.DFA022A0] <<http://www.youtube.com/user/USFoodandDrugAdmin>>

[cid:image005.jpg@01D1C57E.DFA022A0] <<http://www.flickr.com/photos/fdaphotos/>>

[cid:image006.jpg@01D1C57E.DFA022A0]

<<http://www.fda.gov/AboutFDA/ContactFDA/StayInformed/RSSFeeds/default.htm>>

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From: Beckmann, Angelica [mailto:angelica.beckmann@stryker.com]

Sent: Wednesday, March 07, 2018 9:02 AM

To: Anderson, Leigh <Leigh.Anderson@fda.hhs.gov>

Cc: Allison, John <John.Allison@stryker.com>; Mateus, Jennifer <Jennifer.Mateus@stryker.com>; Zheng, Xiaolin <Xiaolin.Zheng@fda.hhs.gov>; Williams, Dhanya K <Dhanya.Kumar@fda.hhs.gov>

Subject: RE: K173841-A1 - Updated (b)(4)

Ms. Leigh,

Thank you for your e-mail and for taking my call this morning.

As I mentioned during the call, I thought that Ms. Williams was responsible for this review only during the week you were out of the office.

Ms. Williams,

Please let me know the best pathway to amend the K173481

(b)(4)

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

(b)(4)

Best regards,

Angelica Beckmann

Director Regulatory Affairs

Stryker Neurovascular

47900 Bayside Pkwy

Fremont, CA 94538

510-413-2900 Office

(b)(6)

Mobile

angelica.beckmann@stryker.com<mailto:angelica.beckmann@stryker.com>

From: Anderson, Leigh [mailto:Leigh.Anderson@fda.hhs.gov]

Sent: Wednesday, March 7, 2018 4:30 AM

To: Beckmann, Angelica

<angelica.beckmann@stryker.com<mailto:angelica.beckmann@stryker.com>>

Cc: Allison, John <John.Allison@stryker.com<mailto:John.Allison@stryker.com>>; Mateus, Jennifer <Jennifer.Mateus@stryker.com<mailto:Jennifer.Mateus@stryker.com>>; Zheng, Xiaolin <Xiaolin.Zheng@fda.hhs.gov<mailto:Xiaolin.Zheng@fda.hhs.gov>>; Williams, Dhanya K <Dhanya.Kumar@fda.hhs.gov<mailto:Dhanya.Kumar@fda.hhs.gov>>

Subject: RE: K173841-A1 - Updated (b)(4)

Dear Ms. Beckmann,

Thank you for your email.

Ms. Dhanya Williams is the Lead Reviewer for K173841, and I have forwarded the email to her, as well as copied her on this reply. Ms. Williams can assist with questions specific to K173841 and review of the submission.

Regards,

Leigh Anderson

Biomedical Engineer

Neurointerventional Devices Branch (NIDB)

Division of Neurological and Physical Medicine Devices (DNPMD)

Center for Devices and Radiological Health (CDRH)

Office of Device Evaluation (ODE)

U.S. Food and Drug Administration

Tel: 301-796-5613

leigh.anderson@fda.hhs.gov<mailto:leigh.anderson@fda.hhs.gov>

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From: Beckmann, Angelica [mailto:angelica.beckmann@stryker.com]

Sent: Tuesday, March 06, 2018 6:04 PM

To: Anderson, Leigh <Leigh.Anderson@fda.hhs.gov<mailto:Leigh.Anderson@fda.hhs.gov>>

Cc: Allison, John <John.Allison@stryker.com<mailto:John.Allison@stryker.com>>; Mateus, Jennifer <Jennifer.Mateus@stryker.com<mailto:Jennifer.Mateus@stryker.com>>; Zheng, Xiaolin <Xiaolin.Zheng@fda.hhs.gov<mailto:Xiaolin.Zheng@fda.hhs.gov>>

Subject: K173841-A1 - Updated (b)(4)

Importance: High

Dear Ms. Anderson,

I hope this e-mail finds you well.

(b)(4)

(b)(4)

I would also like to understand the next steps for the interactive review of K173481.

Kind regards,

Angelica Beckmann
Director Regulatory Affairs
Stryker Neurovascular
47900 Bayside Pkwy
Fremont, CA 94538
510-413-2900 Office
(b)(6) Mobile

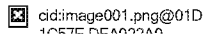
angelica.beckmann@stryker.com<mailto:angelica.beckmann@stryker.com>

Hello Ms. Beckmann,

Thank you very much for getting this updated information to me quickly. I hope to review the rest of the responses and go through (b)(4) in the next few days and if there are any additional interactive requests or information needed interactively I will be in touch with you by close of business on Monday.

Regards,

Dhanya Williams, M.S.
Biologist/Scientific Reviewer
Center for Devices and Radiological Health (CDRH)
Office of Device Evaluation (ODE)
U.S. Food and Drug Administration
Tel: 301-796-6498
dhanya.williams@fda.hhs.gov



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From: Beckmann, Angelica [mailto:angelica.beckmann@stryker.com]
Sent: Thursday, March 08, 2018 2:59 PM
To: Williams, Dhanya K <Dhanya.Kumar@fda.hhs.gov>
Cc: Mateus, Jennifer <Jennifer.Mateus@stryker.com>; K173841@docs.fda.gov; Allison, John <John.Allison@stryker.com>
Subject: RE: K173841 - Interactive request #1 - Updated (b)(4)

Dear Ms. Williams,

Enclosed are the responses to FDA's Interactive Request #1 regarding the 510(k) Submission K173841. The requested information is contained within the attached pdf file.

Please feel free to call me or send email with any additional requests.

Best regards,

Angelica Beckmann
Director Regulatory Affairs
Stryker Neurovascular
47900 Bayside Pkwy
Fremont, CA 94538
(b)(6) Mobile
angelica.beckmann@stryker.com

From: Williams, Dhanya K [mailto:Dhanya.Kumar@fda.hhs.gov]
Sent: Wednesday, March 7, 2018 6:02 AM
To: Beckmann, Angelica <angelica.beckmann@stryker.com>
Cc: Allison, John <John.Allison@stryker.com>; Mateus, Jennifer <Jennifer.Mateus@stryker.com>; K173841@docs.fda.gov; Williams, Dhanya K <Dhanya.Kumar@fda.hhs.gov>
Subject: K173841 - Interactive request #1 - Updated (b)(4)

Hello Ms. Beckmann,

Thank you for your email. As Ms. Anderson noted, I am the lead reviewer for your submission, K173841, and we are still in the process of reviewing your deficiency responses. I will be in touch with you in the next day or two regarding any additional items that need to be addressed as we continue our review, however in the meantime, please address the following:

(b)(4)

(b)(4)

Thank you,

Dhanya Williams, M.S.
Biologist/Scientific Reviewer
Center for Devices and Radiological Health (CDRH)
Office of Device Evaluation (ODE)
U.S. Food and Drug Administration
Tel: 301-796-6498
dhanya.williams@fda.hhs.gov

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From: Anderson, Leigh
Sent: Wednesday, March 07, 2018 7:30 AM
To: 'Beckmann, Angelica' <angelica.beckmann@stryker.com>
Cc: Allison, John <John.Allison@stryker.com>; Mateus, Jennifer <Jennifer.Mateus@stryker.com>; Zheng, Xiaolin <Xiaolin.Zheng@fda.hhs.gov>; Williams, Dhanya K <Dhanya.Kumar@fda.hhs.gov>
Subject: RE: K173841-A1 - Updated (b)(4)

Dear Ms. Beckmann,

Thank you for your email.

Ms. Dhanya Williams is the Lead Reviewer for K173841, and I have forwarded the email to her, as well as copied her on this reply. Ms. Williams can assist with questions specific to K173841 and review of the submission.

Regards,

Leigh Anderson
Biomedical Engineer
Neurointerventional Devices Branch (NIDB)
Division of Neurological and Physical Medicine Devices (DNPMD)
Center for Devices and Radiological Health (CDRH)
Office of Device Evaluation (ODE)
U.S. Food and Drug Administration
Tel: 301-796-5613
leigh.anderson@fda.hhs.gov

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Sent: Tuesday, March 06, 2018 6:04 PM
To: Anderson, Leigh <Leigh.Anderson@fda.hhs.gov>
Cc: Allison, John <John.Allison@stryker.com>; Mateus, Jennifer <Jennifer.Mateus@stryker.com>; Zheng, Xiaolin <Xiaolin.Zheng@fda.hhs.gov>
Subject: K173841-A1 - Updated (b)(4)
Importance: High

Dear Ms. Anderson,
I hope this e-mail finds you well.

(b)(4)

I would also like to understand the next steps for the interactive review of K173481.

Kind regards,

Angelica Beckmann
Director Regulatory Affairs
Stryker Neurovascular
47900 Bayside Pkwy
Fremont, CA 94538
510-413-2900 Office
[REDACTED] Mobile
angelica.beckmann@stryker.com



AXS Catalyst®

Distal Access Catheter

(b)(4)

(b)(4)

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(b)(4)

(b)(4)

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(b)(4)

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(b)(4)

(b)(4)

Stryker Neurovascular

Submission Date:

Response to Interactive Request #2 for K173841-S001, Traditional 510(k)

March 12, 2018

AXS Catalyst Distal Access Catheter

Appendix 2

NV00022382 AXS Catalyst DFU clean version



AXS Catalyst®

Distal Access Catheter

NOTE: This Catheter has two separate indications for use. Read the Directions for Use carefully.

AXS Catalyst®

Distal Access Catheter

Rx ONLY

Caution: Federal Law (USA) restricts this device to sale by or on the order of a physician.

WARNING

Contents supplied STERILE using an ethylene oxide (EO) process. Do not use if sterile barrier is damaged. If damage is found, call your Stryker Neurovascular representative.

For single use only. Do not reuse, reprocess or resterilize. Reuse, reprocessing or resterilization may compromise the structural integrity of the device and/or lead to device failure which, in turn, may result in patient injury, illness or death. Reuse, reprocessing or resterilization may also create a risk of contamination of the device and/or cause patient infection or cross-infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to injury, illness or death of the patient.

After use, dispose of product and packaging in accordance with hospital, administrative and/or local government policy.

DEVICE DESCRIPTION

The AXS Catalyst Distal Access Catheter is a single lumen, variable stiffness catheter designed for use in facilitating the insertion and guidance of appropriately sized interventional devices into the peripheral and neurovascular 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.

User Information

The AXS Catalyst Distal Access Catheter should only be used by physicians trained in interventional endovascular procedures.

Contents

One (1) AXS Catalyst Distal Access Catheter

One (1) Rotating Hemostatic Valve (RHV)

One (1) Tuohy Borst Valve with sideport

Two (2) Peel-away introducer sheaths

Table 1. Compatibility Information

Catheter	Inner Diameter mm (in)	Outer Diameter F (mm) [in]	Effective length (cm)	Overall length (cm)
AXS Catalyst 5	1.47 (0.058)	Prox: 5.6F (1.86) [0.073] Dist: 5.3F (1.76) [0.069]	115, 132	120, 137
AXS Catalyst 6	1.52 (0.060)	Prox: 6.0F (2.01) [0.079] Dist: 5.4F (1.81) [0.071]	132	137

Accessory	Length
RHV	7cm
Tuohy Borst with Sideport	3.5cm

INTENDED USE/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.

CONTRAINDICATIONS

None known.

WARNINGS

- Limited testing has been performed with solutions such as contrast media, and saline. The use of these catheters for delivery of solutions other than the types that have been tested for compatibility is not recommended.
- Not intended for use with power injectors.
- If flow through catheter becomes restricted, do not attempt to clear catheter lumen by infusion. Doing so may cause catheter damage or patient injury. Remove and replace catheter.
- Never advance or withdraw an intravascular device against resistance until the cause of the resistance is determined by fluoroscopy. Movement of the device against resistance could dislodge a clot, perforate a vessel wall, or damage the device.

PRECAUTIONS

- Carefully inspect all devices prior to use. Verify size, length, and condition are suitable for the specific procedure. Ensure the catheter's labeled outer diameter is smaller than the treatment vessel diameter. Do not use a device that has been damaged in any way. Damaged device may cause complications.
- To control the proper introduction, movement, positioning and removal of the catheter within the vascular system, users should employ standard clinical angiographic and fluoroscopic practices and techniques throughout the interventional procedure.
- Use the product prior to the "Use By" date printed on the label.
- To prevent thrombus formation and contrast media crystal formation, maintain a constant infusion of appropriate flush solution through catheter lumen.
- Torquing the catheter may cause damage which could result in kinking or separation of the catheter shaft.

ADVERSE EVENTS

Potential adverse events associated with the use of catheters or with the endovascular procedures include, but are not limited to:

- Access site complications
- Allergic reaction
- Aneurysm perforation
- Aneurysm rupture
- Death
- Embolism (air, foreign body, plaque, thrombus)
- Hematoma
- Hemorrhage
- Infection
- Ischemia
- Neurological deficits
- Pseudoaneurysm
- Stroke
- Transient Ischemic Attack
- Vasospasm
- Vessel dissection
- Vessel occlusion
- Vessel perforation
- Vessel rupture
- Vessel thrombosis

Use of device requires fluoroscopy which presents potential risks to physicians and patients associated with x-ray exposure. Possible risks include, but are not limited to, the following:

- Alopecia
- Burns ranging in severity from skin reddening to ulcers
- Cataracts
- Delayed neoplasia

Adverse Event Reporting

Please notify your Stryker Neurovascular representative immediately if a device malfunctions or patient complication or injury is experienced or suspected. Please make every attempt to retain any suspect device, its associated components and their packaging for return to Stryker Neurovascular.

HOW SUPPLIED

Stryker Neurovascular products are sterile and non-pyrogenic in unopened packaging that is designed to maintain sterility unless the primary product pouch has been opened or damaged.

Do not use if package is opened or damaged.

Do not use if labeling is incomplete or illegible.

Handling and Storage

Store in a cool, dry, dark place.

OPERATIONAL INSTRUCTIONS

Required Additional Items

- Continuous flush set up

PREPARATIONS FOR USE

1. Set-up continuous flush through sheath or guide catheter lumen.
2. Select an appropriately sized catheter based on intended procedure and anatomy.
3. Gently remove contents from pouch using standard sterile technique

Caution: Flush the packaging hoop prior to removal of product to activate the hydrophilic coating of the catheter. Once hydrated, do not allow to dry.

4. Gently remove the catheter and accessories from the hoop and inspect prior to use to verify that they are undamaged. If any damage, replace with a new device.
5. Attach compatible RHV or Tuohy Borst valve based on intended procedure and associated devices, then flush RHV/Tuohy Borst valve and catheter lumen.
6. Set up continuous flush through catheter.

DIRECTIONS FOR USE

1. Gently insert catheter tip through a compatible sheath or guide catheter and over an appropriately sized guidewire.
(Optional) Use the peel-away introducer sheath to assist in insertion of the catheter tip into the sheath/guide catheter valve. Once the catheter is inserted, retract and remove the peel-away introducer sheath.
2. Under fluoroscopic guidance, advance the catheter through the vasculature to the desired location.
3. Once the catheter is at the desired location, insert appropriately sized interventional devices into the selected blood vessel.
4. If used with a retriever, apply aspiration to the catheter using a 60mL syringe during withdrawal of the retrieval device.
5. Continue aspirating until retriever and microcatheter are withdrawn from the catheter.

Note: If using a retriever and withdrawal of the device is difficult, simultaneously withdraw the catheter, microcatheter and retriever as a unit into the sheath/ guide catheter. Remove sheath/guide catheter if necessary.

Table 2. Flow rate

Media (100%)	Size	Approximate Average Flow rate at 43.5 psi (300 Ppa), (ml/min)
--------------	------	---

Saline	0.058 x 115	438
	0.058 x 132	405
	0.060 x 132	445
Omnipaque®-300 (Non-ionic Contrast)	0.058 x 115	158
	0.058 x 132	141
	0.060 x 132	156
MD-76R (Ionic Contrast)	0.058 x 115	103
	0.058 x 132	91
	0.060 x 132	102

WARRANTY

Stryker Neurovascular warrants that reasonable care has been used in the design and manufacture of this instrument. **This warranty is in lieu of and excludes all other warranties not expressly set forth herein, whether express or implied by operation of law or otherwise, including, but not limited to, any implied warranties of merchantability or fitness for a particular purpose.** Handling, storage, cleaning and sterilization of this instrument as well as other factors relating to the patient, diagnosis, treatment, surgical procedures and other matters beyond Stryker Neurovascular's control directly affect the instrument and the results obtained from its use. Stryker Neurovascular's obligation under this warranty is limited to the repair or replacement of this instrument and Stryker

Neurovascular shall not be liable for any incidental or consequential loss, damage or expense directly or indirectly arising from the use of this instrument. Stryker Neurovascular neither assumes, nor authorizes any other person to assume for it, any other or additional liability or responsibility in connection with this instrument. **Stryker Neurovascular assumes no liability with respect to instruments reused, reprocessed or resterilized and makes no warranties, express or implied, including but not limited to merchantability or fitness for a particular purpose, with respect to such instruments.**

Omnipaque is a trademark of GE Healthcare.

AXS Universal Aspiration System

Rx ONLY

Caution: Federal Law (USA) restricts this device to sale by or on the order of a physician.

WARNING

Contents supplied STERILE using an ethylene oxide (EO) process. Do not use if sterile barrier is damaged. If damage is found, call your Stryker Neurovascular representative.

The AXS Catalyst Distal Access Catheter is for single use only. Do not reuse, reprocess or resterilize. Reuse, reprocessing or resterilization may compromise the structural integrity of the device and/or lead to device failure which, in turn, may result in patient injury, illness or death. Reuse, reprocessing or resterilization may also create a risk of contamination of the device and/or cause patient infection or cross-infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to injury, illness or death of the patient.

After use, dispose of product and packaging in accordance with hospital, administrative and/or local government policy.

DEVICE DESCRIPTION

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 Universal Aspiration System is designed to remove thrombus from the neurovasculature using continuous aspiration. The AXS Catalyst Distal Access Catheter delivers aspiration from the Medela Dominant Flex Pump directly to the site of the occlusion to remove the clot. 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 Hemostatic Valve (RHV), Tuohy Borst Valve with Sideport, and Peel Away Introducer. The Rotating Hemostatic 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.

User Information

The AXS Universal Aspiration System should only be used by physicians trained in interventional endovascular procedures.

Contents

One (1) AXS Catalyst Distal Access Catheter

One (1) Rotating Hemostatic Valve (RHV)
 One (1) Tuohy Borst Valve with sideport
 Two (2) Peel-away introducer sheaths

Table 1. Compatibility Information

Catheter	Inner Diameter mm (in)	Outer Diameter F (mm) [in]	Effective length (cm)	Overall length (cm)
AXS Catalyst 5	1.47 (0.058)	Prox: 5.6F (1.86) [0.073] Dist: 5.3F (1.76) [0.069]	115, 132	120, 137
AXS Catalyst 6	1.52 (0.060)	Prox: 6.0F (2.01) [0.079] Dist: 5.4F (1.81) [0.071]	132	137

Accessory	Length
RHV	7cm
Tuohy Borst with Sideport	3.5cm

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.

CONTRAINDICATIONS

None known.

WARNINGS

- Limited testing has been performed with solutions such as contrast media, and saline. The use of these catheters for delivery of solutions other than the types that have been tested for compatibility is not recommended.
- Not intended for use with power injectors.
- If flow through catheter becomes restricted, do not attempt to clear catheter lumen by infusion. Doing so may cause catheter damage or patient injury. Remove and replace catheter.
- Never advance or withdraw an intravascular device against resistance until the cause of the resistance is determined by fluoroscopy. Movement of the device against resistance could dislodge a clot, perforate a vessel wall, or damage the device.
- Excessive aspiration may cause patient complications.

PRECAUTIONS

- Carefully inspect all devices prior to use. Verify size, length, and condition are suitable for the specific procedure. Ensure the catheter's labeled outer diameter is smaller than the treatment vessel diameter. Do not use a device that has been damaged in any way. Damaged device may cause complications.
- To control the proper introduction, movement, positioning and removal of the catheter within the vascular system, users should employ standard clinical angiographic and fluoroscopic practices and techniques throughout the interventional procedure.
- Use the product prior to the "Use By" date printed on the label.
- To prevent thrombus formation and contrast media crystal formation, maintain a constant infusion of appropriate flush solution through catheter lumen.

- Torquing the catheter may cause damage which could result in kinking or separation of the catheter shaft.

ADVERSE EVENTS

Potential adverse events associated with the use of catheters or with the endovascular procedures include, but are not limited to:

- Access site complications
- Allergic reaction
- Aneurysm perforation
- Aneurysm rupture
- Death
- Embolism (air, foreign body, plaque, thrombus)
- Hematoma
- Hemorrhage
- Infection
- Ischemia
- Neurological deficits
- Pseudoaneurysm
- Stroke
- Transient Ischemic Attack
- Vasospasm
- Vessel dissection
- Vessel occlusion
- Vessel perforation
- Vessel rupture
- Vessel thrombosis

Use of device requires fluoroscopy which presents potential risks to physicians and patients associated with x-ray exposure.

Possible risks include, but are not limited to, the following:

- Alopecia
- Burns ranging in severity from skin reddening to ulcers
- Cataracts
- Delayed neoplasia

Adverse Event Reporting

Please notify your Stryker Neurovascular representative immediately if a device malfunctions or patient complication or injury is experienced or suspected. Please make every attempt to retain any suspect device, its associated components and their packaging for return to Stryker Neurovascular.

HOW SUPPLIED

Stryker Neurovascular products are sterile and non-pyrogenic in unopened packaging that is designed to maintain sterility unless the primary product pouch has been opened or damaged.

Do not use if package is opened or damaged.

Do not use if labeling is incomplete or illegible.

Handling and Storage

Store in a cool, dry, dark place.

OPERATIONAL INSTRUCTIONS

Required Additional Items

- Continuous flush set up

PREPARATIONS FOR USE

1. Set-up continuous flush through sheath or guide catheter lumen.
2. Select an appropriately sized catheter based on intended procedure and anatomy.
3. Gently remove contents from pouch using standard sterile technique

Caution: Flush the packaging hoop prior to removal of product to activate the hydrophilic coating of the catheter. Once hydrated, do not allow to dry.

4. Gently remove the catheter and accessories from the hoop and inspect prior to use to verify that they are undamaged. If any damage, replace with a new device.
5. Attach compatible RHV or Tuohy Borst valve based on intended procedure and associated devices, then flush RHV/Tuohy Borst valve and catheter lumen.
6. Set up continuous flush through catheter.
7. Attach the AXS Universal Aspiration Tubing to the Medela Dominant Flex Pump and ensure the aspiration control valve on the tubing is closed. Turn on the Medela Dominant Flex Pump (refer to the Medela Dominant Flex Pump manual). Confirm that the Medela Dominant Flex Pump reads -68kPa to -98kPa [-510mmHg to -735mmHg].

DIRECTIONS FOR USE

1. Gently insert catheter tip through a compatible sheath or guide catheter and over an appropriately sized guidewire.
(Optional) Use the peel-away introducer sheath to assist in insertion of the catheter tip into the sheath/guide catheter valve. Once the catheter is inserted, retract and remove the peel-away introducer sheath.
2. Under fluoroscopic guidance, advance the catheter through the vasculature to the desired location.
3. Tighten the RHV/Tuohy Borst valve to prevent backflow.
4. Connect the AXS Universal Aspiration Tubing to the side port of the rotating hemostasis valve of the AXS Catalyst Distal Access Catheter. To apply aspiration, open the aspiration tubing clamp.
5. Continue to aspirate until the clot is withdrawn.
6. If flow through catheter becomes restricted, do not attempt to clear catheter lumen by infusion. Doing so may cause catheter damage or patient injury. Remove catheter under aspiration and flush catheter outside of patient. If flush is unsuccessful, replace catheter.
7. If not damaged the AXS Catalyst Distal Access Catheter may be used for up to three (3) clot retrieval attempts. A clot retrieval attempt is one (1) advancement and complete withdrawal cycle of the distal access catheter.

Table 2. Flow rate

Media (100%)	Size	Approximate Average Flow rate at 43.5 psi (300 Ppa), (ml/min)
Saline	0.058 x 115	438
	0.058 x 132	405
	0.060 x 132	445
Omnipaque®-300 (Non-Ionic Contrast)	0.058 x 115	158
	0.058 x 132	141
	0.060 x 132	156
MD-76R (Ionic Contrast)	0.058 x 115	103
	0.058 x 132	91
	0.060 x 132	102

WARRANTY

Stryker Neurovascular warrants that reasonable care has been used in the design and manufacture of this instrument. **This warranty is in lieu of and excludes all other warranties not expressly set forth herein, whether express or implied by operation of law or otherwise, including, but not limited to, any implied warranties of merchantability or fitness for a particular purpose.** Handling, storage, cleaning and sterilization of this instrument as well as other factors relating to the patient, diagnosis, treatment, surgical procedures and other matters beyond Stryker Neurovascular's control directly affect the instrument and the results obtained from its use. Stryker Neurovascular's obligation under this warranty is limited to the repair or replacement of this instrument and Stryker

Neurovascular shall not be liable for any incidental or consequential loss, damage or expense directly or indirectly arising from the use of this instrument. Stryker Neurovascular neither assumes, nor authorizes any other person to assume for it, any other or additional liability or responsibility in connection with this instrument. **Stryker Neurovascular assumes no liability with respect to instruments reused, reprocessed or resterilized and makes no warranties, express or implied, including but not limited to merchantability or fitness for a particular purpose, with respect to such instruments.**

Omnipaque is a trademark of GE Healthcare.



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Sponsor Address**

Stryker Australia Pty Ltd
8 Herbert Street
St Leonards, NSW 2065
Australia



**Legal
Manufacturer**

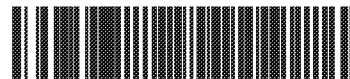
Stryker Neurovascular
47900 Bayside Parkway
Fremont, CA 94538
USA
USA Customer Service 855-91 NEURO (916-3876)



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2018-03

NV00022382-01

Organizer: Williams, Dhanya K : Dhanya.Kumar@fda.hhs.gov
Subject: K173841 - (b)(4)
Location: Webex
Start Time: 2018-03-07T13:30:00-05:00
End Time: 2018-03-07T14:00:00-05:00
Attendees: Zheng, Xiaolin : Xiaolin.Zheng@fda.hhs.gov, 'Beckmann, Angelica' : angelica.beckmann@stryker.com, Allison, John : John.Allison@stryker.com, Mateus, Jennifer, Jennifer.Mateus@stryker.com, K173841@docs.fda.gov : K173841@docs.fda.gov, Ellis, Kristin (Contractor) : kristin.ellis@stryker.com

(b)(4)

Please see updated time to 1:30pm upon sponsor*s request.

Hello all,

I am setting up this brief call with your team and NIDB branch chief Dr. Xiaolin Zheng to discuss your AXS Catalyst (K173841) submission in regards to the (b)(4)

(b)(4)

Right now I have set this call up for 12:30pm EST, however please let me know if you would like me to reschedule for 1:30pm EST instead.

Thank you,
Dhanya Williams
Tel: 301-796-6498

WEBEX Info:

-- Do not delete or change any of the following text. --

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Food and Drug Administration
CDRH/ODE/DNPMD/NIDB
WO66 RM2664
10903 New Hampshire Ave
Silver Spring, MD 20993-0002
301-796-6498

Premarket Notification 510(k) Review

Date: March 14, 2018

Reviewer: Dhanya K Williams

Subject: Traditional 510(k)# K173841

Applicant: Stryker

Contact Name: Angelica Beckmann

Correspondent Firm: Stryker

Received Date: December 18, 2017

Pro Code(s): NRY **Class:** II **Reg #:** 870.1250

Pro Code(s): DQY **Class:** II **Reg #:** 870.1250

Device Trade Name: AXS Catalyst Distal Access Catheter 058 x 115cm; AXS Catalyst Distal Access Catheter 058 x 132cm; AXS Catalyst Distal Access Catheter 060 x 132cm

Contact Title: Director, Regulatory Affairs

Phone: (510) 413-2900 **Email:** angelica.beckmann@stryker.com

Due Date: March 18, 2018

Reg Name: Percutaneous Catheter

Reg Name: Percutaneous catheter

Predicate Devices:

Submission #	Pro Code	Device Trade Name	Applicant
K090752	NRY	Penumbra System (penumbra Reperfusion Catheter 054), Model Psc054; (penumbra Separator 054), Model Pss054	Penumbra, Inc.
K151667	DQY	Axs Catalyst Distal Access Catheter 058x115cm, Axs Catalyst Distal Access Catheter 058x132cm, Axs Catalyst Distal Access Catheter 060x132cm	Stryker

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March 18, 2018</br></br><p>We have completed our review. Please refer to the attached letter for details.</p>

<p>If you have any questions, please contact the lead reviewer assigned to your submission, Dhanya Williams.</p>

<p>*** This is a system-generated email notification ***</p>

Indications for Use

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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Section 019 Performance Testing – Bench

Performance Testing – Bench details are provided on the following pages.

Section 019 Performance Testing – Bench

Design Verification & Validation Testing / Summary of Design Control Activities

Stryker Neurovascular took the FDA issued guidance Pre-Clinical and Clinical Studies for Neurothrombectomy Devices into account when submitting the Subject Device and its performance evaluation data. The guidance document outlines requirements in three major areas of investigation: Biocompatibility, Pre-clinical Testing (including bench and animal testing), and Clinical Studies. This section of the 510(k) will address the pre-clinical bench testing.

Pre-clinical Evaluation

Per the guidance, pre-clinical evaluation consists of bench and animal tests which are used to establish the usability, safety, and effectiveness of the Subject Device to serve as a neurothrombectomy implement. Bench testing utilized the AXS Catalyst and its prescribed accessories (Medela Dominant Flex Pump, AXS Universal Liner Set, AXS Universal Aspiration Tubing), where applicable. Discussion of the test objectives, endpoints, pass/fail criteria, methods and conditions, test unit description and rationale, sample size and rationale, and conclusions drawn can be found in the referenced protocols and reports listed in **Section 019, Table 1** below.

Usability

The usability of the device was also assessed in Design Verification and Design Validation bench testing in which the maneuverability, flexibility, durability, and torque strength were evaluated.

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An overview of

the Usability Testing is provided below with the results provided in **Section 019, Table 2**.

Effectiveness

The effectiveness of the Subject Device as a neurothrombectomy implement was assessed with bench testing. The ability of the catheter to maintain lumen patency during aspiration was evaluated in Usability and Design Validation Testing.

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An overview of the Usability Testing

is provided below and the results are summarized in **Section 019, Table 2**. An overview of the Design Validation Testing for clot aspiration is provided below and the results are summarized in **Section 019, Table 3**. The Subject Device was found to be as effective as the currently marketed Reference Predicate.

The results of design verification and design validation testing conducted on the AXS Catalyst™ Distal Access Catheter when used as part of the aspiration system, which consists of the AXS Catalyst™ Distal Access Catheter and the aspiration accessories (Medela Dominant Flex Pump with Suction Jar, AXS Universal Aspiration Tubing, and AXS

Universal Liner Set), demonstrate that it performs as designed, and is suitable for the additional indication for use.

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Section 019, Table 1 lists the protocols and reports for the testing conducted on AXS Catalyst Distal Access Catheter when used as part of the aspiration system. **Section 019, Table 1** also provides protocols and reports for the previously cleared testing conducted on the AXS Catalyst Distal Access Catheter.

Section 019, Table 1: Design Validation and Design Verification Protocols and Reports		
Document Number	Document Title	Location
(b)(4)	Protocol, Design Validation Study for the AXS Catalyst Distal Access Catheters in a Flow Model with Clot Aspiration	Section 019, Attachment 19A
	DVal Report, Design Validation Study for the AXS Catalyst Distal Access Catheters in a Flow Model with Clot Aspiration	Section 019, Attachment 19B
	Protocol, Non-GLP Design Validation Study for the AXS Catalyst Distal Access Catheters in a Flow Model with Clot Aspiration	K163237-S001, Attachment 11
	DVal Report, Clot Aspiration for AXS Catalyst Distal Access Catheters	K163237, Section 019, Attach 1
	TM, Buckling Test, Lotus Catheter	K151667, Attachment H
	TM, Lotus Advance Tracking Force	Attachment 2 of Technical Report (b)(4) provided in Section 19, Attachment 19C
	Product Characterization Technical Report, AXS Catalyst Catheter	Section 19, Attachment 19C
	Adjunctive Aspiration, Lotus Catheter	K151667, Attachment H-13

Section 019, Table 1: Design Validation and Design Verification Protocols and Reports		
(b)(4)	Document Title	Location
	Direct Aspiration, Lotus Catheter	K163237-S001, Attachment 9
	DV Protocol, Cat 5 and Cat 6 Medela Pump Compatibility	K163237-S001, Attachment 10
	DV Report, Cat 5 and Cat 6 Medela Pump Compatibility	K163237, Section 019, Attach 2
	Accelerated Aging Protocol, AXS Catalyst Distal Access Catheter, 25 Months	K163237-S001, Attachment 7
	Accelerated Aging Report, AXS Catalyst Distal Access Catheter, 25 Month	K163237-S001, Attachment 8
	DV Protocol, AXS Catalyst Distal Access Catheter	K151667, Attachment E-1
	DV Report (t=0), AXS Catalyst Distal Access Catheter	K151667, Attachment E-2
	Accelerated Aging (7 Month) Protocol, AXS Catalyst Distal Access Catheter	K151667, Attachment E-3
	Accelerated Aging Report, AXS Catalyst Distal Access Catheter, 7 Month	K151667, Attachment E-4
	Accelerated Aging Protocol, AXS Catalyst Distal Access Catheter, 25 Months	K151667, Attachment E-5
	Accelerated Aging Report, AXS Catalyst Distal Access Catheter, 25 Month	K151667-S001, Attachment K
	Real Time Aging Protocol, AXS Catalyst Distal Access Catheter, 25 Months	K151667, Attachment E-6
	Lotus Packaging Design Verification & Aging Protocol	K151667, Attachment E-9
	AXS Catalyst Catheter Packaging Design Verification and Aging Report	Section 015, Attachment 15B

Aspiration: Usability Testing

Design Validation Testing incorporating end users was performed to evaluate the ability of the AXS Catalyst 5 and AXS Catalyst 6 Distal Access Catheters to capture clot in tortuous anatomy when used with the aspiration accessories, which include the Medela Dominant Flex Pump with Suction Jar, AXS Universal Aspiration Tubing, and AXS

Universal Liner Set. The AXS Catalyst Distal Access Catheters and aspiration accessories were compared to the Primary Predicate Penumbra ACE60 Reperfusion Catheter used with the Penumbra MAX pump. The usability testing is summarized in **Section 019, Table 2** below.

Section 019, Table 2: Overview of Usability Testing Results – Clot Aspiration

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Section 019, Attachment 19D.

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Previously Completed Testing

As the design of the device has not changed, and the intent of the submission is to add an indication for use, the previously cleared testing submitted as part of **K151667** remains in effect and was not duplicated.

An overview of the previously cleared bench testing is provided in **Section 019, Table 6** below for reference.

Section 019, Table 6: Previously Cleared Bench Testing Summary		
Test	Test Method Summary	Conclusions
Dimensional Verification	(b)(4)	
Tip Configuration		
Surface Integrity		

Section 019, Table 6: Previously Cleared Bench Testing Summary		
Test	Test Method Summary	Conclusions
Tip Buckling	(b)(4)	
Catheter lubricity and durability		
Trackability		
Tensile Strength		

Section 019, Table 6: Previously Cleared Bench Testing Summary		
Test	Test Method Summary	Conclusions
Liquid Leak Resistance	(b)(4)	
Air Leak Resistance		
Catheter Torsional Bond Strength		

Section 019, Table 6: Previously Cleared Bench Testing Summary		
Test	Test Method Summary	Conclusions
Flexural Fatigue	(b)(4)	
Catheter Kink Radius		
Catheter Tip and Lumen Patency (Adjunctive Aspiration)		

Section 019, Table 6: Previously Cleared Bench Testing Summary		
Test	Test Method Summary	Conclusions
Chemical Compatibility	(b)(4)	
Hub Gauging		
Simulated Use		

Risk Assessment

Risk assessment of the AXS Catalyst Distal Access Catheter when used in conjunction with the aspiration accessories has been conducted in accordance with EN ISO 14971.

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Conclusion

Results of verification and validation testing are appropriate for use in determining that the AXS Catalyst™ Distal Access Catheter subject device when used in conjunction with the aspiration accessories is substantially equivalent to the predicate devices.

Section 019 Performance Testing – Bench

Attachment 19A - (b)(4) Protocol, Design Validation Study for the AXS Catalyst Distal Access Catheters in a Flow Model with Clot Aspiration

Attachment is individually paginated.

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Section 019 Performance Testing – Bench

Attachment 19B – (b)(4) DVal Report, Design Validation Study for the AXS Catalyst Distal Access Catheters in a Flow Model with Clot Aspiration

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Section 019 Performance Testing – Bench

Attachment 19C – (b)(4) Product Characterization Technical Report AXS Catalyst Catheter

Attachment is individually paginated.

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Section 019 Performance Testing – Bench

Attachment 19D – (b)(4) Neurovascular Challenge Path Justification

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Section 019 Performance Testing – Bench

Attachment 19E – (b)(4) Direct Aspiration, Lotus Catheter (b)(4)

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Section 020 Performance Testing – Animal

Performance Testing – Animal details are provided on the following pages.

Section 020 Performance Testing – Animal

Two GLP Animal Studies were conducted to evaluate Direct Aspiration of the AXS Catalyst Distal Access Catheter in combination with the Medela Dominant Flex Surgical Suction Pump. The two studies are summarized below.

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Section 020 Performance Testing – Animal

Attachment 20A - (b)(4) GLP Report

Attachment is individually paginated.

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Final Report

GLP Efficacy and Safety Evaluation of the Stryker AXS Aspiration Solution for Neurothrombectomy in a Chronic Swine Model

Study Number:

(b)(4)

Issue Date:

Study Initiation Date:

Submitted to:

Stryker Neurovascular
47900 Bayside Parkway
Fremont, CA 94538-6515

Submitted by:

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(b)(4)

Date

12/13/17

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Section 021 Clinical Summary

Details for the Clinical Summary are provided on the following pages.

Section 021 Clinical Information

Stryker Neurovascular took the FDA issued guidance Pre-Clinical and Clinical Studies for Neurothrombectomy Devices into account when submitting the Subject Device and its performance evaluation data. The guidance document outlines requirements in three major areas of investigation: Biocompatibility, Pre-clinical Testing (including bench and animal testing), and Clinical Studies. This section of the 510(k) will address Clinical Studies.

Through the pre-clinical evaluations completed and described in **Section 019** and **Section 020** of this 510(k) submission, Stryker Neurovascular has determined that the Subject Device is substantially equivalent to both the Reference Predicate (AXS Catalyst) and the Primary Predicate (Penumbra Reperfusion Catheter, aka 5Max and 5Max ACE). As such, it has shown to be equivalent in dimensions, technology, safety, and effectiveness. It will be used in the same manner, has the same intended use, and poses no additional risks (see **Section 013** for a more detailed substantial equivalence discussion).

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Section 021 Clinical Summary

Attachment 21A – (b)(4) AXS Catalyst Catheter Clinical Experience Summary

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Appendix D: Copies of Included Literature

Copies of included literature are attached in the document's properties page in PLM.

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Initial Experience Using the 5MAX™ ACE Reperfusion Catheter in Intra-arterial Therapy for Acute Ischemic Stroke

Seby John, Muhammad S. Hussain, Gabor Toth, Mark Bain, Ken Uchino, Ferdinand K. Hui
Cerebrovascular Center, Cleveland Clinic, Cleveland, OH, United States

Objectives : The 5MAX ACE is a new large bore aspiration catheter available for vessel recanalization for treatment of acute ischemic stroke (AIS). We report our initial experience with its use.

Methods : A retrospective analysis of patients undergoing intra-arterial therapy for AIS using the 5MAX ACE reperfusion catheter at our institution was performed. Patient demographics, clinical characteristics and procedural data were obtained from chart review. Successful recanalization was defined as achievement of Thrombolysis in Cerebral Infarction score (TICI) 2b-3 and time to recanalization was defined as time from groin puncture to achievement of at least TICI 2b recanalization.

Results : The 5MAX ACE was used in 15 patients from July-October 2013. Direct aspiration was used as the primary technique in 10/15 (67%) patients. Out of these, aspiration alone was sufficient for recanalization in 3 (20%) patients. In the remaining 7 (47%) patients, additional devices were used. In 5/15 (33%) patients, combined aspiration/stentriever thrombectomy using Solitaire™ (3/5 patients) and Penumbra 3D Separator™ (2/5 patients) were used as the primary technique. Successful recanalization (TICI 2b-3) was achieved in 11/15 (73%) patients. Average time from groin puncture to successful recanalization was 46 +/- 30 minutes (range 14-98 minutes). There were no procedural complications.

Conclusion : The 5MAX ACE is a useful recanalization tool, either by direct aspiration or combined stentriever/aspiration. It may be most advantageous with large clots in the internal carotid artery. The potential for effective and faster recanalization using this device alone or in combination may be a good topic for future study.

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Keywords Acute stroke, Cerebral revascularization, Endovascular procedures, Mechanical aspiration

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INTRODUCTION

Intra-arterial therapy (IAT) is a treatment option in patients with severe acute ischemic stroke (AIS) from arterial occlusion who do not respond to intravenous

tissue plasminogen activator (tPA) or in whom tPA is contraindicated. Efficient and timely recanalization of the occluded vessel is an extremely important goal in IAT. With continuing advancements in the development of endovascular devices and techniques, more

options are now available for management of AIS. Using newer thrombectomy devices, better recanalization rates can be achieved in much shorter times compared to older devices.^{5,6)} The 5MAX ACE reperfusion catheter (Penumbra, Inc., Alameda, CA, USA), a new large bore aspiration catheter available for vessel recanalization, was launched in July 2013. We report on our initial experience with the use of this catheter.

MATERIALS AND METHODS

This was a retrospective case series analysis study of patients undergoing IAT for AIS using the 5MAX ACE reperfusion catheter. The neuroendovascular procedure log of our institution was searched in order to identify all patients in whom the catheter was used since the time it became available. Patient demographics, clinical characteristics, and procedural data were obtained from chart review. Successful recanalization was defined as achievement of TICI score 2b-3. Time to recanalization was defined as time from groin puncture to achievement of at least TICI score 2b recanalization.

Technique

The 5MAX ACE reperfusion catheter can be used in several ways in the endovascular treatment of AIS. Direct aspiration involves placement of a large bore aspiration catheter at the face of the clot and aspirating until the device becomes occlusive.⁴⁾ This technique has become increasingly feasible with modern, ultra-flexible intermediate lumen catheters, leading some centers to use the approach as a first line endovascular technique for IAT in AIS.⁸⁾ Other techniques include catheter with mechanical disruption using the Penumbra Separator (Penumbra, Inc., Alameda, California, USA) or in conjunction with a stent-retriever, such as the Trevo[®] (Stryker, Kalamazoo, MI, USA) or Solitaire[™] (Covidien, Plymouth, MN, USA) providing aspiration at the clot during device retrieval.²⁾ There is no universal protocol for method of mechanical thrombectomy and the technique is op-

erator dependent. In most cases of large vessel occlusion, direct aspiration technique is used as the primary method for mechanical thrombectomy. For MCA occlusions, some operators use stent-trievers in combination with direct aspiration as the primary technique. Two patients in our cohort were part of a clinical trial wherein in the Separator 3D device was used.

Patients who underwent IAT were selected per the AIS therapy protocols instituted in our hospital. Cerebral vessel access was established using a guide sheath; either a 6F Neuron[™] Max 088 (Penumbra, Inc., Alameda, CA, USA) or a 6F/7F Shuttle (Cook, Inc., Bloomington, IN, USA). For extra support, the guide sheath was advanced as distal as possible in the internal carotid artery (ICA) for anterior circulation strokes, usually at the skull base or the petrous segment. For the two patients with basilar artery thrombus, the guide sheath was advanced up to the distal V2 segment.

The following technique was used for most patients: under road map assistance, the 5MAX ACE was advanced to the face of the clot over a microcatheter (3MAX reperfusion catheter [Penumbra, Inc., Alameda, CA, USA]) and a 0.016 inch microwire (Fathom [Boston Scientific Corp., Natick, MA, USA]). The wire and the microcatheter were advanced very gently across the clot into a bifurcation branch of the middle cerebral artery (MCA) followed by advancement of the 5MAX ACE. Once the 5MAX ACE was immediately adjacent to the clot, the microcatheter and microwire were removed. Manual suction was applied to the 5MAX ACE using a 0.6 dL syringe. Once a good seal was obtained, the 5MAX ACE catheter was slowly pulled out, maintaining the aspiration. During removal, simultaneous suction to the side port of the guide sheath was applied using a 0.6 dL syringe. Once the 5MAX ACE was removed from the body, the guide sheath was opened to allow back bleeding of possible clots, and then flushed forward once it was confirmed that there were no more clots (Fig. 1). This process using the tri-axial unit was re-

5MAX ACE IN STROKE INTRA-ARTERIAL THERAPY

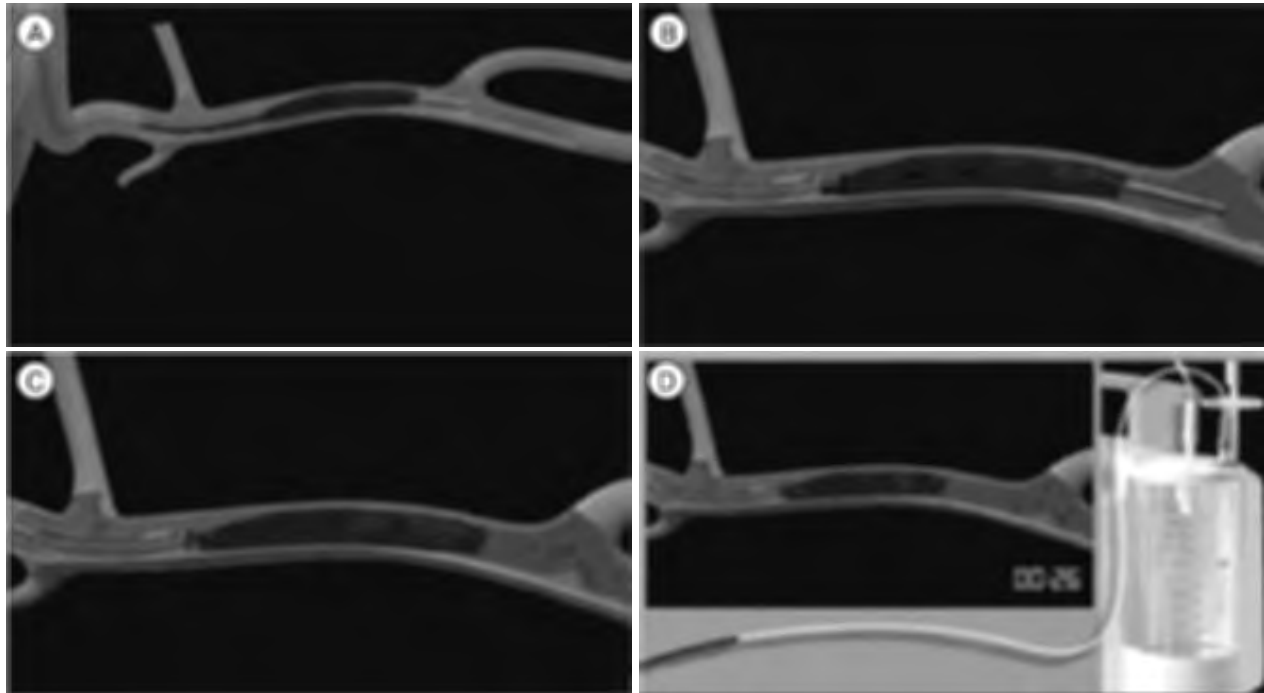


Fig. 1. Diagram showing the direct aspiration technique. First (A), the microwire is advanced past the clot and the microcatheter is advanced to the face of the clot. The 5MAX ACE is then advanced over the microcatheter to the face of the clot (B). The microwire and microcatheter are then removed (C), and suction is applied to the 5MAX ACE (D).

peated if necessary. Additional devices including stent-retriever, separator with aspiration or direct aspiration through smaller sized catheters (4MAX or 3MAX reperfusion Penumbra catheters) were used for persistent clots or embolization into smaller caliber arteries (Figs. 2 and 3).

The second technique involving the use of 5MAX ACE was combined aspiration/stentriever thrombectomy using Solitaire™ (ev3/Covidien, Plymouth, MN, USA). After establishing cerebral vascular access as described above, a microcatheter for Solitaire delivery was placed within the 5MAX ACE and advanced to the site of occlusion under road map assistance. The 5MAX ACE was advanced as distally as safely possible. The microwire and microcatheter were advanced through and beyond the thrombus. The microwire was then removed and the stent was deployed over the site of the thrombus. Once satisfactorily deployed, the microcatheter was removed. After 5 minutes, aspiration/stent thrombectomy was performed

by pulling the stent into the distal access catheter while applying simultaneous aspiration to the 5MAX ACE using a 0.6 dL syringe. Additional thrombectomy attempts were performed as needed (Fig. 4).

RESULTS

Fifteen patients who underwent IAT for AIS from July to October 2013, in whom the 5MAX ACE reperfusion catheter was used as described above, were included in the study. The characteristics of the patients are shown in Table 1. The cohort included 10 males (67%), with a median age of 73 years (range 46-89). The median National Institutes of Health Stroke Scale (NIHSS) score at admission was 13 (range 0-27). Six (40%) patients received intravenous tPA prior to undergoing IAT. Thirteen (87%) patients had vessel occlusion in the anterior circulation (ICA 8 [53%], M1 5 [33%]), and 2 (13%) had basilar artery thrombus. Direct aspiration through the 5MAX ACE

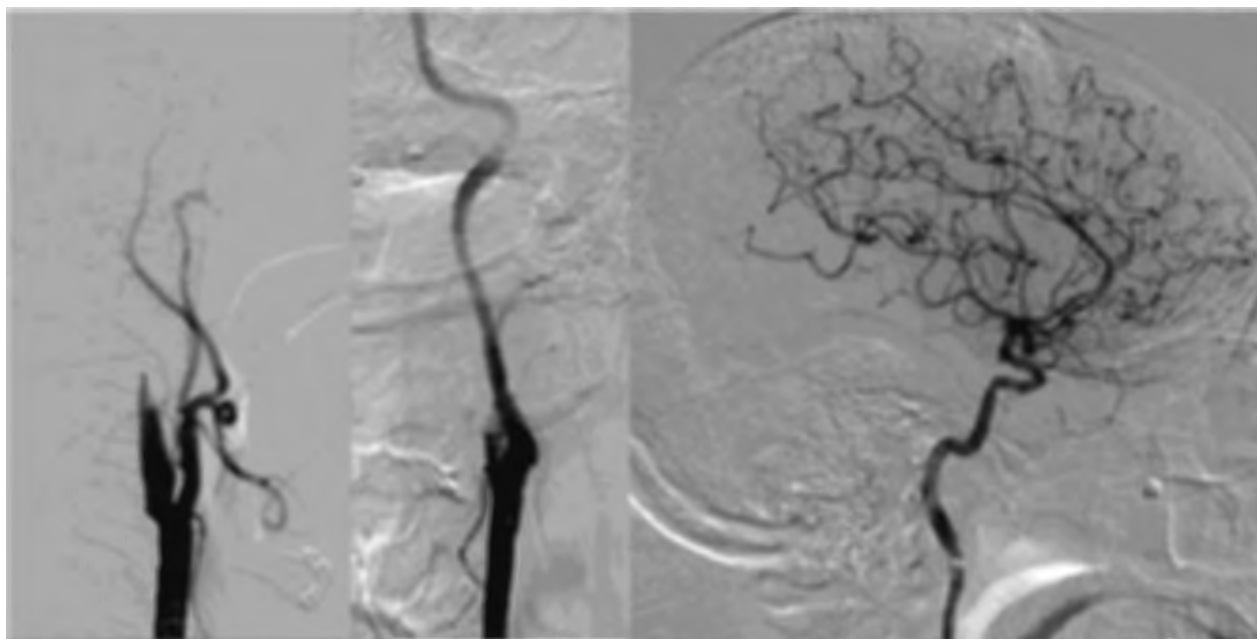


Fig. 2. Patient No 1. Left internal carotid artery (LICA) thrombus with thrombolysis in cerebral infarction (TICI) score 0 flow. After the first attempt with direct aspiration, flow was restored in the LICA. Post intervention angiogram shows TICI score 3 recanalization.

was used as the first thrombectomy technique in 10/15 (67%) patients. Out of these 10 patients, direct aspiration alone was sufficient for recanalization in 3

(20%) patients. In the remaining 7 (47%) patients, additional devices were used for recanalization (Solitaire in 5 patients and Penumbra separator in 2 patients).

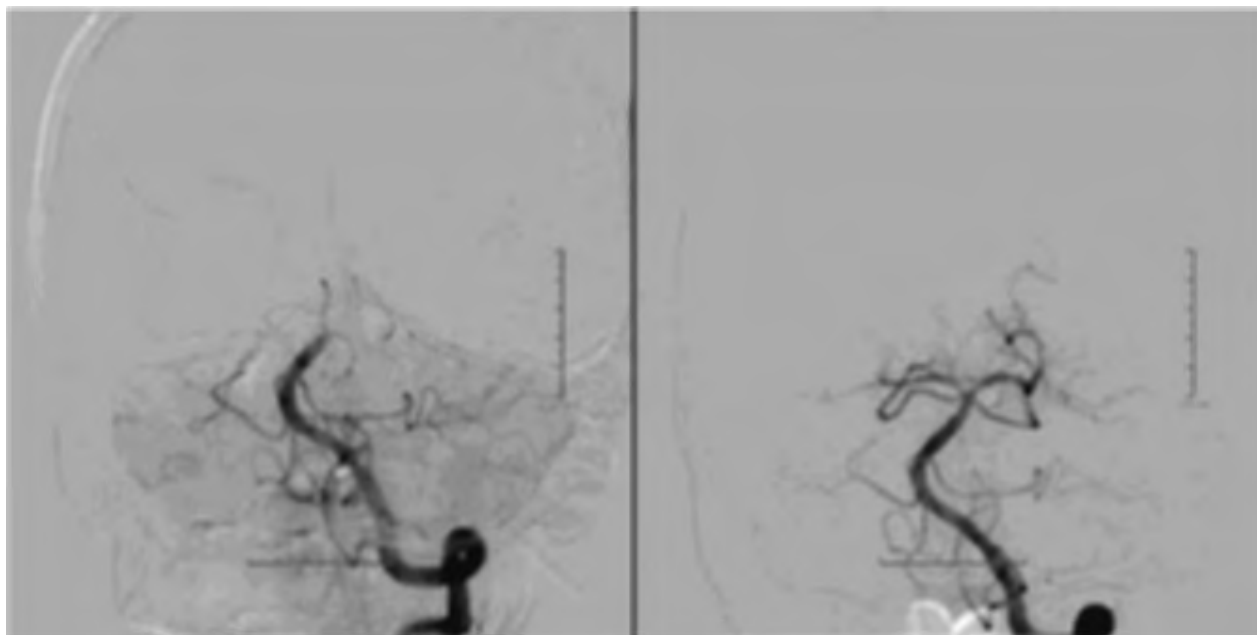


Fig. 3. Patient No. 15. Basilar apex is occluded with absence of opacification of bilateral posterior cerebral arteries. First two attempts at direct aspiration were unsuccessful. After the third attempt at direct aspiration, the basilar occlusion was recanalized with establishment of thrombolysis in cerebral infarction score 2b flow.

5MAX ACE IN STROKE INTRA-ARTERIAL THERAPY

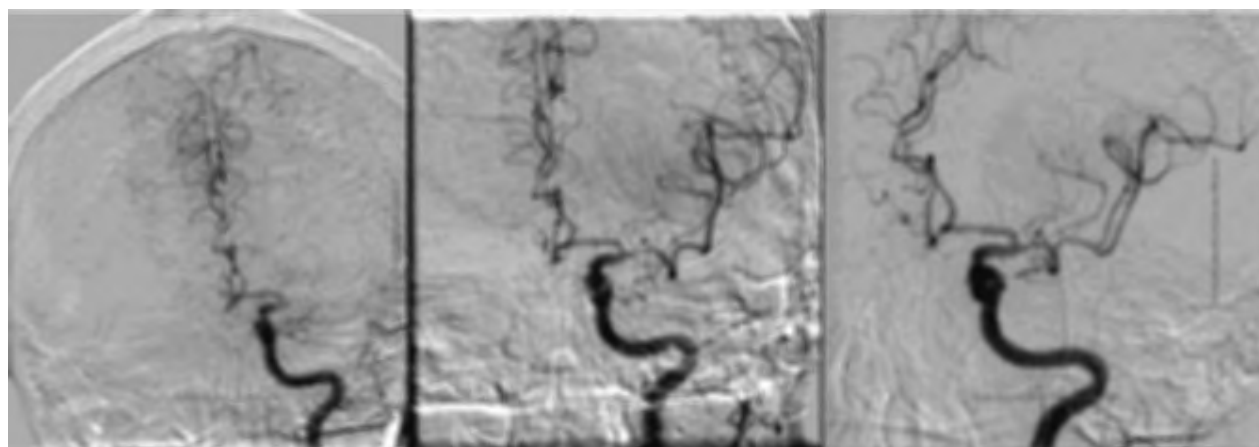


Fig. 4. Patient No 6. Left middle cerebral artery is occluded in the proximal segment with thrombolysis in cerebral infarction (TICI) score 0 flow. After the first attempt at combined stent retriever thrombectomy and aspiration, the LM1 was recanalized, with TICI score 2b flow subsequently established.

One patient with a basilar artery thrombus also had severe atherosclerotic stenotic disease that was stented with a Wingspan™ stent (Stryker, Kalamazoo, MI, USA). In 5/15 (33%) patients, combined aspiration/stent-retriever thrombectomy was performed using Solitaire (3/5 patients) and Penumbra 3D separator (2/5 patients) as the primary thrombectomy techniques. Successful recanalization (TICI score 2b-3) was achieved in 11/15 (73%) patients. TICI score 3 recanalization was achieved in 5 (33%) patients. Average time from groin puncture to successful recanalization was 46 +/- 30 minutes (range 14-98 minutes). There were no procedural complications in any of the patients who underwent IAT. There were no parenchymal hematomas (PH1 and PH2) as defined by European Cooperative Acute Stroke Study definitions in any patients post procedure. Two (13%) patients passed away during hospitalization. From a stroke standpoint (NIHSS), both of these patients showed significant improvement post procedure, but passed away later from complications of premorbid medical illnesses, and subsequent withdrawal of care in one case. Of the remaining 13 patients, 10 (77%) showed an improvement in NIHSS at the time of discharge. Modified rankin scale (mRS) score at 3-month follow-up was available for 12 patients. Four (33%) patients achieved good outcome of mRS 0-2.

DISCUSSION

The 5MAX ACE reperfusion catheter, a new flexible large bore aspiration catheter from Penumbra, increases aspiration force at the catheter tip, and can be used for direct aspiration, aspiration with clot maceration, or with stent-retrievers and analogues for clot in-situ aspiration during device retrieval. The direct aspiration technique and the combined use of stent retriever and direct aspiration for thrombectomy represent substantial improvements in endovascular technique for treatment of AIS and the 5MAX ACE facilitates the use of these techniques enabling effective recanalization in significantly shorter periods of time.⁴⁽⁸⁾ With regard to clinical outcomes, a high percentage of patients (77%) showed improvement in NIHSS at discharge. Two patients with unsuccessful recanalization expectedly showed worsening of NIHSS, and in the last patient who had worsening NIHSS, recanalization was achieved along with improvement in examination post procedure, but worsening developed later due to additional infarcts. Despite improvements in NIHSS, only 33% of patients with follow-up achieved good outcome of 0-2 as measured by the mRS. Patients in our small cohort were older with multiple medical co-morbidities, which might explain the outcomes. This should be further examined in larger

Table 1. Summary of clinical and angiographic characteristics of patients treated with the 5 MAX ACE catheter for acute ischemic stroke (N = 15)

Pt.	Age	Sex	Initial NIHSS	IV tPA	Thrombus location	Initial TICI score	Final TICI score	Time to recan (min)	Guide catheter	Primary technique	Additional devices	PH 1/2 ICH	D/C NIHSS	3-month mRS	Death
1	73	M	27	Y	LICA	0	3	68	Neuron MAX	DA	None	No	0	0	No
2	46	F	9	Y	RICA, RM1, RA1	0	0	NA	Shuttle	DA	Solitaire	No	14	NA	No
3	76	M	16	N	RM1	0	2a	NA	Neuron MAX	3D Separator	3Max Separator	No	13	4	No
4	56	M	9	Y	LICA	0	2b	14	Shuttle	DA	None	No	14	3	No
5	88	F	23	N	RICA	0	2b	80	Shuttle	DA	Solitaire, microwire disruption	No	16	NA	No
6	89	F	23	Y	LM1	0	2b	23	Shuttle	SA	None	No	3	4	No
7	71	M	0	N	Basilar	0	3	98	Shuttle	DA	5 Max Separator, Wingspan	No	0	0	No
8	83	F	4	N	RICA	0	0	NA	Shuttle	DA	Solitaire	No	NA	6	Yes
9	47	M	13	Y	LICA	0	3	17	Shuttle	DA	None	No	4	2	No
10	82	M	13	N	LM1	0	3	29	Shuttle	SA	None	No	NA	6	Yes
11	80	F	18	N	RICA, RM1 +2	0	2b	53	Shuttle	DA	Solitaire	No	15	5	No
12	66	M	10	N	LM1	0	0	NA	Shuttle	SA	5 Max Separator	No	15	5	No
13	49	M	22	N	LICA, LM1	0	2b	77	Shuttle	DA	Solitaire	No	12	NA	No
14	84	M	15	N	RM1	0	3	27	Neuron MAX	3D Separator	None	No	4	4	No
15	61	M	2	Y	Basilar	0	2b	20	Shuttle	DA	3 Max Separator, microwire disruption	No	1	0	No

NIHSS = National Institutes of Health Stroke Scale; tPA = tissue plasminogen activator; TICI = thrombolysis in cerebral infarction; ICH = intracerebral hemorrhage; mRS = modified rankin scale; LICA = left internal carotid artery; RICA = right internal carotid artery

studies using the device.

TICI score 2b-3 recanalization was achieved in 73% of patients. In analysis by the involved vessel, successful recanalization was achieved in 75% of ICA, 60% of M1, and 100% of basilar artery occlusion. We felt that the direct aspiration technique was particularly effective in patients with an extensive clot burden in the ICA extending to the MCA. Direct aspiration alone resulted in successful extraction of clot in three patients with ICA thrombus. In cases where additional devices were used, direct aspiration resulted in successful recanalization of the ICA, proximal M1 and basilar artery but subsequent Solitaire, Penumbra separator device or microwire thrombus disruption was used for distal M1, M2, and M3 segments of

MCA and P2 segment of posterior cerebral artery recanalization. In cases where direct aspiration failed as the primary thrombectomy method, use of additional devices also did not result in successful recanalization of the vessel. Combined stent retriever/aspiration with Solitaire or Penumbra Separator 3D as the first thrombectomy method was used only in patients with M1 thrombus. Distal embolization in the territory of the affected vessel was seen more commonly with the later methods using Solitaire or Penumbra separator. Distal aspiration attributable to direct aspiration occurred in three patients. This likely occurred when crossing the clot with the microwire and microcatheter and as such this step should be performed with extreme care.

5MAX ACE IN STROKE INTRA-ARTERIAL THERAPY

Compared to previously reported thrombectomy experiences, recanalization using the 5MAX ACE was achieved at significantly faster rates, at a mean of 46 minutes and as early as 14 minutes. Despite its size, the 5MAX ACE was easy to navigate and showed superior trackability. The Penumbra aspiration catheters have undergone multiple iterations, and the newer generation catheters have superior trackability, especially at the tip. Compared to its predecessors, this allows for easy navigation over obdurating the micro-catheter across the ophthalmic bend, and the authors have not experienced significant trouble with navigation. The 5MAX ACE has an inner lumen diameter of 0.068" proximally and a tapered distal lumen with a diameter of 0.060". This is in comparison to its predecessor, the 5MAX, which has a proximal and distal inner lumen diameter of 0.064" and 0.054", respectively. The design specification of the catheter implies increased suction transmission to the catheter tip, as flow impedance varies by the reciprocal of the luminal radius cubed. Given the large inner lumen, large pieces of clot could be extracted, and often times the clot was extracted in toto. The lumen can fit the 5MAX ACE or 3MAX separator and the Separator 3D in cases where the vessel cannot be recanalized by direct aspiration.

Although head to head comparisons are inaccurate, recanalization rates using the 5MAX ACE, using either direct aspiration or as an adjunct to other devices, were comparable to the rates observed in TREVO 2⁵⁾ or the Penumbra Pivotal Stroke trial, and⁷⁾ or superior to those observed in the SWIFT trial.⁶⁾ Recently, a multi-center case series on the use of the 5MAX, 3MAX, and Neuron Max reperfusion catheters using direct aspiration as the primary thrombectomy method in 37 patients reported 100% successful recanalization at an even faster rate (mean 28.1 minutes) compared to our current series.⁴⁾ This series described patients in whom only direct aspiration was used. In addition, an important factor to note is the location of thrombus that included ICA in 19% of patients and MCA in 62% of patients. The MCA occlusions also in-

cluded some M2 and M3 segment thrombi. Despite the limitation of small numbers in our series, it contained significantly more ICA occlusions (53%) and only included M1 segment thrombus. Rates of basilar artery thrombus were comparable between the two series - although one of our cases included underlying stenosis. The difference in rates and times of recanalization is likely related to a number of factors, but may importantly be related to greater difficulty in recanalizing ICA and M1 occlusions due to larger thrombus burden. Even so, the rates of ICA (75%) and M1 (60%) recanalization were significantly higher than the rates achieved in the Interventional Management of Stroke III trial, which recorded 38% and 44%, respectively.¹⁾ The result observed in our small sample using the 5 MAX ACE is comparable to that reported in the SPEED study using the Penumbra 054 Reperfusion Catheter System. The 5 MAX ACE, with a distal lumen diameter of 0.060", is 0.006" more than the 054 system, which translates to a gain in cross sectional area of approximately 23%.³⁾

We feel that the greatest advantage of the 5MAX ACE is its use in recanalizing ICA occlusions from large thrombus using direct aspiration. When compared to the disadvantages of the stent retriever technique including proximal/distal embolization, stent fracture, and poor navigability, the simple technique of direct aspiration combined with the large inner lumen and easy navigability of the 5MAX ACE makes this an attractive first option for use in IAT. Direct aspiration as a first line maneuver confers lower cost of materials, and may actually be faster, as no clot intercalation time is necessary. If the large bore aspiration catheter can be safely advanced to M1 segments and the like, it does not take much time to attempt direct aspiration, which can be quickly followed by stent-retrieval as the operator deems necessary. However, the clinical benefits beyond the intra-procedural savings of reduced number of devices can only be determined by a head to head trial comparing a number of permutations of single and combined techniques and device combinations.

This study has multiple limitations, particularly the small sample size and the retrospective nature of the study. A further limitation is the heterogeneity of the clinical scenarios, including sub-acute strokes, underlying atherosclerotic lesions and tandem lesions. Angiographic recanalization rates and time to recanalization were both derived by self-adjudicated results. Beyond recanalization end points, we have incomplete clinical end points due to the short follow-up period.

CONCLUSION

The 5MAX ACE is a useful tool in the armamentarium of neurointerventionalists for treatment of AIS, either by direct aspiration or combined stent retriever/aspiration. Our review of our initial experience suggests that there were no procedural complications directly attributable to the device in our series. Its use as a standalone technique seems feasible, and it may be advantageous with large clots in the ICA. The potential for effective and faster recanalization using this device alone or in combination may be a good topic for future study.

Disclosure

The authors report no conflict of interest concerning the materials or methods used in this study or the findings specified in this paper.

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ORIGINAL RESEARCH

ADAPT FAST study: a direct aspiration first pass technique for acute stroke thrombectomy

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ABSTRACT

Background The development of new revascularization devices has improved recanalization rates and time, but not clinical outcomes. We report a prospectively collected clinical experience with a new technique utilizing a direct aspiration first pass technique with large bore aspiration catheter as the primary method for vessel recanalization.

Methods 98 prospectively identified acute ischemic stroke patients with 100 occluded large cerebral vessels at six institutions were included in the study. The ADAPT technique was utilized in all patients. Procedural and clinical data were captured for analysis.

Results The aspiration component of the ADAPT technique alone was successful in achieving Thrombolysis in Cerebral Infarction (TICI) 2b or 3 revascularization in 78% of cases. The additional use of stent retrievers improved the TICI 2b/3 revascularization rate to 95%. The average time from groin puncture to at least TICI 2b recanalization was 37 min. A 5MAX demonstrated similar success to a 5MAX ACE in achieving TICI 2b/3 revascularization alone (75% vs 82%, $p=0.43$). Patients presented with an admitting median National Institutes of Health Stroke Scale (NIHSS) score of 17.0 (12.0–21.0) and improved to a median NIHSS score at discharge of 7.3 (1.0–11.0). Ninety day functional outcomes were 40% (modified Rankin Scale (mRS) 0–2) and 20% (mRS 6). There were two procedural complications and no symptomatic intracerebral hemorrhages.

Discussion The ADAPT technique is a fast, safe, simple, and effective method that has facilitated our approach to acute ischemic stroke thrombectomy by utilizing the latest generation of large bore aspiration catheters to achieve previously unparalleled angiographic outcomes.

large bore aspiration catheters as a first approach for thrombectomy has recently been reported.⁷ The purpose of this study was to follow-up the initial experience with a prospective report of all stroke cases that had undergone a direct aspiration first pass technique (ADAPT) with a large bore aspiration catheter as the primary method for vessel recanalization.

METHODS

Under an institutional review board approved protocol, prospectively identified patient data were collected on all stroke patients undergoing the ADAPT technique at the Medical University of South Carolina, Swedish Medical Center, Vanderbilt University, Stonybrook University, Erlanger Medical Center, and University of Buffalo. Patients were selected for intervention as per the investigator protocol at each site. Usual practice was advanced imaging with CT/CT angiography and CT perfusion for patient selection. Patients included in this study were identified to have a large vessel cerebral vessel occlusion with viable ischemic penumbra and less than one-third ischemic vascular territory.

The ADAPT technique has been described previously.⁷ Briefly, a large guide catheter (Neuron 088; Penumbra, Oakland, California, USA) was advanced as far distally into the cervical or proximal petrous internal carotid artery (ICA) as possible. The largest caliber aspiration catheter that the vessel would accommodate was selected for each case, usually a 5MAX (Penumbra) or 5MAX ACE (Penumbra), for distal ICA, proximal middle cerebral artery, and basilar occlusions. This catheter was advanced to the level of the thrombus, usually coaxially over a 016 microwire (Fathom; Boston Scientific Corp, Fremont, California, USA) and Velocity microcatheter (Penumbra). Other obturating catheters, such as 3MAX or smaller microcatheters, can also be used in conjunction with any compatible microwire. With the large bore aspiration catheter at the face of the thrombus, aspiration was applied with either a 20 or 60 mL syringe or Penumbra aspiration pump. Absence of flow within the aspiration system confirmed engagement with the thrombus. At this point, the catheter was gently advanced for 1–2 mm to ensure solid engagement with the thrombus. Aspiration was left for approximately 20 s, and if no flow through the system was found then the catheter

INTRODUCTION

Early and efficient revascularization of large vessel occlusions has been shown to correlate with improved outcomes in selected patients with acute ischemic stroke.^{1–3} Aspiration thrombectomy using the Penumbra system, while an effective technique for achieving revascularization, has yielded only modest clinical results.^{4–6} Stent retrievers have also been shown to be effective for vessel recanalization, with similar clinical outcomes.^{2,3}

Recent advances in catheter technology have included very large, easily trackable, aspiration thrombectomy catheters that can now more easily and reliably navigate the cerebrovasculature. A novel technique using this newest generation of

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118



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was slowly withdrawn. If aspiration failed, then the large aspiration catheter was reinserted up to the level of the thrombus and repeat aspiration attempted. At the operator's discretion, additional devices (such as stent retrievers) were used if aspiration alone failed.

Patient demographic, angiographic, and clinical data were collected. The degree of vessel occlusion before and after treatment was defined by the modified Thrombolysis in Cerebral Infarction (TICI) classification and adjudicated by the operator. Successful revascularization was defined as a TICI score $\geq 2b$ post-treatment. Procedure time was defined as the time from groin access to at least TICI 2b revascularization. Symptomatic intracerebral hemorrhage (sICH) was defined as presence of hemorrhage after treatment, with worsening of clinical examination by ≥ 4 points on the National Institutes of Health Stroke Scale (NIHSS). The 90 day functional outcomes were determined by the modified Rankin Scale (mRS), and were obtained from the available clinic records. A good functional outcome was defined as an mRS score of ≤ 2 at 90 days. Mortality was defined as death occurring within 90 days of initial presentation. The 5MAX ACE became clinically available during the present study. Outcomes for 5MAX and 5MAX ACE were compared.

Data were tracked at each site. De-identified data were submitted to the sponsoring institution (Medical University of South Carolina) which performed the primary analysis. Statistical analyses were performed using SAS V9.3 (SAS Institute, Cary, North Carolina, USA). Differences between groups were tested using Student's *t* test for continuous measures and a χ^2 test for categorical measures. Differences between groups were tested using Fisher's exact test for categorical measures with expected cell sizes < 5 . All tests were two sided and assessed at a significance level of 0.05.

RESULTS

Patient demographics and procedural data

Ninety-eight patients with 100 occlusions were treated at the six institutions, including 46 women, with an average age of 66 years (median 69, SD=15.7). The average time from when the patient was last seen normal to groin puncture was 8.5 h (mean 507 min; median 241.5 min, SD=506 min). The overall successful revascularization rate (TICI 2b-3) was 95%. The average time to TICI 2b or 3 revascularization was 36.6 min (SD=26.4 min). The aspiration component of the ADAPT technique alone was successful in achieving successful revascularization of the occluded vessel 78% of the time. When the aspiration component of ADAPT was successful as a standalone technique, the average time from femoral access to final revascularization was 31.6 min (SD=23.3 min). In those cases where an adjunctive device was required, revascularization times were significantly ($p < 0.0001$) prolonged (average 56.8 min (SD=29.1 min)).

Ten of 100 (10%) cases had downstream emboli within the initially affected territory, all of which were subsequently removed with either subsequent aspiration at the occlusion site or utilization of a stent retriever. There were no instances of embolization to a new territory (ENT). Two (2%) device related complications were encountered. One case was related to vessel dissection trying to advance the 5MAX catheter through an occlusion that after aspiration thrombectomy revealed an underlying intracranial stenosis, which was successfully stented. One complication was related to advancing a 5MAC ACE from the distal ICA into the mid M1 middle cerebral artery without using an obturating microwire or microcatheter, and resulted in significant vessel dissection, which was unable to be opened.

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Table 1 Comparison of the 5MAX and 5MAX ACE final outcomes

	5MAX	5MAX ACE	p Value
No of cases	44	44	
Mean time to revascularization (min)	37.7	35.6	0.71
TICI 2b (%)	54.6	36.4	0.09
TICI 3 (%)	40.9	61.4	0.06
mRS 0–2 (%)	34	50	0.19

TICI 3 revascularization was achieved more frequently with 5MAX ACE than with 5MAX (61.4% vs 40.9%; $p=0.055$).

mRS, modified Rankin Scale; TICI, Thrombolysis in Cerebral Infarction.

The primary ADAPT revascularization catheter was 5MAX in 44 cases, 5MAX ACE in 44 cases, 4MAX (Penumbra) in six cases, 3MAX (Penumbra) in four cases, Navien 058 (EV3 Covidien) in one case, and Neuron 088 MAX (Penumbra) in one case. TICI 2b or 3 revascularization with aspiration alone was achieved in 75% of cases in which a 5MAX was the primary catheter versus 82% ($p=0.44$) when a 5MAX ACE was used (table 1).

Clinical outcomes

There were no incidences of postprocedure sICH. The presenting NIHSS was 17.2 (median 17.0; SD=6.4) on average and improved to an average of 7.3 (median 4.0; SD=7.5) at discharge (table 2).

mRS was available in 81 of 98 patients (83%) (table 3). Forty per cent of patients achieved an mRS score of 0–2 and 20% an mRS score of 6 at the 3 month follow-up. In the 78% of cases

Table 2 Baseline characteristics

Variable	
Mean age (years)	66.3
Gender	
Men (n (%))	46 (47)
Women (n (%))	52 (53)
NIHSS	
Pretreatment	17.2/17.0*
Post-treatment	7.3/4.0*
IV tPA	
Yes (n (%))	27 (28)
No (n (%))	70 (72)
Average time to groin puncture (h)	8.5
Average time to TICI 2b/3 recanalization (min)	37
Site of occlusion (n (%))	
Right M1	20 (20)
Right M2	11 (11)
Right ICA	3 (3)
Right ICA terminus	3 (3)
Left M1	23 (23)
Left M2	7 (7)
Left ICA	6 (6)
Left ICA terminus	11 (11)
Basilar	5 (5)
Right cervical ICA–MCA	8 (8)
Left cervical ICA–MCA	3 (3)

*Mean/median values.

ICA, internal carotid artery; IV tPA, intravenous tissue plasminogen activator; MCA, middle cerebral artery; NIHSS, National Institutes of Health Stroke Scale; TICI, Thrombolysis in Cerebral Infarction.

Table 3 Demographics and outcomes of ADAPT FAST cases

Outcome parameter	
TICI pretreatment (n (%))	
0	96 (96)
1	1 (1)
2a	3 (3)
TICI post-treatment (n (%))	
0–2a	5 (5)
2b	44 (44)
3	51 (51)
NIHSS	
Pretreatment	17.2
Post-treatment	7.3
90 day mRS (n (%))	
0	10 (13)
1	16 (20)
2	5 (6)
3	12 (15)
4	11 (14)
5	8 (10)
6	15 (19)
Missing	23 (23)
sICH (n (%))	0 (0)

The 90 day mRS outcomes calculated on percentage of patients that had a follow-up (n=79).

mRS, modified Rankin Scale; NIHSS, National Institutes of Health Stroke Scale; sICH, symptomatic intracerebral hemorrhage; TICI, Thrombolysis in Cerebral Infarction.

where ADAPT alone was successful, 47% of patients achieved an mRS score of 0–2 and 14% resulted in an mRS score of 6. In the cases where ADAPT required a stent retriever or was unsuccessful, 18% achieved mRS 0–2 and 35% resulted in mRS 6.

DISCUSSION

Catheter aspiration thrombectomy has been reported previously, but as either a bailout after traditional techniques had failed or as a strategy by which to achieve revascularization of an occluded large extracranial artery.^{8–12} ADAPT represents a novel revascularization strategy made possible by the availability of newer, flexible, atraumatic, large bore aspiration catheters.

These catheters are easily navigated into the intracranial circulation and provide a large cross sectional area for the aspiration and engagement of the occluding thrombus. This technique is based on using aspiration alone as the primary mechanism of thrombectomy and, if initially unsuccessful, then incorporating adjunctive alternatives such as a stent retriever to achieve revascularization. The technique was successful alone in achieving TICI 2b/3 revascularization in 78% of cases or with adjunctive devices in 95% of cases. On average, revascularization was achieved within 37 min of groin puncture, and in 15 min or less from groin puncture in more than 20 cases. These efficient revascularization metrics were manifest clinically, with average discharge NIHSS improvement of 10 points and with favorable clinical functional outcomes (mRS 0–2 at 90 days) in 40% of cases.

Compared with the outcomes of stent retriever data, ADAPT yielded similar rates of good functional outcome (mRS 0–2), mortality, and device related complications (table 4).^{2 3 13–16}

In the present series using ADAPT, fewer sICH were observed, and times to recanalization were, on average, probably shorter. It is likely that ADAPT produced higher rates of recanalization; however, this is difficult to establish with the documented methods of assessing successful recanalization used in the predicate stent retriever studies. With ADAPT, TICI 2b–3 revascularization was achieved with aspiration alone in 78% of cases compared with rates of TICI 2a–3 recanalization (ranging from 68% to 83%) for stent retrievers. A modified TICI score of 2a indicates a large area of non-perfused brain parenchyma and is increasingly not considered technically successful revascularization.¹⁷ The final procedural TICI 2b/3 revascularization was 95% with ADAPT, which is higher than that achieved in the STAR study (85%) and in the NASA study (76%).^{14 16}

The NASA registry recently reported an organized retrospective experience of 354 stroke cases from 24 centers.¹⁴ The overall results were similar to those reported in the meta-analysis by Walcott *et al.*¹³ A subgroup analysis from the NASA study was subsequently reported to determine if the use of a balloon guide catheter (BGC) improved outcomes.¹⁸ The use of a BGC significantly improved TICI 3 revascularization rates to 54%, although overall TICI 2b/3 revascularization rates remained similar at 75%. This is similar to the TICI 3 rate of 51% but remains lower than the final 95% TICI 2b/3 revascularization we were able to achieve with ADAPT. Stent retriever

Table 4 Comparison of outcomes from current ADAPT FAST, SWIFT, TREVO, NASA, and stent retriever meta-analysis

	ADAPT FAST (n=100)	SWIFT trial (n=89)	TREVO trial (n=88)	STAR study (n=202)	NASA registry (n=354)	Solitaire data* (n=355)	Trevo data* (n=221)
TICI 2a/2b/3 (%)	N/A	83†	90	N/A	87.5	82	83
Device TICI 2b/3 (%)	78	75.9†	68†	79† 91§	72.5	NR	NR
Final TICI 2b/3 (%)	95	75.9†	68†	85	72.5	82	83
mRS 0–2 (%)	40	36	40	55	42	47	51
Mortality (%)	20	17	34	19	30.2	14	31
Time to final revascularization (min)	37	NR	NR	NR	50¶	NR	NR
Device related complications (%)	2	8.6	9	7.5	NR	6	5
Symptomatic ICH (%)	0	2	7	4	9.9	6	8

*Meta-analysis of real world published experience.

†Site reported rate of recanalization.

‡Core laboratory reported.

§Site investigator reported data.

¶Time to revascularize after guide catheter access.

ICH, intracerebral hemorrhage; mRS, modified Rankin Scale; N/A, not applicable; NR, not reported; TICI, Thrombolysis in Cerebral Infarction.

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procedures have been shown to be significantly faster with use of a BGC (average of 120 min), which is markedly longer than the average 38 min ADAPT case.¹⁶ However, the times are difficult to compare as the BGC definition of procedure time was from groin access to groin closure whereas the ADAPT procedure time was groin access to at least TICI 2b revascularization. Finally, average discharge NIHSS score in those with BGC was 12 versus 17.5 when a BGC was not used, which is higher than our average discharge NIHSS score of 7.

One main advantage of ADAPT as a firstline approach is that it is versatile. The technique does not preclude the operator from incorporating other devices if aspiration alone is not working. Having the large bore aspiration catheter at the face of the clot facilitates the use of adjunctive devices, such as stent retrievers, as it provides a direct conduit to the thrombus. The technique of using stent retrievers in conjunction with local aspiration at the face of the clot has also been reported, with very high rates of technical success and good neurological outcomes. This approach was originally proposed to address the high incidence of ENT that has been reported with thrombectomy.¹⁹ Kurre *et al*¹⁹ reported in 175 occluded vessels a TICI 2b/3 revascularization rate of 91% and an improvement in ENT to 3.5% from 14% when distal aspiration was used with stent retrievers. Using combined local aspiration with stent retrieval,²⁰ Humphries *et al*²⁰ recently reported minimal ENT (<5%) with very high rates of revascularization (TICI 2b-3 of 88%) and low (5%) sICH rates. This approach is also being validated in the ongoing Penumbra three-dimensional separator trial.

ADAPT is technically straightforward, requiring only the navigation of a catheter to the face of the occlusion followed by the application of aspiration. The operator typically does not have to completely traverse the occlusion, and in most cases no additional devices have to be deployed or manipulated. Aspiration alone with the larger 5MAX ACE (0.060 inner diameter) catheter resulted, on average, in 82% TICI 2b/3 revascularization rates compared with the original 5MAX (0.054 inner diameter) catheter of 75%. This validates the intuitive concept of the improved aspiration performance of a larger bore catheter. In addition, clot extraction with ADAPT places little or no traction on the parent artery and regional penetrating arteries. As such, the potential for endothelial injury is likely to be far lower, possibly accounting for the absence of sICH in our current series.²¹ The ability of ADAPT to engage the face of the thrombus and avoid superselective contrast injections into the ischemic region may also contribute to the lower hemorrhage rate.²² Intracranial hemorrhage reportedly occurs in as many as 41% of stroke patients after thrombectomy with stent retrievers, of which approximately one-fifth lead to a symptomatic deterioration.^{2 3 5 14 18}

ADAPT was, on average, faster than traditional methods of thrombectomy, particularly when the strategy worked as a stand-alone technique, as it did in the majority of cases. Moreover, thrombus which was difficult to extract with ADAPT, and was also typically challenging to clear with adjunctive devices, reflected in the marked prolongation of procedural times (57 vs 32 min) observed in those cases in which adjunctive devices were required.

ADAPT seemed to cause minimal clot disruption and fragmentation, often allowing the extraction of the occlusive embolus en bloc with a single pass. This may decrease the frequency and number of downstream emboli. In vitro tests have shown that stent retriever and traditional aspiration thrombectomy (performed with a separator) result in fragmentation of the embolus during extraction, creating downstream emboli and

potentially emboli to previously uninvolved vascular territories.²³ When fragmentation of the embolus did occur with ADAPT (observed in 10% of cases in the present series), the emboli were usually large enough and proximal enough to allow extraction using aspiration alone with a smaller catheter, such as 3MAX in the M2 middle cerebral artery segment or a stent retriever.

Similar functional outcomes (mRS 0–2) of 40% were found with ADAPT as with other previously reported thrombectomy strategies,^{2 3 5 14 18} despite a relatively long average time (8.5 h) from symptom onset to treatment in the present series. These rates of favorable neurological outcome are similar to those reported in previous studies using a modern perfusion guided imaging paradigm to select patients for intervention rather than time alone.²⁴ The variability in patient selection can affect clinical outcomes and is a limitation of this study. It is important to consider however, that the operator reported assessments in the current study are more prone to bias in comparison with independently assessed and monitored outcomes reported in some of the comparative thrombectomy device trials.

CONCLUSION

This multicenter series supports the hypothesis that, in comparison with modern thrombectomy techniques, ADAPT is a fast, simple, efficient, and safe strategy to achieve revascularization in patients with acute ischemic stroke secondary to a large vessel occlusion. In the minority of cases in which aspiration alone is unsuccessful in achieving complete revascularization, the platform is versatile, allowing the rapid incorporation of adjunctive devices (such as stent retrievers).

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(b)(4)

The Penumbra 5MAX ACE Catheter Is Safe, Efficient, and Cost Saving as a Primary Mechanical Thrombectomy Device for Large Vessel Occlusions in Acute Ischemic Stroke

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Background: Reperfusion of large vessel occlusions in acute stroke can improve patient outcomes. The purposes of this study were to assess the safety and efficacy of the Penumbra 5MAX ACE catheter for revascularization of large vessels and to compare its cost to the cost of stent retrievers.

Methods: In this retrospective, single-center case review study, data were captured on consecutive patients treated with the Penumbra 5MAX ACE as first-line therapy during an 11-month period. Good functional outcome was defined as a modified Rankin Scale score of ≤ 2 at discharge. Results were directly compared with previously published data for stent retrievers, and length of stay was analyzed in relation to revascularization.

Results: The 31 patients studied had a mean age of 66.3 ± 17.8 years and a mean National Institutes of Health Stroke Scale score of 19.4 ± 5.7 . Intravenous tissue recombinant plasminogen activator therapy was initiated in 35.5% (11/31) of patients. A Thrombolysis in Cerebral Infarction (TICI) grade of 2b-3 reperfusion after endovascular therapy was achieved in 26/31 (83.9%) of cases; TICI grade 3 was achieved in 19/31 (61.3%) patients. The average time from groin puncture to TICI grade 2b-3 reperfusion was 40 minutes. The average estimated cost for aspiration with the 5MAX ACE alone was \$4,916 per case compared with an estimated cost of \$9,620 if a stent retriever was used as the primary device. Our actual average cost per case, including all adjunctive devices used in the neurointerventional procedure, was \$6,997. Good functional outcome was achieved in 19/31 (61.3%) patients. Two patients experienced symptomatic intracerebral hemorrhage (6.5%), and 1 (3.2%) patient died. The length of stay was significantly shorter among patients with TICI grade 2b-3 reperfusion compared to patients with TICI grade < 2 (6.8 ± 5.34 days vs 15.8 ± 11.32 days, respectively; $P < 0.05$).

Conclusion: These findings suggest that direct aspiration with the large-bore 5MAX ACE catheter can be considered a first-line approach to mechanical thrombectomy for large vessel occlusions. Our results demonstrated high rates of successful reperfusion in a timely manner with excellent clinical outcomes, although our sample size was small. In addition, this direct-aspiration technique has important cost-savings potential compared to stent retrievers.

Keywords: Intracranial thrombosis, ischemia, reperfusion, stroke, thrombectomy

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INTRODUCTION

Acute ischemic stroke is the fourth leading cause of death in the United States and is also the leading cause of long-term disability in the country.^{1,2} Strokes attributable to large vessel occlusion or proximal vessel occlusion have a poor prognosis if allowed to follow their natural course, but with early revascularization treatment, patient outcomes have improved and mortality has decreased.^{3,4} Much has been published about the advances in techniques for mechanical

approaches to revascularization of large vessel occlusion,^{5,6} and in 2015, intraarterial treatment to achieve revascularization was demonstrated to be safe while improving outcomes.⁷ The purpose of this study was to assess the safety and effectiveness of achieving revascularization of proximal or large vessel occlusion using the Penumbra 5MAX ACE catheter with ADAPT (A Direct Aspiration First Pass Technique). Also, because care must be provided in a cost-effective manner in today's medical environment, we

also compared the cost of the Penumbra 5MAX ACE catheter with the cost of stent retrievers.

METHODS

A retrospective review of the medical records from September 2013 to July 2014 was conducted of all patients with large vessel occlusion strokes who were treated with mechanical thrombectomy using ADAPT and the recently introduced (June 2013) 5MAX ACE catheter (Penumbra, Inc.) as first-line therapy. Patient selection for endovascular treatment of large vessel occlusion acute stroke at our institution is based on noncontrast computed tomography (CT), CT angiogram, and whole brain 320-slice CT perfusion imaging, regardless of time of onset. This study was conducted after institutional review board approval, and informed consent was obtained from patients or their legal representatives in accordance with the Helsinki Declaration of 1975, as revised in 2005.

Data on age, sex, and presentation National Institutes of Health Stroke Scale (NIHSS) score were recorded. The NIHSS lists 11 specific abilities that are scored on numerical scales, with 0 indicating normal function and higher scores indicating some level of impairment. The maximum possible score is 42, and the minimum score is 0. Groin puncture time, reperfusion time, Thrombolysis in Cerebral Infarction (TICI) grade flow before and after the procedure, and procedural complications were also recorded. The TICI grading system is a tool for determining the response to thrombolytic therapy for ischemic stroke. The grades range from 0 (no perfusion) to 3 (complete perfusion). TICI subcategory grade 2b indicates complete filling of all of the expected vascular territory but with slower than normal filling. Follow-up data in the form of the modified Rankin Scale (mRS) score at discharge was also obtained from the medical records. The mRS is used to measure the degree of disability in carrying out daily activities for people who have had a stroke or have some other neurological disability. The scale is scored from 0 (no disability) to 6 (death). Higher scores indicate greater disability.

Thrombectomy cases using ADAPT with the 5MAX ACE were selected based on vessel size and the interventionist's opinion that the catheter was the proper size for the occluded vessel. Patients with distal lesions (M2 or further) or with small caliber proximal vessels for which the 5MAX ACE was considered too large were not treated with the device, and hence, are not included in this discussion.

However, all patients in whom the following technique was used during the specified time frame are included in the study cohort. The technique involves an 8 French groin sheath through which a NeuronMAX 088 access catheter (Penumbra, Inc.) is advanced over a Davis diagnostic catheter (Torcon NB Advantage Catheter; Cook Medical) and an angled Glidewire (Terumo) into the internal carotid or vertebral artery of the affected side. Once in position, the 5MAX ACE aspiration catheter is advanced to the proximal segment of the thrombus with the aid of either a 3MAX aspiration catheter or a Velocity microcatheter (Penumbra, Inc.) with the support of a Fathom microwire (Boston Scientific Corporation). Whether to use a 3MAX or a Velocity microcatheter was the operator's decision (twice the 5MAX ACE was advanced over a Fathom microwire alone). Direct aspiration using the Penumbra reperfusion system (ADAPT)

was the first-line therapy. If unsuccessful despite at least 2 attempts or if thrombus fragmentation was identified, additional small aspiration catheters or adjunctive thrombectomy devices were used.

Because the neurointerventionists at our institution have been using this method primarily rather than stent retrievers, a direct comparison of the 2 techniques at our institution would be unfair and poorly powered in the stent retriever arm. Therefore, we compared our results to published series on stent retrievers by other experienced authors.^{7,8}

Successful reperfusion was defined by postprocedure TICI flow of grade 2b or 3. Good functional outcome was defined as an mRS score of 0-2 at discharge. Symptomatic intracerebral hemorrhage (sICH) was defined as hematoma associated with a worsening NIHSS score of 4 points or more.

The expected cost of the devices was totaled for each case using market/list prices to eliminate the variability of pricing among different institutions (a methodology that has been used in other publications for device cost analysis)⁹ and compared with what the cost would have been for an uncomplicated case using the Solitaire stent retriever device (Covidien/ev3). Costs for the Penumbra system aspiration cases included the cost of all reperfusion catheters (the 5MAX ACE plus any other adjunctive tools if required), 6 French long sheath (NeuronMAX), as well as coaxial delivery catheters (3MAX or Velocity), canister, and aspiration tubing. Costs for the Solitaire stent retriever cases used as first-line therapy included the cost of balloon guide catheter, microcatheter, and stent retriever (as recommended by parent company). Using device list prices, price estimates for comparison are shown in Table 1. Sheaths, microwires, diagnostic catheters, and closure devices were not included in the cost analysis as they are used in the same fashion for both techniques. As noted, the costs shown in Table 1 are the expected costs based on list prices. For the purposes of analysis in this study, however, we used our average cost for each procedure, and the procedures' total average costs differ slightly from the total expected costs.

The data obtained were compared with previously published data: the Multicenter Randomized Clinical Trial of Endovascular Treatment for Acute Ischemic Stroke in the Netherlands (MR CLEAN)⁷ and the North American Solitaire Stent Retriever Acute Stroke (NASA) Registry.⁸ The effect of successful revascularization on length of stay was compared using the Tukey honest significant difference (HSD) test.

RESULTS

Demographics

A total of 31 patients were included in our study. All were treated with the 5MAX ACE catheter as the primary tool for mechanical thrombectomy. The patients' mean age was 66.3 years $\pm$ 17.8, and their mean admission NIHSS score was 19.4 $\pm$ 5.7 (Table 2). The target occlusion was located in the proximal middle cerebral artery in 24 (77.4%) patients, in the internal carotid artery in 6 (19.4%) patients, and in the basilar artery in 1 (3.2%) patient. Eleven (35.5%) patients had received intravenous recombinant tissue plasminogen activator.

Table 1. Thrombectomy Options: Cost Comparison

Stent Retriever Thrombectomy Devices	Price	ADAPT Thrombectomy Devices ^c	Price of the ADAPT Procedure if Velocity Is Used	Price of the ADAPT Procedure if 3MAX Is Used
Cello balloon guide catheter ^a	\$1,100	5MAX ACE	\$2,490	\$2,490
Marksman catheter ^a	\$1,100	NeuronMAX 088	\$ 495	\$ 495
Solitaire revascularization device ^a	\$7,200	Velocity Microcatheter	\$1,090	
Prowler or similar microcatheter ^b	\$ 750	3MAX Aspiration Catheter		\$1,690
		MAX Aspiration Tubing	\$ 370	\$ 370
		MAX Canister	\$ 370	\$ 370
Total	\$10,150	Total	\$4,815	\$5,415

Note: Cost estimates are based on list pricing for devices recommended by the manufacturer for each procedure. Consequently, these costs are the expected costs for the procedures. For the purposes of analysis in this study, however, we used our average cost for each procedure, and the average cost differs slightly from the expected cost. ADAPT, A Direct Aspiration First Pass Technique.

^aDevice manufactured by Covidien/ev3.

^bDevice manufactured by Cordis Neurovascular/Johnson & Johnson.

^cAll devices manufactured by Penumbra, Inc.

Revascularization and Outcomes

TICI grade 2b-3 reperfusion was achieved in 26 (83.9%) patients, while TICI grade 3 was attained in 19 (61.3%) patients. Of the 83.9% of patients who achieved TICI grade 2b-3, successful revascularization by aspiration with the Penumbra system was performed in 84.6% (22/26) of the patients.

In a further breakdown of devices used to achieve TICI grade 2b-3, 73.1% (19/26) of patients achieved reperfusion with ADAPT and the 5MAX ACE catheter alone, 15.4% (4/26) of patients required the addition of a separator or smaller aspiration catheter, and 11.5% (3/26) of patients required the addition of a stent retriever.

Overall, rescue therapy was used in 35.5% (11/31) of the patient cohort. In one case, rescue therapy was used when the 5MAX ACE could not be advanced past the ophthalmic segment of the internal carotid artery to reach the thrombus. The rescue techniques used were the Penumbra separator (n=5), smaller aspiration catheters (n=6), and stent retrievers (n=5). Some cases required more than one rescue

therapy tool. A noteworthy observation is that 7 of our first 15 cases required additional devices (rescue) compared to only 4 in the last 16 cases, suggesting a short learning curve for using this new device. In the 5 cases in which TICI grade 2b-3 was not achieved, rescue therapy with stent retrievers was attempted in 2/5 (40%) of the cases, smaller aspiration catheters were used in 2/5 (40%), and the last case was aborted because of contrast extravasation during the procedure.

The average time from groin puncture to TICI grade 2b-3 reperfusion was 40 minutes (Table 3). Good functional outcome was reported in 19 (61.3%) patients. The mean discharge mRS score was 2.3 ± 1.8 . Thirteen patients were discharged to home (41.9%), 11 to rehabilitation (35.5%), 2 to a nursing home (6.5%), 2 to a skilled nursing facility (6.5%), and 1 to hospice (3.2%). One patient was transferred to another institution (3.2%), and we were not able to obtain information on the final discharge disposition. The transfer was done at the request of the family so that the patient could be cared for closer to their home. One (3.2%) patient died.

Table 2. Baseline Demographics of the Current Series vs the NASA Registry and MR CLEAN^{7,8}

Variable	Current Series (n=31)	NASA Registry (n=354)	MR CLEAN (n=500)
Mean age $\pm$ SD, years	66.3 $\pm$ 17.8	67 $\pm$ 15.2	65.8 (range, 54.4-76.0)
Left hemisphere	48.4% (15/31)	N/R	48.9%
Target occlusion			
Middle cerebral artery	77.4% (24/31)	56%	73.8%
Internal carotid artery	19.4% (6/31)	23.2%	25.7%
Basilar artery	3.2% (1/31)	10.2%	0%
Mean NIHSS score at admission ^a	19.4 $\pm$ 5.7	18.1 $\pm$ 6.6	17 (range, 14-21)
Administered intravenous recombinant tissue plasminogen activator	35.5% (11/31)	N/R	87.1%

MR CLEAN, Multicenter Randomized Clinical Trial of Endovascular Treatment for Acute Ischemic Stroke in the Netherlands; NASA, North American Solitaire Stent Retriever Acute Stroke; N/R, not reported.

^aThe National Institutes of Health Stroke Scale (NIHSS) is composed of 11 items, each of which scores a specific ability on a numerical scale, with 0 indicating normal function. Consequently, a higher score indicates some level of impairment. Individual scores are summed to calculate a total score. The maximum possible score is 42, and the minimum score is 0.

Table 3. Study Results of the Current Series vs the NASA Registry and MR CLEAN^{7,8}

Variable	Current Series (n=31)	NASA Registry (n=354)	MR CLEAN (n=500)
Mean time from groin puncture to reperfusion, minutes	40 ± 16	77	N/R
Mean time from arterial puncture to TICI grade 2b-3 reperfusion, minutes ^a	40 ± 14	N/R	N/R
Postprocedure TICI grade 2b-3 ^a	83.9% (26/31)	72.5%	58.7%
Postprocedure TICI grade 3 ^a	61.3% (19/31)	40.2%	24%
Overall rescue therapy	35.5% (11/31)	25.7%	N/R
Adjunctive use of stent retrievers as rescue therapy	16.1% (5/31)	N/R	N/R
Mortality	3.2% (1/31)	30.2%	21%
Procedure-related complications	9.7% (3/31)	N/R	8.6%
Symptomatic intracerebral hemorrhage	6.5% (2/31)	9.9%	7.7%
Extravasation	3.2% (1/31)	N/R	0.9% (2/233)
Mean discharge modified Rankin Scale score ± SD ^b	2.3 ± 1.8	N/R	N/R
Good functional outcome (modified Rankin Scale score of 0-2 at discharge) ^b	61.3% (19/31)	42% (at 90 days)	32.6% (at 90 days)

MR CLEAN, Multicenter Randomized Clinical Trial of Endovascular Treatment for Acute Ischemic Stroke in the Netherlands; NASA, North American Solitaire Stent Retriever Acute Stroke; N/R, not reported.

^aThe Thrombolysis In Cerebral Infarction (TICI) grading system is a tool for determining the response to thrombolytic therapy for ischemic stroke. The grades range from 0 (no perfusion) to 3 (complete perfusion). TICI subcategory grade 2b indicates complete filling of all of the expected vascular territory, but the filling is slower than normal. TICI grade 2b-3 is widely regarded as a successful angiographic outcome.

^bThe modified Rankin Scale is used to measure the degree of disability in carrying out daily activities for people who have had a stroke or have some other neurological disability. The scale is scored from 0 (no disability) to 6 (death). Higher scores indicate greater disability.

The average length of stay increased as the reperfusion grade decreased: TICI grade 3 = 5.7 ± 3.65 days, TICI grade 2b = 9.14 ± 8.33 days, and TICI grade <2b = 15.8 ± 11.32 days. These findings are statistically significant when compared based on angiographic outcome using the Tukey HSD test (TICI grade 2b-3 vs TICI grade <2b: 6.8 ± 5.34 days vs 15.8 ± 11.32 days, $P < 0.05$).

Regarding procedure-related complications, 2 patients experienced sICH (6.5%), and 1 patient suffered extravasation of contrast (3.2%). Procedure-related complications were similar in all series: current series 9.7%; MR CLEAN 8.6%; NASA Registry 9.9% (the NASA Registry only reports sICH as procedure-related complications).

Cost Comparison

Our average cost for aspiration with the 5MAX ACE alone was \$4,916. In contrast, our average cost when a stent retriever is used as the primary device is \$9,620, so aspiration with the 5MAX ACE alone can save 49% in potential costs. However, these average costs do not reflect the increased cost of rescue therapy tools that are used in approximately 26% of stent retriever cases according to the NASA Registry.⁸ In our study, the average cost of all cases, including all adjunctive devices, was \$6,997 per patient. Compared with the cost of using a stent retriever as primary device, this average cost illustrates a potential savings of approximately 26% (Figure).

DISCUSSION

This initial clinical experience supports considering the use of the 5MAX ACE catheter as first-line therapy for large vessel occlusion in acute ischemic stroke. Our analysis

suggests that direct aspiration with a large bore catheter first using ADAPT⁶ may represent an important potential cost-saving approach to vessel revascularization that in our experience results in high rates of reperfusion with rapid procedural times, enabling excellent clinical outcomes with acceptable safety.

Regarding angiographic and technical outcomes, the percentage of our patients showing reperfusion to TICI grade 2b-3—83.9%—is higher than the percentages reported in the NASA Registry (72.5%)⁸ and in the MR CLEAN study (58.7%).⁷ Reperfusion to TICI grade 3 in 61.3% of our patients is also higher than the rates reported in the NASA Registry (40.2%) and MR CLEAN (24%) and is comparable to a 2014 publication describing the ADAPT FAST technique that achieved reperfusion to TICI grade 3 in 61% of subjects treated with the 5MAX ACE catheter and 41% of those treated with the 5MAX.¹⁰ We believe that the larger lumen of the 5MAX ACE catheter may lead to higher TICI grade 3 rates compared with the 5MAX.

Our mean time to reperfusion of 40 minutes using the 5MAX ACE is similar to the report of 36 minutes published in 2014¹⁰ for a study using a similar technique, while in the NASA Registry,⁸ the average time to revascularization is approximately 77 minutes using stent retrievers as first-line therapy.

Good functional outcome (mRS score ≤ 2) was seen in 61.3% of our patients, a finding that compares favorably with the 32.6% of patients with good functional outcomes reported in MR CLEAN⁷ and the 42% in the NASA Registry.⁸ In our cohort, 24 (77.4%) patients were discharged to home or rehabilitation, another indicator of a satisfactory outcome. Our sICH rate of 6.5% is comparable to the 9.9% in the

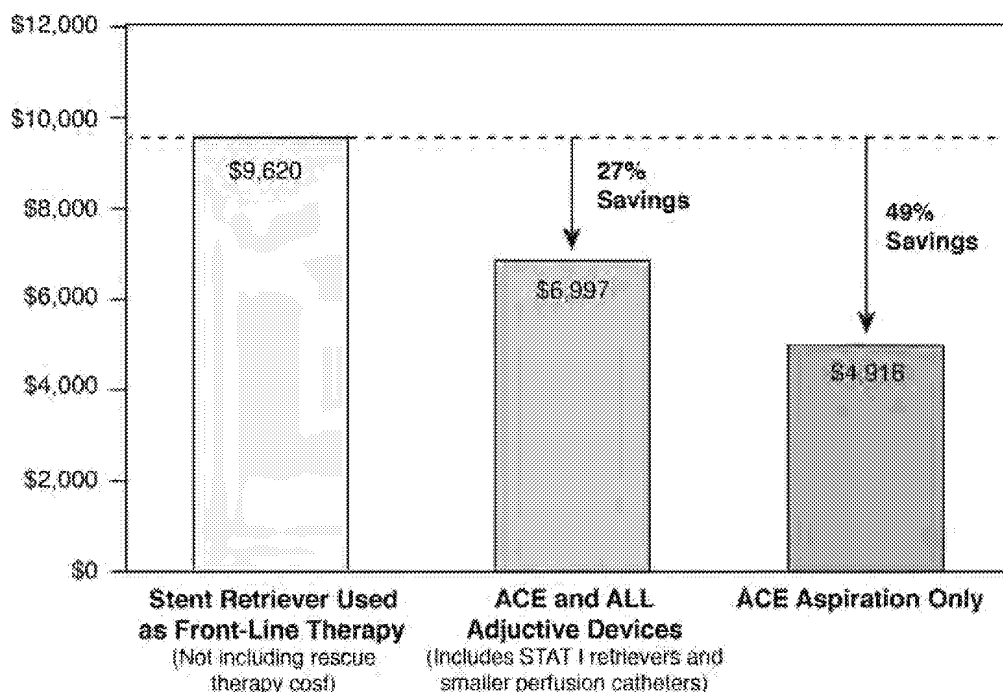


Figure. Comparison of average costs for aspiration with the 5MAX ACE alone vs the 5MAX ACE plus adjunctive devices when needed vs the use of a stent retriever as first-line therapy.

NASA Registry and the 7.7% in MR CLEAN.^{7,8} The death rate in our group was 3.2% vs 30.2% in NASA registry and 21% in MR CLEAN.^{7,8}

The purpose of the cost analysis is to provide a basic understanding of the relative procedural device costs between ADAPT using the 5MAX ACE catheter and stent retrievers in practice. Hospital administrators are acutely aware of device costs for procedures. Both endovascular and open surgeons are being tasked to reduce costs and to justify inclusion of new products, sometimes by omitting other products, as in the authors' experience.

We do not warrant that our cost analysis defines cost effectiveness because such a determination requires a complete evaluation of the patient's care.¹¹ However, device costs are a major cost in the treatment of large vessel occlusions and are the only costs that the interventionalist may completely control.

A study by Turk et al provides support for our cost-saving findings.¹¹ In a single-center retrospective study of mechanical thrombectomy, the average device cost of \$15,798 for a stent retriever (the Solitaire or Trevo) with local aspiration was significantly higher than the \$10,263 cost of the traditional Penumbra system and the \$7,421 cost for ADAPT.¹¹ Their data thus showed a 53% cost savings with ADAPT compared to a stent retriever with local aspiration, consistent with our data showing a potential 49% cost savings with ADAPT. These investigators included all costs, whereas we did not include the costs of wires, diagnostic catheters, sheaths, or closure devices. In our study, the potential cost savings for our institution was approximately 26% when we added all cases together, including all rescue therapy costs, and compared the cost with the cost of successful revascularization with a stent retriever as the only tool. If we consider that rescue therapy is required in at least

26% of stent retriever cases,⁸ the cost savings could be much greater than our estimate.

Despite our small sample size, our data show that good angiographic results correlate with shorter length of stay. Shorter hospitalizations have the potential to produce additional cost savings in the treatment of large vessel occlusion strokes. The authors believe that improvement in cerebral perfusion—not the actual device that was used to perform the successful thrombectomy—reduces length of stay.

One limitation of this study is the lack of a comparison group of stent retriever cases performed at the same institution. Because the current protocol shared by the 2 neurointerventionalists is to start with ADAPT, stent retrievers are used primarily for smaller arteries, for tortuous anatomy, and as rescue therapy following thromboaspiration. Another limitation is the lack of blinded core laboratory adjudication of angiographic endpoints; a metaanalysis of trial data on angiographic evaluation of aneurysms has shown that local centers may overestimate their results.¹² Furthermore, our study is limited to a single center, which makes the results potentially less generalizable, and the data analysis is retrospective rather than prospective. While the sample size is small compared to the data emerging from multicenter randomized controlled trials, this report of a relatively new device shows the potential for important cost savings while maintaining a high degree of clinical effectiveness. Although the preponderance of currently available trial data is based on stent retrievers, the authors believe that ADAPT deserves continued consideration as first-line therapy and should be studied further with a randomized, prospective cost-benefit analysis to guide future recommendations for acute stroke care.

CONCLUSION

This single-center retrospective review of mechanical thrombectomy cases using the large bore 5MAX ACE catheter and ADAPT suggests that it should be considered as a first-line approach for treatment for large vessel occlusions. This technique resulted in high rates of successful reperfusion, rapid reperfusion times, and excellent clinical outcomes with important potential cost savings compared to the first-line use of stent retrievers.

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ORIGINAL RESEARCH

Initial clinical experience using the two-stage aspiration technique (TSAT) with proximal flow arrest by a balloon guiding catheter for acute ischemic stroke of the anterior circulation

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ABSTRACT**Background** Our initial experience using the two-stage aspiration technique (TSAT) with proximal flow arrest by a balloon guiding catheter is presented. In TSAT, aspiration is applied with the 5MAX ACE and also with the 3MAX catheter with a Penumbra aspiration pump, while arresting proximal flow by balloon inflation.**Methods** In patients treated with TSAT, clinical data including National Institutes of Health Stroke Scale (NIHSS) score at admission and the modified Rankin Scale (mRS) score at discharge, as well as procedural data including the Thrombolysis in Cerebral Infarction (TICI) score, procedural time, and complications were analyzed.**Results** Thirty-four consecutive patients (19 men (56%); mean age 73 years) were treated with TSAT using a balloon guiding catheter. The patients presented with a mean NIHSS score of 17.4 and 23 (68%) patients received IV tissue plasminogen activator. Median time from groin puncture to successful recanalization was 41 min (range 15–160 min). All patients were successfully revascularized; TICI 2b or better recanalization was achieved in 30 (88%) patients. No patient required an additional procedure such as use of a stent retriever. Procedure-related complications occurred in two (5.9%) patients (vessel injury and guidewire perforation). Symptomatic intracranial hemorrhage occurred in one patient and asymptomatic hemorrhagic infarction occurred in two patients. There were no cases of embolization to new territory (ENT). The mean NIHSS score at discharge improved to 6.1. Sixteen patients (47%) achieved a good outcome with an mRS score of 0–2 at discharge (mean hospitalization period 20 days).**Conclusions** TSAT with proximal flow arrest by a balloon guiding catheter is an effective and safe method to achieve good clinical and angiographic outcomes. This method may reduce ENT in the direct aspiration first-pass thrombectomy (ADAPT) technique.

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Efficiency of the Penumbra 5MAX ACE Reperfusion Catheter in Acute Ischemic Stroke Patients

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Takuya Kanamaru, MD, Arata Abe, MD, Satoshi Suda, MD, Seiji Okubo, MD, and
Kazumi Kimura, MD

Objective: This study was performed to investigate whether the Penumbra 5MAX ACE is superior to other Penumbra systems. *Materials and Methods:* We performed a retrospective, single center analysis of patients with acute ischemic stroke with occlusion of the internal carotid artery or middle cerebral artery (M1 segment) who underwent endovascular therapy using a Penumbra system. The reperfusion success rate, puncture-to-revascularization time, and number of passes were assessed. Multivariate regression analysis was conducted to evaluate independent factors related to revascularization within 60 minutes. Successful revascularization was defined by a thrombolysis in cerebral infarction score $\geq 2b$. *Results:* The Penumbra 5MAX ACE was used in 24 of the 40 patients (60%). Although the revascularization success rate was similar between patient groups ($P = .229$), the number of passes was significantly lower ($1.5 \pm .8$ versus 2.6 ± 1.3 , $P = .006$) and the puncture-to-revascularization time was shorter (50 ± 26 minutes versus 116 ± 69 minutes, $P = .002$) in patients treated with the Penumbra 5MAX ACE. The Penumbra 5MAX ACE was identified as an independent factor for early revascularization (odds ratio, 5.80; $P = .041$). Among patients with a premorbid modified Rankin Scale score of 0-1, a modified Rankin Scale score of 0-2 at 3 months was observed in 15 of the 19 patients (79%) treated with the Penumbra 5MAX ACE and in 8 of the 16 (50%) who were not ($P = .072$). *Conclusion:* Acute revascularization therapy using the Penumbra 5MAX ACE can achieve rapid successful recanalization and tend to improve clinical outcomes. **Key Words:** Penumbra 5MAX ACE—acute ischemic stroke—endovascular therapy—revascularization.
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Efficacy of a coaxial system with a compliant balloon catheter for navigation of the Penumbra reperfusion catheter in tortuous arteries: technique and case experience

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OBJECTIVE The authors describe a method by which they easily and atraumatically navigate a large-bore reperfusion catheter of the Penumbra system to an embolus by using a coaxial system with a compliant balloon catheter in patients with tortuous arteries.

METHODS A retrospective review of the prospective endovascular database was performed to identify cases in which a coaxial system with a compliant balloon catheter (Scepter C, MicroVention/Terumo; or TransForm C, Stryker Neurovascular) and a large-bore reperfusion catheter of the Penumbra system (Penumbra, Inc.) was used. The authors achieved a stable guiding sheath position and delivered the coaxial system with a compliant balloon catheter and a large-bore reperfusion catheter. Then, the balloon was inflated somewhat when the distal tip of the balloon was slightly advanced from the tip of the reperfusion catheter, and together the coaxial system was advanced to an embolus over a 0.014-in guidewire, even around the corner. When the distal tip of the balloon catheter reached the embolus, the authors deflated the balloon and navigated the large-bore reperfusion catheter to the embolus. Finally, the aspiration of the embolus with the Penumbra MAX pump was begun.

RESULTS Between May 2014 and September 2015, the authors used this technique in 17 cases: 16 cases of middle cerebral artery occlusion (including 5 cases of internal carotid artery occlusion) and 1 case of basilar artery occlusion (age range 36–88 years, mean age 74.7 years, 13 men). For the reperfusion catheter of the Penumbra system, the 5MAX ACE was used in 15 cases, and the 5MAX was used in 2 cases. As a compliant balloon catheter, the Scepter C was used in 16 cases, and the TransForm C was used in 1 case. The technique was successful in 16 cases (94.1%). No parent artery dissections were noted in any cases. Catheter-induced vasospasm was noted in 1 case, but the vasospasm was transient.

CONCLUSIONS A coaxial system with a compliant balloon catheter can help safely and easily to navigate the large-bore reperfusion catheter of the Penumbra system to an embolus in patients with tortuous arteries.

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KEY WORDS coaxial system; compliant balloon catheter; reperfusion catheter; Penumbra system; aspiration; vascular disorders; diagnostic and operative techniques

FOR patients with acute stroke due to major intracranial vessel occlusion, a direct aspiration first pass technique (ADAPT) with a large-bore reperfusion catheter of the Penumbra system (Penumbra, Inc.) is an efficient management strategy and does not increase the incidence of symptomatic intracranial hemorrhage.³ However, when we used the 3MAX reperfusion catheter as an

inner catheter in cases of severe tortuosity of the vasculature, it could be impossible or hazardous to advance the large-bore reperfusion catheter of the Penumbra system to an embolus along the outer curvature of the vessel in tortuous arteries, mainly because of the gap between the 2 catheters at the distal tip. We describe our experiences in a series of cases in which we used a coaxial system with a

ABBREVIATIONS ADAPT = a direct aspiration first pass technique; BA = basilar artery; ICA = internal carotid artery; MCA = middle cerebral artery; OphA = ophthalmic artery.

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compliant balloon catheter and the large-bore reperfusion catheter of the Penumbra system designed to decrease the gap between the 2 catheters. We have named this strategy the “Rocket” technique, because the edge of this coaxial system appears to have the shape of a rocket.

Methods

A retrospective review of our prospective endovascular database identified 17 cases treated between May 2014 and September 2015 in which we used the Rocket technique. All patients had tortuosity of the extracranial or intracranial artery. We did not try the standard technique with a large-bore reperfusion catheter and a 3MAX reperfusion catheter in any of the 17 cases.

Operative Technique

Initial angiography was typically performed through a 4-Fr diagnostic catheter positioned within the proximal parent artery (Fig. 1). This diagnostic catheter was then exchanged, along with the femoral sheath, for a 6-Fr long sheath (KSAW Shuttle; Cook, Inc.) or a 9-Fr balloon-guiding catheter (Optimo; Tokai Medical Products, Inc.), which was positioned within the proximal parent artery. Then, we used the coaxial system of a compliant balloon catheter (Scepter C, MicroVention/Terumo; or TransForm C, Stryker Neurovascular) and a 5MAX ACE or 5MAX reperfusion catheter of the Penumbra system (Penumbra, Inc.) to decrease the gap between the 2 catheters at the distal tip along the outer curvature of the vessel. We achieved a stable guiding sheath position and then delivered the coaxial system with a compliant balloon catheter and reperfusion catheter. Then, the balloon was inflated somewhat when the tip of the balloon was advanced slightly from the tip of the reperfusion catheter, while referring to the markers of the balloon on angiographic studies. We advanced the coaxial system together over a 0.014-in guidewire even around the corner, while taking care not to penetrate an embolus with the guidewire. When the distal tip of the balloon catheter reached the embolus, we deflated the balloon

and navigated the large-bore reperfusion catheter to the embolus over the balloon catheter and the 0.014-in guidewire. In using Scepter C, we could detect the distal tip of the balloon catheter on angiographic studies. Finally, we began the aspiration of the embolus with the Penumbra MAX pump.

Results

We used the Rocket technique to perform ADAPT in 17 cases (patient age range 36–88 years, mean patient age 74.7 years, 13 men): 16 cases with middle cerebral artery (MCA) occlusion and 1 case with basilar artery (BA) occlusion (Table 1). In 5 cases we used this technique to manage MCA occlusion after forced suction by a 9-Fr balloon-guiding catheter for internal carotid artery (ICA) occlusion. For the reperfusion catheter of the Penumbra system, 5MAX ACE was used in 15 cases, and 5MAX was used in 2 cases. As a compliant balloon catheter, Scepter C was used in 16 cases (Figs. 2 and 3) and TransForm C was used in 1 case. All patients had tortuosity of the extracranial or intracranial artery. The technique was successful in 16 cases (94.1%); in 1 case we could not navigate the coaxial system with Scepter C and 5MAX ACE (Fig. 3). The technique with Scepter C was successful at the first attempt in each case, and the 1 case in which TransForm C was used was successful on a second attempt. Boluses of calcium channel blockers were not used in any of the cases. Parent artery dissection was not noted in any cases. Catheter-induced vasospasm was noted in 1 case, but this vasospasm was transient.

Discussion

This case series demonstrated a new technique to easily and atraumatically navigate a large-bore reperfusion catheter to an embolus in patients with tortuous arteries. In patients with acute stroke due to major intracranial vessel occlusion, ADAPT with a large-bore reperfusion catheter of the Penumbra system is an efficient management strategy and does not increase the incidence of symptomatic intracranial hemorrhage.³ However, in cases of severe tortuosity of the vasculature, it can be impossible or hazardous to navigate a large-bore reperfusion catheter of the Penumbra system to an embolus when a 3MAX reperfusion catheter is used as the inner catheter, mainly because of the gap between the 2 catheters at the distal tip. We often had failed to navigate a large-bore reperfusion catheter with a 3MAX reperfusion catheter in the patients with tortuous anatomy before this study.

When a coaxial system with a 5MAX reperfusion catheter and a 3MAX reperfusion catheter are used, the gap between the 2 catheters at the distal tip is 0.004 in, because the inner diameter of the 5MAX reperfusion catheter is 0.054 in and the outer diameter of the 3MAX reperfusion catheter is 0.050 in. When using the 5MAX ACE reperfusion catheter and the 3MAX reperfusion catheter, the gap is 0.010 in. This gap has no impact in a straight vessel, but in the context of a tortuous artery, it can make it difficult and sometimes impossible to navigate a large-bore reperfusion catheter to an embolus, especially around a corner (Fig. 4), because the large-bore reperfusion catheter can

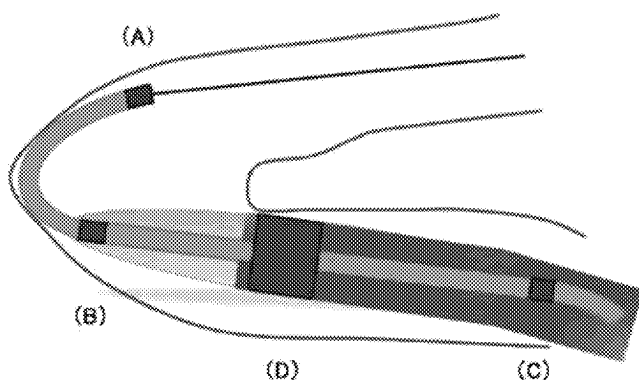


FIG. 1. This drawing demonstrates the Rocket technique as performed using angiographic studies. Four markers are detected and are labeled as follows. The distal tip marker of the balloon catheter (A)—only Scepter, exclusive of TransForm; the distal marker of the balloon (B); the proximal marker of the balloon (C); and the tip marker of the reperfusion catheter (D). Figure is available in color online only.

K. Takahira et al.

TABLE 1. Characteristics and procedural details in 17 patients with occlusion of tortuous arteries

Case No.	Age (yrs)	Sex	Location	NIHSS Score	Catheter	Reperfusion Catheter	Balloon Catheter	Guidewire	TICI Score*	Complication
1	84	M	Rt MCA	14	Shuttle 6-Fr	5MAX	Scepter C	Traxcess 0.014	2b	None
2	78	M	BA	37	Shuttle 6-Fr	5MAX	Scepter C	Synchro2 Soft 0.014	2a	None
3	80	M	Lt MCA	26	Shuttle 6-Fr	5MAX ACE	Scepter C	Synchro2 Soft 0.014	3	None
4	80	M	Rt MCA	18	Shuttle 6-Fr	5MAX ACE	Scepter C	Synchro2 Soft 0.014	2b	None
5	82	M	Lt MCA	23	Shuttle 6-Fr	5MAX ACE	Scepter C	ASAHI CHIKAI 0.014	3	None
6	71	M	Rt MCA	19	Shuttle 6-Fr	5MAX ACE	TransForm C	Transend EX Soft Tip 0.014	3	None
7	67	F	Rt MCA	14	Shuttle 6-Fr	5MAX ACE	Scepter C	Synchro2 Soft 0.014	3	None
8	36	F	Lt MCA	9	Shuttle 6-Fr	5MAX ACE	Scepter C	Synchro2 Soft 0.014	3	Slight vasospasm
9	72	M	Rt MCA	3	Shuttle 6-Fr	5MAX ACE	Scepter C	Synchro2 Soft 0.014	3	None
10	80	F	Lt ICA	31	Optimo 9-Fr	5MAX ACE	Scepter C	Synchro2 Soft 0.014	2b	None
11	88	M	Lt ICA	6	Optimo 9-Fr	5MAX ACE	Scepter C	Synchro2 Soft 0.014	2b	None
12	64	M	Lt ICA	17	Optimo 9-Fr	5MAX ACE	Scepter C	Synchro2 Soft 0.014	2b	None
13	86	M	Lt ICA	20	Optimo 9-Fr	5MAX ACE	Scepter C	ASAHI CHIKAI 0.014	2b	None
14	65	M	Lt MCA	24	Shuttle 6-Fr	5MAX ACE	Scepter C	ASAHI CHIKAI 0.014	3	None
15	66	F	Lt MCA	11	Shuttle 6-Fr	5MAX ACE	Scepter C	ASAHI CHIKAI 0.014	3	None
16	83	M	Rt MCA	15	Shuttle 6-Fr	5MAX ACE	Scepter C	ASAHI CHIKAI 0.014	3	None
17	88	M	Rt ICA	22	Optimo 9-Fr	5MAX ACE	Scepter C	ASAHI CHIKAI 0.014	2a	None

NIHSS = National Institutes of Health Stroke Scale; TICI = thrombolysis in cerebral infarction.

* According to Higashida et al.

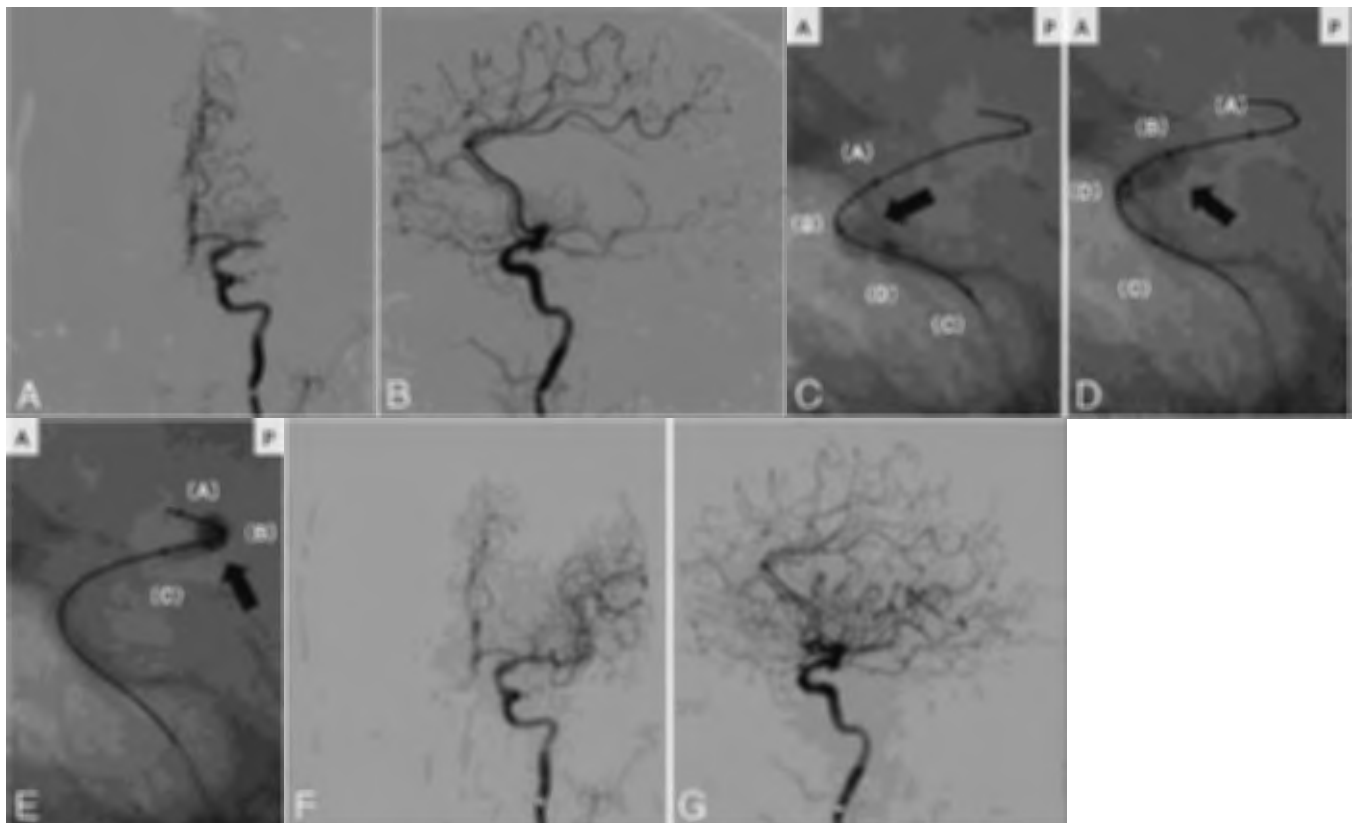


FIG. 2. Case 5. Angiography obtained in an 82-year-old man with left MCA occlusion. Left ICA angiogram demonstrated moderate tortuosity (A and B). A Scepter C 4 × 10-mm balloon (arrows) was inflated in the horizontal segment of the ICA, and a coaxial system with a 5MAX ACE and a Scepter C was easily navigated over an ASAHI CHIKAI (Asahi Intecc Co., Ltd.) 0.014-in guidewire (C–E). Following treatment, angiography demonstrated no evidence of carotid dissection or injury (F and G). See Fig. 1 legend for definitions of the markers in parentheses in panels C–E.

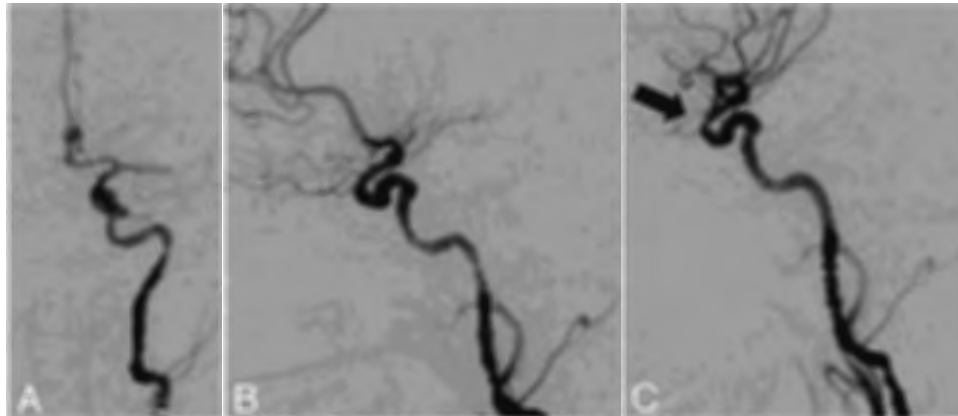


FIG. 3. Case 8. Angiography obtained in a 36-year-old woman with left MCA occlusion. Left ICA angiogram demonstrated severe tortuosity (A and B). We tried to navigate a coaxial system with a Scepter C 4 × 10-mm balloon and 5MAX ACE, but were unsuccessful due to significant stress on the vessel wall at the corner near the ophthalmic artery (OphA). After using steam to shape the tip of the 5MAX ACE along the curvature, we could navigate the coaxial system over a Synchro2 soft 0.014-in guidewire (Stryker Neurovascular) to the embolus. Following treatment, angiography demonstrated mild vasospasm (arrow) at the distal part of the OphA, but no evidence of carotid dissection (C). The vasospasm improved immediately.

be advanced along the outside of the inner catheter. Even if it is possible to advance the inner catheter toward the periphery, it can be hazardous or impossible to advance the large-bore reperfusion catheter because the stress due to the gap damages the vessel wall, and traumatic injury happens as a result of this damage. This problem can increase the technical difficulty, the procedure time, and the risk of complications. Therefore, we did not try the standard technique in all 17 cases at first.

A coaxial system with a compliant balloon catheter can address these technical limitations. First, the placement of a compliant balloon that fills the gap between the 2 catheters at the distal tip can reduce the stress along the vessel wall and enable the safe advancement of a large-bore reperfusion catheter around the corner. A compliant balloon is so soft and supple that it can reduce the risk of vasospasm and traumatic injury, even in severely tortuous vessels. The degree of balloon inflation can also be mod-

fied to avoid damaging a large-bore catheter and the vessel wall. Also, the presence of a distal tip in a compliant balloon catheter is important. The length of the distal tip is 5 mm in Scepter C and 3.25 mm in TransForm C. By using the length, the coaxial system can be navigated together even around the corner, as if it were a single catheter. Also, in using Scepter C, the distal tip marker of the balloon catheter can help visualization on angiographic studies, to avoid penetrating an embolus. Finally, the balloon catheter can be navigated beyond the tortuous anatomy over a 0.014-in guidewire. A 0.014-in guidewire might be better than a 0.010-in guidewire in advancing the coaxial system together, because the 0.014-in guidewire has superior operability and trackability. When the balloon is deflated, the large-bore reperfusion catheter can be gently guided to the embolus over the balloon catheter and the 0.014-in guidewire.

A similar concept has not been described for acute

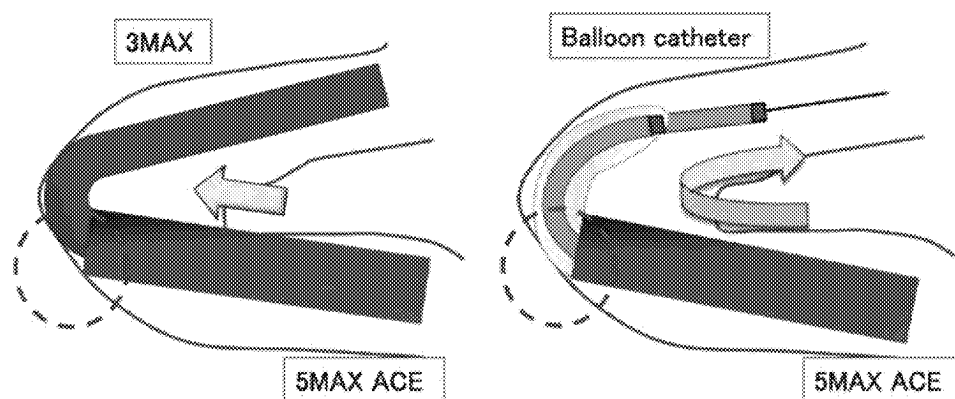


FIG. 4. These drawings demonstrate the structures of the coaxial system in each pattern at the curvature of the vessel. **Left:** When using the 3MAX reperfusion catheter, the gap between the 2 catheters often creates stress on the vessel wall (straight arrow), and it is hazardous or impossible to navigate a large-bore reperfusion catheter to an embolus. **Right:** When using the Scepter C, filling the balloon can reduce the gap between the 2 catheters, and it is possible to navigate a large-bore reperfusion catheter easily even at the curvature of a tortuous artery (curved arrow). The dashed circles designate the vessel wall area under stress. Figure is available in color online only.

K. Takahira et al.

stroke treatment, but a novel technique has been reported for navigation of a catheter with a compliant balloon catheter in cases of a tortuous artery. Peeling and Fiorella² used balloon-assisted guide catheter positioning to overcome extreme cervical carotid tortuosity. Those investigators used a compliant balloon (Scepter, HyperForm, HyperGlide; ev3, Covidien) as an anchor to achieve distal positioning of a flexible guiding catheter beyond the extreme cervical carotid tortuosity when performing coil embolization for an intracranial aneurysm in the anterior circulation. When using this technique, there were no perioperative complications (e.g., vasospasm or vascular damage) in any of the 12 patients, and hypercompliant balloon catheters could be reliably used to facilitate safe and rapid distal positioning of the flexible guiding catheters beyond the severe cervical carotid tortuosity. In our cases, parent artery dissections were not noted, and catheter-induced vasospasm was mild and transient in 1 case. These data suggest that the Rocket technique, in which a compliant balloon catheter is used, can be an effective and safe strategy for the management of acute stroke.

The Rocket technique has several limitations. First, a large-bore reperfusion catheter of the Penumbra system can be damaged at the distal tip or at other parts. In 1 case, slight damage was noted at the distal tip of the reperfusion catheter, which might have resulted from overexpansion of the balloon. The damage to other portions of the reperfusion catheter might be due to the gap between the 2 catheters or to the catheters' stiffness. Second, the compliant balloon can be damaged due to the stress on the vessel wall in advancing the coaxial system. Third, this procedure can require significant technical skill on the part of the operators. Finally, this technique may be associated with a slightly longer procedural time and an increased risk of traumatic injury or vasospasm, because increasing the stability of the whole construction by inflating a balloon may make navigation more difficult.

In 1 case (Case 8), we could not navigate the coaxial system with the Scepter C and the 5MAX ACE reperfusion catheter (Fig. 3). The patient was a 36-year-old woman who had severe tortuosity of the ICA. In most previous cases similar to this one, we put out the balloon as much as one-third of its length from the tip of the reperfusion catheter and navigated the coaxial system together after inflating the balloon slightly to reduce the gap between the 2 catheters. But the balloon was bent at the corner of the vessel, and advancing the coaxial system could create significant stress on the vessel wall. In this case, the stress against the vessel wall precluded navigation of the coaxial system at the distal part of the ophthalmic artery (OphA), and mild catheter-induced vasospasm occurred at the corner. After using steam to shape the tip of the 5MAX ACE

along the curvature, we could navigate the coaxial system together to the embolus. Thereby, we recognized that it was important when we inflated a balloon that we put it out only slightly, or less than one-third of its length from the tip of the reperfusion catheter. When doing so, the Rocket technique was successful in all subsequent cases after Case 8, and catheter-induced vasospasm did not occur in any of the remaining 9 cases. Additional cases of intracranial major vessel occlusion with tortuous arteries are needed to further refine the Rocket technique, because we studied only 17 cases in this series.

Conclusions

A coaxial system with a compliant balloon catheter was effective and safe for navigation of a large-bore reperfusion catheter of the Penumbra system to the embolus in patients with tortuous arteries.

Acknowledgments

We express the deepest appreciation to individuals who contributed to the study or to manuscript preparation.

References

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2. Peeling L, Fiorella D: Balloon-assisted guide catheter positioning to overcome extreme cervical carotid tortuosity: technique and case experience. *J Neurointerv Surg* 6:129–133, 2014
3. Turk AS, Frei D, Fiorella D, Mocco J, Baxter B, Siddiqui A, et al: ADAPT FAST study: a direct aspiration first pass technique for acute stroke thrombectomy. *J Neurointerv Surg* 6:260–264, 2014

Disclosures

The authors report no conflict of interest concerning the materials or methods used in this study or the findings specified in this paper.

Author Contributions

Conception and design: Takahira, Kataoka. Acquisition of data: Takahira. Analysis and interpretation of data: Takahira. Drafting the article: Takahira. Administrative/technical/material support: Kataoka, Endo, Ogino. Study supervision: Kataoka, Nakamura.

Correspondence

Kazuki Takahira, Nakamura Memorial Hospital, Department of Neurosurgery, South 1, West 14, Chuo-ku, Sapporo 0608570, Japan. email: tkhrkzk@gmail.com.

ORIGINAL RESEARCH

Direct aspiration first pass technique for the treatment of acute ischemic stroke: initial experience at a European stroke center

Annika Kowoll,¹ Anushe Weber,¹ Anastasios Mpotsaris,² Daniel Behme,³ Werner Weber¹

¹Department of Radiology and Neuroradiology, University Medical Center Langendreer, Ruhr-University-Bochum, Bochum, Germany

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DB and WW contributed equally.

DB, AW, AK, AM, and WW changed departments in 2014, and had been part of the Department of Radiology and Neuroradiology, Klinikum Vest, Recklinghausen, where the patients were treated.

Received 16 October 2014
Revised 7 December 2014
Accepted 26 December 2014
Published Online First
12 January 2015

ABSTRACT

Introduction Over the past decade, endovascular techniques for the treatment of acute ischemic stroke have emerged significantly. However, revascularization rates are limited at approximately 80%, and mechanical thrombectomy procedures still last about 1 h. Therefore, we investigated the novel direct aspiration first pass technique for its efficacy and safety.

Methods Our neurointerventional database was screened for patients who received mechanical thrombectomy for acute ischemic stroke using the Penumbra 5MAX ACE aspiration catheter on an intention to treat basis between November 2013 and June 2014. Procedural data, including modified Thrombolysis in Cerebral Infarction (mTICI) score, procedural timings, and complications, as well as clinical data at admission and discharge, were analyzed.

Results 54 patients received mechanical thrombectomy using the 5MAX ACE. Median age was 69 (39–94) years (54% were men). Baseline National Institutes of Health Stroke Scale (NIHSS) score was 15 (2–27) and 44/54 (81%) patients received intravenous thrombolysis. Vessel occlusion sites were 91% anterior circulation and 9% posterior circulation. A successful revascularization result (mTICI $\geq 2b$) was achieved in 93% of cases whereas direct aspiration alone was successful in 30/54 (56%) cases; among these, median time from groin puncture to revascularization was 30 min (9–113). Symptomatic intracranial hemorrhage occurred in 2/54 (4%) patients, and embolization to new territories in 3/54 (6%). Median NIHSS at discharge was 6 (0–24); 46% of patients were independent at discharge.

Conclusions The direct aspiration first pass technique proved to be fast, effective, and safe. Promising revascularization results can be achieved quickly in more than 50% of patients using this technique as the firstline option. Nevertheless, stent retrievers are still warranted in approximately 40% of cases to achieve a favorable revascularization result.

(b)(4)

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Hello all,

I am setting up this brief call with your team and NIDB branch chief Dr. Xiaolin Zheng to discuss your AXS Catalyst (K173841) submission in regards to the (b)(4)

(b)(4)

Right now I have set this call up for 12:30pm EST, however please let me know if you would like me to reschedule for 1:30pm EST instead.

Thank you,

Dhanya Williams

Tel: 301-796-6498

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Hello Ms. Beckmann,

Thank you very much. We will review and be back in touch if we need anything else or have any questions.

Regards,

Dhanya Williams, M.S.

Biologist/Scientific Reviewer

Center for Devices and Radiological Health (CDRH)

Office of Device Evaluation (ODE)

U.S. Food and Drug Administration

Tel: 301-796-6498

dhanya.williams@fda.hhs.gov

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From: Beckmann, Angelica [mailto:angelica.beckmann@stryker.com]

Sent: Tuesday, March 13, 2018 11:57 AM

To: Williams, Dhanya K <Dhanya.Kumar@fda.hhs.gov>

Cc: K173841@docs.fda.gov

Subject: RE: K173841 - Interactive request #2 - (b)(4)

Importance: High

Dear Ms. Williams,

Thank you for your e-mail.

Enclosed are the responses to FDA's Interactive Request regarding additional information needed. The requested information is contained within the attached pdf file.

Please feel free to call me or send email with any additional requests.

Best regards,

Angelica Beckmann

Director Regulatory Affairs

Stryker Neurovascular

47900 Bayside Pkwy

Fremont, CA 94538

(b)(6) Mobile

angelica.beckmann@stryker.com<mailto:angelica.beckmann@stryker.com>

From: Williams, Dhanya K [mailto:Dhanya.Kumar@fda.hhs.gov]

Sent: Monday, March 12, 2018 11:24 AM

To: Beckmann, Angelica

<angelica.beckmann@stryker.com<mailto:angelica.beckmann@stryker.com>>

Cc: K173841@docs.fda.gov<mailto:K173841@docs.fda.gov>; Williams, Dhanya K
<Dhanya.Kumar@fda.hhs.gov<mailto:Dhanya.Kumar@fda.hhs.gov>>

Subject: K173841 - Interactive request #2 - (b)(4)

Importance: High

Hello Ms. Beckmann,

We are nearing the completion of our review, however after (b)(4)
(b)(4) "Response to FDA Interactive Request #1 Rev 2 (002)" that you
provided interactively on 3/8/18, we have identified two items that need to be
addressed:

(b)(4)

(b)(4)

Please feel free to email me or call me at 301-796-6498 if you need any clarification.

(b)(4)

Thank you,

Dhanya Williams, M.S.

Biologist/Scientific Reviewer

Center for Devices and Radiological Health (CDRH)

Office of Device Evaluation (ODE)

U.S. Food and Drug Administration

Tel: 301-796-6498

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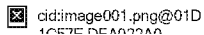
Hello Ms. Beckmann,

Thank you for your email. As Ms. Anderson noted, I am the lead reviewer for your submission, K173841, and we are still in the process of reviewing your deficiency responses. I will be in touch with you in the next day or two regarding any additional items that need to be addressed as we continue our review, however in the meantime, please address the following:

(b)(4)

Thank you,

Dhanya Williams, M.S.
Biologist/Scientific Reviewer
Center for Devices and Radiological Health (CDRH)
Office of Device Evaluation (ODE)
U.S. Food and Drug Administration
Tel: 301-796-6498
dhanya.williams@fda.hhs.gov



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From: Anderson, Leigh
Sent: Wednesday, March 07, 2018 7:30 AM
To: 'Beckmann, Angelica' <angelica.beckmann@stryker.com>
Cc: Allison, John <John.Allison@stryker.com>; Mateus, Jennifer <Jennifer.Mateus@stryker.com>; Zheng, Xiaolin <Xiaolin.Zheng@fda.hhs.gov>; Williams, Dhanya K <Dhanya.Kumar@fda.hhs.gov>
Subject: RE: K173841-A1 - Updated: (b)(4)

Dear Ms. Beckmann,

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118

Thank you for your email.

Ms. Dhanya Williams is the Lead Reviewer for K173841, and I have forwarded the email to her, as well as copied her on this reply. Ms. Williams can assist with questions specific to K173841 and review of the submission.

Regards,

Leigh Anderson
Biomedical Engineer
Neurointerventional Devices Branch (NIDB)
Division of Neurological and Physical Medicine Devices (DNPMD)
Center for Devices and Radiological Health (CDRH)
Office of Device Evaluation (ODE)
U.S. Food and Drug Administration
Tel: 301-796-5613
leigh.anderson@fda.hhs.gov

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From: Beckmann, Angelica [<mailto:angelica.beckmann@stryker.com>]
Sent: Tuesday, March 06, 2018 6:04 PM
To: Anderson, Leigh <Leigh.Anderson@fda.hhs.gov>
Cc: Allison, John <john.allison@stryker.com>; Mateus, Jennifer <jennifer.mateus@stryker.com>; Zheng, Xiaolin <Xiaolin.Zheng@fda.hhs.gov>
Subject: K173841-A1 - Updated (b)(4)
Importance: High

Dear Ms. Anderson,
I hope this e-mail finds you well.

(b)(4)

(b)(4)

I would also like to understand the next steps for the interactive review of K173481.

Kind regards,

Angelica Beckmann
Director Regulatory Affairs
Stryker Neurovascular
47900 Bayside Pkwy
Fremont, CA 94538
510-413-2900 Office
(b)(6) Mobile
angelica.beckmann@stryker.com

Ms. Beckmann,

Yes, you can call me at 301-796-6498. I am also available right now if that would help, otherwise 12:30pm EST would be fine.

Thank you,

Dhanya Williams, M.S.

Biologist/Scientific Reviewer

Center for Devices and Radiological Health (CDRH)

Office of Device Evaluation (ODE)

U.S. Food and Drug Administration

Tel: 301-796-6498

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From: Beckmann, Angelica [mailto:angelica.beckmann@stryker.com]

Sent: Wednesday, March 07, 2018 9:12 AM

To: Williams, Dhanya K <Dhanya.Kumar@fda.hhs.gov>

Cc: Allison, John <John.Allison@stryker.com>; Mateus, Jennifer <Jennifer.Mateus@stryker.com>; K173841@docs.fda.gov

Subject: RE: K173841 - Interactive request #1 - Updated (b)(4)

Ms. Williams,

Thank you for your e-mail.

I will be available for a phone call at 12:30 pm (EST).

Should I call your desk phone number?

Regards

Angelica

From: Williams, Dhanya K [mailto:Dhanya.Kumar@fda.hhs.gov]

Sent: Wednesday, March 7, 2018 6:02 AM

To: Beckmann, Angelica
<angelica.beckmann@stryker.com<mailto:angelica.beckmann@stryker.com>>

Cc: Allison, John <John.Allison@stryker.com<mailto:John.Allison@stryker.com>>; Mateus, Jennifer <Jennifer.Mateus@stryker.com<mailto:Jennifer.Mateus@stryker.com>>; K173841@docs.fda.gov<mailto:K173841@docs.fda.gov>; Williams, Dhanya K <Dhanya.Kumar@fda.hhs.gov<mailto:Dhanya.Kumar@fda.hhs.gov>>

Subject: K173841 - Interactive request #1 - Updated (b)(4)

Hello Ms. Beckmann,

Thank you for your email. As Ms. Anderson noted, I am the lead reviewer for your submission, K173841, and we are still in the process of reviewing your deficiency responses. I will be in touch with you in the next day or two regarding any additional items that need to be addressed as we continue our review, however in the meantime, please address the following:

(b)(4)

(b)(4)

Thank you,

Dhanya Williams, M.S.

Biologist/Scientific Reviewer

Center for Devices and Radiological Health (CDRH)

Office of Device Evaluation (ODE)

U.S. Food and Drug Administration

Tel: 301-796-6498

dhanya.williams@fda.hhs.gov<mailto:dhanya.williams@fda.hhs.gov>

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Subject: RE: K173841-A1 - Updated (b)(4)

Dear Ms. Beckmann,

Thank you for your email.

Ms. Dhanya Williams is the Lead Reviewer for K173841, and I have forwarded the email to her, as well as copied her on this reply. Ms. Williams can assist with questions specific to K173841 and review of the submission.

Regards,

Leigh Anderson

Biomedical Engineer

Neurointerventional Devices Branch (NIDB)

Division of Neurological and Physical Medicine Devices (DNPMD)

Center for Devices and Radiological Health (CDRH)

Office of Device Evaluation (ODE)

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leigh.anderson@fda.hhs.gov<mailto:leigh.anderson@fda.hhs.gov>

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Sent: Tuesday, March 06, 2018 6:04 PM

To: Anderson, Leigh <Leigh.Anderson@fda.hhs.gov<mailto:Leigh.Anderson@fda.hhs.gov>>

Cc: Allison, John <John.Allison@stryker.com<mailto:John.Allison@stryker.com>>; Mateus, Jennifer <Jennifer.Mateus@stryker.com<mailto:Jennifer.Mateus@stryker.com>>; Zheng, Xiaolin <Xiaolin.Zheng@fda.hhs.gov<mailto:Xiaolin.Zheng@fda.hhs.gov>>

Subject: K173841-A1 - Updated (b)(4)

Importance: High

Dear Ms. Anderson,

I hope this e-mail finds you well.

(b)(4)

(b)(4)

(b)(4)

I would also like to understand the next steps for the interactive review of K173481.

Kind regards,

Angelica Beckmann

Director Regulatory Affairs

Stryker Neurovascular

47900 Bayside Pkwy

Fremont, CA 94538

510-413-2900 Office

(b)(6)

Mobile

angelica.beckmann@stryker.com<mailto:angelica.beckmann@stryker.com>

From: [Williams, Dhanya K](#)
To: [Zheng, Xiaolin](#)
Cc: [Williams, Dhanya K](#)
Subject: FW: K173841 - Interactive request #1 - Updated (b)(4)
Date: Thursday, March 08, 2018 6:31:16 AM
Attachments: (b)(4)
[image008.png](#)

Hi Lin,

(b)(5)

Thanks,
Dhanya

From: Beckmann, Angelica [mailto:angelica.beckmann@stryker.com]
Sent: Wednesday, March 07, 2018 11:41 PM
To: Williams, Dhanya K <Dhanya.Kumar@fda.hhs.gov>
Cc: Allison, John <John.Allison@stryker.com>; Mateus, Jennifer <Jennifer.Mateus@stryker.com>;

K173841@docs.fda.gov; Ellis, Kristin (Contractor) <kristin.ellis@stryker.com>

Subject: RE: K173841 - Interactive request #1 - Updated (b)(4)

Dear Ms. Williams,

(b)(4)

Best regards,

Angelica Beckmann

Director Regulatory Affairs

Stryker Neurovascular

47900 Bayside Pkwy

Fremont, CA 94538

510-413-2900 Office

(b)(6) Mobile

angelica.beckmann@stryker.com

From: Williams, Dhanya K [<mailto:Dhanya.Kumar@fda.hhs.gov>]

Sent: Wednesday, March 7, 2018 6:02 AM

To: Beckmann, Angelica <angelica.beckmann@stryker.com>

Cc: Allison, John <John.Allison@stryker.com>; Mateus, Jennifer <Jennifer.Mateus@stryker.com>;
K173841@docs.fda.gov; Williams, Dhanya K <Dhanya.Kumar@fda.hhs.gov>

Subject: K173841 - Interactive request #1 - Updated (b)(4)

Hello Ms. Beckmann,

Thank you for your email. As Ms. Anderson noted, I am the lead reviewer for your submission, K173841, and we are still in the process of reviewing your deficiency responses. I will be in touch with you in the next day or two regarding any additional items that need to be addressed as we continue our review, however in the meantime, please address the following:

(b)(4)

(b)(4)

Thank you,

Dhanya Williams, M.S.
Biologist/Scientific Reviewer
Center for Devices and Radiological Health (CDRH)
Office of Device Evaluation (ODE)
U.S. Food and Drug Administration
Tel: 301-796-6498
dhanya.williams@fda.hhs.gov



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From: Anderson, Leigh

Sent: Wednesday, March 07, 2018 7:30 AM

To: 'Beckmann, Angelica' <angelica.beckmann@stryker.com>

Cc: Allison, John <John.Allison@stryker.com>; Mateus, Jennifer <Jennifer.Mateus@stryker.com>; Zheng, Xiaolin <Xiaolin.Zheng@fda.hhs.gov>; Williams, Dhanya K <Dhanya.Kumar@fda.hhs.gov>

Subject: RE: K173841-A1 - Updated (b)(4)

Dear Ms. Beckmann,

Thank you for your email.

Ms. Dhanya Williams is the Lead Reviewer for K173841, and I have forwarded the email to her, as well as copied her on this reply. Ms. Williams can assist with questions specific to K173841 and review of the submission.

Regards,

Leigh Anderson

Biomedical Engineer

Neurointerventional Devices Branch (NIDB)

Division of Neurological and Physical Medicine Devices (DNPMD)

Center for Devices and Radiological Health (CDRH)

Office of Device Evaluation (ODE)

U.S. Food and Drug Administration

Tel: 301-796-5613

leigh.anderson@fda.hhs.gov

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From: Beckmann, Angelica [<mailto:angelica.beckmann@stryker.com>]

Sent: Tuesday, March 06, 2018 6:04 PM

To: Anderson, Leigh <Leigh.Anderson@fda.hhs.gov>

Cc: Allison, John <John.Allison@stryker.com>; Mateus, Jennifer <Jennifer.Mateus@stryker.com>; Zheng, Xiaolin <Xiaolin.Zheng@fda.hhs.gov>

Subject: K173841-A1 - Updated (b)(4)

Importance: High

Dear Ms. Anderson,

I hope this e-mail finds you well.

(b)(4)

(b)(4)

I would also like to understand the next steps for the interactive review of K173481.

Kind regards,

Angelica Beckmann

Director Regulatory Affairs

Stryker Neurovascular

47900 Bayside Pkwy

Fremont, CA 94538

510-413-2900 Office

(b)(6) Mobile

angelica.beckmann@stryker.com

From: [Williams, Dhanya K](#)
To: [Herrmann, Robert](#)
Cc: [Williams, Dhanya K](#)
Subject: FW: K173841 - Interactive request #2 - (b)(5)
Date: Tuesday, March 13, 2018 12:16:46 PM
Attachments: [K173841-S001 Response to FDA Interactive Request#2.pdf](#)
[image001.png](#)
Importance: High

Hi Robert,

(b)(5)

Thanks,
Dhanya

From: Beckmann, Angelica [<mailto:angelica.beckmann@stryker.com>]
Sent: Tuesday, March 13, 2018 11:57 AM
To: Williams, Dhanya K <Dhanya.Kumar@fda.hhs.gov>
Cc: K173841@docs.fda.gov
Subject: RE: K173841 - Interactive request #2 - (b)(4)
Importance: High

Dear Ms. Williams,

Thank you for your e-mail.

Enclosed are the responses to FDA's Interactive Request regarding additional information needed.
The requested information is contained within the attached pdf file.

Please feel free to call me or send email with any additional requests.

Best regards,

Angelica Beckmann

Director Regulatory Affairs

Stryker Neurovascular

47900 Bayside Pkwy

Fremont, CA 94538

(b)(6) Mobile

angelica.beckmann@stryker.com

From: Williams, Dhanya K [<mailto:Dhanya.Kumar@fda.hhs.gov>]
Sent: Monday, March 12, 2018 11:24 AM

To: Beckmann, Angelica <angelica.beckmann@stryker.com>

Cc: K173841@docs.fda.gov; Williams, Dhanya K <Dhanya.Kumar@fda.hhs.gov>

Subject: K173841 - Interactive request #2 - (b)(4)

Importance: High

Hello Ms. Beckmann,

(b)(4)

Please feel free to email me or call me at 301-796-6498 if you need any clarification.

(b)(4)

Thank you,

Dhanya Williams, M.S.

Biologist/Scientific Reviewer

Center for Devices and Radiological Health (CDRH)

Office of Device Evaluation (ODE)

U.S. Food and Drug Administration

Tel: 301-796-6498

dhanya.williams@fda.hhs.gov



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From: [Anderson, Leigh](#)
To: [Williams, Dhanya K](#)
Cc: [Zheng, Xiaolin](#)
Subject: FW: K173841-A1 - Updated (b)(5)
Date: Wednesday, March 07, 2018 7:23:56 AM
Attachments: (b)(5)
Importance: High

Hi Dhanya,

(b)(5)

Thanks
Leigh

From: Beckmann, Angelica [mailto:angelica.beckmann@stryker.com]
Sent: Tuesday, March 06, 2018 6:04 PM
To: Anderson, Leigh <Leigh.Anderson@fda.hhs.gov>
Cc: Allison, John <John.Allison@stryker.com>; Mateus, Jennifer <Jennifer.Mateus@stryker.com>;
Zheng, Xiaolin <Xiaolin.Zheng@fda.hhs.gov>
Subject: K173841-A1 - Updated (b)(4)
Importance: High

Dear Ms. Anderson,
I hope this e-mail finds you well.

(b)(4)

(b)(4)

I would also like to understand the next steps for the interactive review of K173481.

Kind regards,

Angelica Beckmann

Director Regulatory Affairs

Stryker Neurovascular

47900 Bayside Pkwy

Fremont, CA 94538

510-413-2900 Office

(b)(6) Mobile

angelica.beckmann@stryker.com

Section 014 Proposed Labeling

Attachment 14A – Redline Copy of DFU, (b)(4)

Attachment is individually paginated.

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

(b)(4)

From: [Williams, Dhanya K](#)
To: [Zheng, Xiaolin](#)
Cc: [Williams, Dhanya K](#)
Subject: FW: K173841-S001 - Interactive request #1 rev 2
Date: Thursday, March 08, 2018 11:56:36 PM
Attachments: [K173841-S001 Response to FDA Interactive Request #1 Rev 2.pdf](#)

Hi Lin,

(b)(5)

Thanks,
Dhanya

From: Beckmann, Angelica [<mailto:angelica.beckmann@stryker.com>]
Sent: Thursday, March 08, 2018 11:52 PM
To: Williams, Dhanya K <Dhanya.Kumar@fda.hhs.gov>
Cc: Mateus, Jennifer <Jennifer.Mateus@stryker.com>; K173841@docs.fda.gov; Zheng, Xiaolin <Xiaolin.Zheng@fda.hhs.gov>; Allison, John <John.Allison@stryker.com>
Subject: K173841-S001 - Interactive request #1 rev 2

Dear Ms. Williams,

(b)(4)

Please feel free to call me or send email with any additional requests.

Best regards,

Angelica Beckmann
Director Regulatory Affairs
Stryker Neurovascular
47900 Bayside Pkwy
Fremont, CA 94538
(b)(6) Mobile
angelica.beckmann@stryker.com

From: Williams, Dhanya K
To: Katz, Elizabeth
Subject: FW: Proposal for feedback: (b)(5)
Date: Friday, January 05, 2018 2:45:00 PM
Attachments: image007.png

From: Williams, Dhanya K
Sent: Friday, June 23, 2017 3:27 PM
To: Anderson, Leigh <Leigh.Anderson@fda.hhs.gov>
Cc: Williams, Dhanya K <Dhanya.Kumar@fda.hhs.gov>
Subject: Proposal for feedback: (b)(5)

Hi Leigh,

(b)(5)

Let me know what you think, thanks!

Dhanya Williams, M.S.
Biologist/Scientific Reviewer
Center for Devices and Radiological Health (CDRH)
Office of Device Evaluation (ODE)
U.S. Food and Drug Administration
Tel: 301-796-6498
dhanya.williams@fda.hhs.gov



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From: Anderson, Leigh
Sent: Monday, June 19, 2017 2:23 PM
To: Williams, Dhanya K
Subject: FW: [REDACTED]

(b)(4)

Hi Dhanya,

(b)(5)

(b)(5)

Thanks,
Leigh

From: Anderson, Leigh
Sent: Monday, June 19, 2017 2:01 PM
To: 'Mateus, Jennifer'
Cc: Beckmann, Angelica; Ellis, Kristin (Contractor)
Subject: RE: (b)(4)

Dear Ms. Mateus,

Thanks for your email in follow-up to our teleconference today.

(b)(4)

Regards,

Leigh Anderson

Biomedical Engineer

Neurointerventional Devices Branch (NIDB)

Division of Neurological and Physical Medicine Devices (DNPMD)

Center for Devices and Radiological Health (CDRH)

Office of Device Evaluation (ODE)

U.S. Food and Drug Administration

Tel: 301-796-5613

leigh.anderson@fda.hhs.gov

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NOTE: Please be advised this communication is consistent with 21 CFR 10.85 (k) and constitutes an informal communication. This represents my best judgment at this time but does not constitute an advisory opinion, does not necessarily represent the formal position of FDA, and does not bind or otherwise obligate or commit the agency to the views expressed.

From: Mateus, Jennifer [mailto:Jennifer.Mateus@stryker.com]

Sent: Monday, June 19, 2017 1:28 PM

To: Anderson, Leigh

Cc: Beckmann, Angelica; Ellis, Kristin (Contractor)

Subject: (b)(4)

Dear Ms. Anderson,

(b)(4)

Best regards,

Jennifer Mateus

Senior Director, Regulatory Affairs

47900 Bayside Parkway

Fremont, CA 94538

T: 510-413-2752

C: (b)(6)

jennifer.mateus@stryker.com

From: Williams, Dhanya K
To: Katz, Elizabeth
Subject: FW: (b)(4)
Date: Friday, January 05, 2018 2:46:00 PM

From: Anderson, Leigh
Sent: Thursday, July 06, 2017 8:37 AM
To: Mateus, Jennifer <Jennifer.Mateus@stryker.com>
Cc: Beckmann, Angelica <angelica.beckmann@stryker.com>; Ellis, Kristin (Contractor) <kristin.ellis@stryker.com>; (b)(4) @docs.fda.gov
Subject: RE: (b)(4)

Dear Ms. Mateus,

(b)(4)

Regards,

Leigh Anderson
Biomedical Engineer
Neurointerventional Devices Branch (NIDB)
Division of Neurological and Physical Medicine Devices (DNPMD)
Center for Devices and Radiological Health (CDRH)

Office of Device Evaluation (ODE)
U.S. Food and Drug Administration
Tel: 301-796-5613
leigh.anderson@fda.hhs.gov

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From: Mateus, Jennifer [<mailto:Jennifer.Mateus@stryker.com>]
Sent: Monday, June 19, 2017 2:06 PM
To: Anderson, Leigh
Cc: Beckmann, Angelica; Ellis, Kristin (Contractor)
Subject: Re: (b)(4)

Thank you! Appreciate your support.

Best regards,
Jennifer Mateus

On Jun 19, 2017, at 11:01 AM, Anderson, Leigh <Leigh.Anderson@fda.hhs.gov> wrote:

Dear Ms. Mateus,

Thanks for your email in follow-up to our teleconference today.

(b)(4)

Regards,

Leigh Anderson
Biomedical Engineer
Neurointerventional Devices Branch (NIDB)
Division of Neurological and Physical Medicine Devices (DNPMD)
Center for Devices and Radiological Health (CDRH)

Office of Device Evaluation (ODE)
U.S. Food and Drug Administration
Tel: 301-796-5613
leigh.anderson@fda.hhs.gov

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NOTE: Please be advised this communication is consistent with 21 CFR 10.85 (k) and constitutes an informal communication. This represents my best judgment at this time but does not constitute an advisory opinion, does not necessarily represent the formal position of FDA, and does not bind or otherwise obligate or commit the agency to the views expressed.

From: Mateus, Jennifer [<mailto:Jennifer.Mateus@stryker.com>]
Sent: Monday, June 19, 2017 1:28 PM
To: Anderson, Leigh
Cc: Beckmann, Annelica; Ellis, Kristin (Contractor)
Subject: (b)(4)

Dear Ms. Anderson,

(b)(4)

(b)(4)

Best regards,

Jennifer Mateus

Senior Director, Regulatory Affairs

47900 Bayside Parkway

Fremont, CA 94538

T: 510-413-2752

C: (b)(6)

jennifer.mateus@stryker.com

From: [Williams, Dhanya K](#)
To: [Zheng, Xiaolin](#)
Cc: [Williams, Dhanya K](#)
Subject: K173841 (b)(5)
Date: Thursday, February 08, 2018 2:57:03 PM
Attachments: [image001.png](#)

Hi Lin,

(b)(5)

Thank you,

Dhanya Williams, M.S.
Biologist/Scientific Reviewer
Center for Devices and Radiological Health (CDRH)
Office of Device Evaluation (ODE)
U.S. Food and Drug Administration
Tel: 301-796-6498
dhanya.williams@fda.hhs.gov



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From: Williams, Dhanya K
To: Herrmann, Robert
Subject: Please review updated: (b)(5): K173841 - Engineering consult request
Date: Monday, March 12, 2018 7:01:00 AM
Attachments: [image001.png](#)
K173841-S001 Response to FDA Interactive Request #1 Rev 2.pdf
Importance: High

Hi Robert,

(b)(5)

Thanks,
Dhanya

From: Williams, Dhanya K
Sent: Wednesday, January 03, 2018 4:03 PM
To: Herrmann, Robert <Robert.Herrmann@fda.hhs.gov>
Subject: K173841 - Engineering consult request

Hello Robert,

(b)(5)

(b)(5)

I appreciate your help!!

Thanks,

Dhanya Williams, M.S.
Biologist/Scientific Reviewer
Center for Devices and Radiological Health (CDRH)
Office of Device Evaluation (ODE)
U.S. Food and Drug Administration
Tel: 301-796-6498
dhanya.williams@fda.hhs.gov



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<https://www.research.net/s/cdrhcustomerservice?O=400&D=460&B=461&E=&S=E>

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From: [Zheng, Xiaolin](#)
To: [Williams, Dhanya K](#); [Anderson, Leigh](#)
Subject: RE: K173841-A1 - Updated **(b)(5)**
Date: Wednesday, March 07, 2018 8:03:59 AM

(b)(5)

Thanks,
Lin

From: Williams, Dhanya K
Sent: Wednesday, March 07, 2018 7:33 AM
To: Zheng, Xiaolin <Xiaolin.Zheng@fda.hhs.gov>; Anderson, Leigh <Leigh.Anderson@fda.hhs.gov>
Subject: RE: K173841-A1 - Updated **(b)(5)**

Hello Lin,

(b)(5)

Thanks,
Dhanya

From: Zheng, Xiaolin
Sent: Wednesday, March 07, 2018 7:31 AM
To: Anderson, Leigh <Leigh.Anderson@fda.hhs.gov>; Williams, Dhanya K <Dhanya.Kumar@fda.hhs.gov>
Subject: Re: K173841-A1 - Updated **(b)(5)**

Hi Leigh and Dhanya,

(b)(5)

Lin

From: Anderson, Leigh <Leigh.Anderson@fda.hhs.gov>
Date: March 7, 2018 at 7:23:56 AM EST
To: Williams, Dhanya K <Dhanya.Kumar@fda.hhs.gov>
Cc: Zheng, Xiaolin <Xiaolin.Zheng@fda.hhs.gov>
Subject: FW: K173841-A1 - Updated **(b)(5)**
Importance: High

Hi Dhanya,

(b)(5)

Thanks
Leigh

From: Beckmann, Angelica [<mailto:angelica.beckmann@stryker.com>]

Sent: Tuesday, March 06, 2018 6:04 PM

To: Anderson, Leigh <Leigh.Anderson@fda.hhs.gov>

Cc: Allison, John <John.Allison@stryker.com>; Mateus, Jennifer <Jennifer.Mateus@stryker.com>;
Zheng, Xiaolin <Xiaolin.Zheng@fda.hhs.gov>

Subject: K173841-A1 - Updated (b)(4)

Importance: High

Dear Ms. Anderson,

(b)(4)

(b)(4)

I would also like to understand the next steps for the interactive review of K173481.

Kind regards,

Angelica Beckmann

Director Regulatory Affairs

Stryker Neurovascular

47900 Bayside Pkwy

Fremont, CA 94538

510-413-2900 Office

(b)(6) Mobile

angelica.beckmann@stryker.com

From: Anderson, Leigh
To: Williams, Dhanya K; Zheng, Xiaolin
Subject: RE: K173841-A1 - Updated (b)(5)
Date: Wednesday, March 07, 2018 7:33:53 AM

Hi Dhanya,

(b)(5)

From: Williams, Dhanya K
Sent: Wednesday, March 07, 2018 7:33 AM
To: Zheng, Xiaolin <Xiaolin.Zheng@fda.hhs.gov>; Anderson, Leigh <Leigh.Anderson@fda.hhs.gov>
Subject: RE: K173841-A1 - Updated (b)(5)

Hello Lin,

(b)(5)

Thanks,
Dhanya

From: Zheng, Xiaolin
Sent: Wednesday, March 07, 2018 7:31 AM
To: Anderson, Leigh <Leigh.Anderson@fda.hhs.gov>; Williams, Dhanya K
<Dhanya.Kumar@fda.hhs.gov>
Subject: Re: K173841-A1 - Updated (b)(5)

Hi Leigh and Dhanya,

(b)(5)

Lin

From: Anderson, Leigh <Leigh.Anderson@fda.hhs.gov>

Date: March 7, 2018 at 7:23:56 AM EST

To: Williams, Dhanya K <Dhanya.Kumar@fda.hhs.gov>

Cc: Zheng, Xiaolin <Xiaolin.Zheng@fda.hhs.gov>

Subject: FW: K173841-A1 - Updated (b)(5)

Importance: High

Hi Dhanya,

(b)(5)

Thanks

Leigh

From: Beckmann, Angelica [<mailto:angelica.beckmann@stryker.com>]

Sent: Tuesday, March 06, 2018 6:04 PM

To: Anderson, Leigh <Leigh.Anderson@fda.hhs.gov>

Cc: Allison, John <John.Allison@stryker.com>; Mateus, Jennifer <Jennifer.Mateus@stryker.com>;
Zheng, Xiaolin <Xiaolin.Zheng@fda.hhs.gov>

Subject: K173841-A1 - Updated (b)(4)

Importance: High

Dear Ms. Anderson,

I hope this e-mail finds you well.

(b)(4)

(b)(4)

I would also like to understand the next steps for the interactive review of K173481.

Kind regards,

Angelica Beckmann

Director Regulatory Affairs

Stryker Neurovascular

47900 Bayside Pkwy

Fremont, CA 94538

510-413-2900 Office

(b)(6) Mobile

angelica.beckmann@stryker.com

From: [Zheng, Xiaolin](#)
To: [Williams, Dhanya K](#); [Anderson, Leigh](#)
Subject: RE: K173841-A1 - Updated (b)(5)
Date: Wednesday, March 07, 2018 8:07:51 AM

(b)(5)

-Lin

From: Williams, Dhanya K
Sent: Wednesday, March 07, 2018 8:07 AM
To: Zheng, Xiaolin <Xiaolin.Zheng@fda.hhs.gov>; Anderson, Leigh <Leigh.Anderson@fda.hhs.gov>
Subject: RE: K173841-A1 - Updated (b)(5)

Hi Lin,

(b)(5)

Thanks,
Dhanya

From: Zheng, Xiaolin
Sent: Wednesday, March 07, 2018 8:04 AM
To: Williams, Dhanya K <Dhanya.Kumar@fda.hhs.gov>; Anderson, Leigh <Leigh.Anderson@fda.hhs.gov>
Subject: RE: K173841-A1 - Updated (b)(5)

(b)(5)

Thanks,
Lin

From: Williams, Dhanya K
Sent: Wednesday, March 07, 2018 7:33 AM
To: Zheng, Xiaolin <Xiaolin.Zheng@fda.hhs.gov>; Anderson, Leigh <Leigh.Anderson@fda.hhs.gov>
Subject: RE: K173841-A1 - Updated (b)(5)

Hello Lin,

(b)(5)

Thanks,

Dhanya

From: Zheng, Xiaolin

Sent: Wednesday, March 07, 2018 7:31 AM

To: Anderson, Leigh <Leigh.Anderson@fda.hhs.gov>; Williams, Dhanya K <Dhanya.Kumar@fda.hhs.gov>

Subject: Re: K173841-A1 - Updated (b)(5)

Hi Leigh and Dhanya,

(b)(5)

Lin

From: Anderson, Leigh <Leigh.Anderson@fda.hhs.gov>

Date: March 7, 2018 at 7:23:56 AM EST

To: Williams, Dhanya K <Dhanya.Kumar@fda.hhs.gov>

Cc: Zheng, Xiaolin <Xiaolin.Zheng@fda.hhs.gov>

Subject: FW: K173841-A1 - Updated (b)(5)

Importance: High

Hi Dhanya,

(b)(5)

Thanks

Leigh

From: Beckmann, Angelica [<mailto:angelica.beckmann@stryker.com>]

Sent: Tuesday, March 06, 2018 6:04 PM

To: Anderson, Leigh <Leigh.Anderson@fda.hhs.gov>

Cc: Allison, John <John.Allison@stryker.com>; Mateus, Jennifer <jennifer.Mateus@stryker.com>; Zheng, Xiaolin <Xiaolin.Zheng@fda.hhs.gov>

Subject: K173841-A1 - Updated (b)(4)

Importance: High

Dear Ms. Anderson,
I hope this e-mail finds you well.

(b)(4)

(b)(4)

I would also like to understand the next steps for the interactive review of K173481.

Kind regards,

Angelica Beckmann

Director Regulatory Affairs

Stryker Neurovascular

47900 Bayside Pkwy

Fremont, CA 94538

510-413-2900 Office

(b)(6) Mobile

angelica.beckmann@stryker.com

From: Williams, Dhanya K
To: [Zheng, Xiaolin](#)
Subject: RE: K173841 - Interactive request #1 - Updated (b)(5)
Date: Thursday, March 08, 2018 9:14:00 AM
Attachments: [image003.png](#)

Hi Lin,

(b)(5)

Thanks,
Dhanya

From: Zheng, Xiaolin
Sent: Thursday, March 08, 2018 9:05 AM
To: Williams, Dhanya K <Dhanya.Kumar@fda.hhs.gov>
Subject: RE: K173841 - Interactive request #1 - Updated (b)(5)

Hi Dhanya:

(b)(5)

Thanks,
Lin

From: Williams, Dhanya K
Sent: Thursday, March 08, 2018 6:31 AM
To: Zheng, Xiaolin <Xiaolin.Zheng@fda.hhs.gov>
Cc: Williams, Dhanya K <Dhanya.Kumar@fda.hhs.gov>
Subject: FW: K173841 - Interactive request #1 - Updated (b)(5)

Hi Lin,

(b)(5)

(b)(5)

Thanks,
Dhanya

From: Beckmann, Angelica [<mailto:angelica.beckmann@stryker.com>]

Sent: Wednesday, March 07, 2018 11:41 PM

To: Williams, Dhanya K <Dhanya.Kumar@fda.hhs.gov>

Cc: Allison, John <John.Allison@stryker.com>; Mateus, Jennifer <Jennifer.Mateus@stryker.com>;
K173841@docs.fda.gov; Ellis, Kristin (Contractor) <kristin.ellis@stryker.com>

Subject: RE: K173841 - Interactive request #1 - Updated (b)(4)

Dear Ms. Williams,

(b)(4)

(b)(4)

Best regards,

Angelica Beckmann

Director Regulatory Affairs

Stryker Neurovascular

47900 Bayside Pkwy

Fremont, CA 94538

510-413-2900 Office

(b)(6) Mobile

angelica.beckmann@stryker.com

From: Williams, Dhanya K [<mailto:Dhanya.Kumar@fda.hhs.gov>]

Sent: Wednesday, March 7, 2018 6:02 AM

To: Beckmann, Angelica <angelica.beckmann@stryker.com>

Cc: Allison, John <John.Allison@stryker.com>; Mateus, Jennifer <Jennifer.Mateus@stryker.com>;
K173841@docs.fda.gov; Williams, Dhanya K <Dhanya.Kumar@fda.hhs.gov>

Subject: K173841 - Interactive request #1 - Updated (b)(4)

Hello Ms. Beckmann,

Thank you for your email. As Ms. Anderson noted, I am the lead reviewer for your submission, K173841, and we are still in the process of reviewing your deficiency responses. I will be in touch with you in the next day or two regarding any additional items that need to be addressed as we continue our review, however in the meantime, please address the following:

(b)(4)

(b)(4)

Thank you,

Dhanya Williams, M.S.
Biologist/Scientific Reviewer
Center for Devices and Radiological Health (CDRH)
Office of Device Evaluation (ODE)
U.S. Food and Drug Administration
Tel: 301-796-6498
dhanya.williams@fda.hhs.gov



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From: Anderson, Leigh

Sent: Wednesday, March 07, 2018 7:30 AM

To: 'Beckmann, Angelica' <angelica.beckmann@stryker.com>

Cc: Allison, John <John.Allison@stryker.com>; Mateus, Jennifer <Jennifer.Mateus@stryker.com>; Zheng, Xiaolin <Xiaolin.Zheng@fda.hhs.gov>; Williams, Dhanya K <Dhanya.Kumar@fda.hhs.gov>

Subject: RE: K173841-A1 - Updated [(b)(4)]

Dear Ms. Beckmann,

Thank you for your email.

Ms. Dhanya Williams is the Lead Reviewer for K173841, and I have forwarded the email to her, as well as copied her on this reply. Ms. Williams can assist with questions specific to K173841 and review of the submission.

Regards,

Leigh Anderson

Biomedical Engineer

Neurointerventional Devices Branch (NIDB)

Division of Neurological and Physical Medicine Devices (DNPMD)

Center for Devices and Radiological Health (CDRH)

Office of Device Evaluation (ODE)

U.S. Food and Drug Administration

Tel: 301-796-5613

leigh.anderson@fda.hhs.gov

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From: Beckmann, Angelica [<mailto:angelica.beckmann@stryker.com>]

Sent: Tuesday, March 06, 2018 6:04 PM

To: Anderson, Leigh <Leigh.Anderson@fda.hhs.gov>

Cc: Allison, John <John.Allison@stryker.com>; Mateus, Jennifer <Jennifer.Mateus@stryker.com>; Zheng, Xiaolin <Xiaolin.Zheng@fda.hhs.gov>

Subject: K173841-A1 - Updated (b)(4)

Importance: High

Dear Ms. Anderson,

I hope this e-mail finds you well.

(b)(4)

(b)(4)

I would also like to understand the next steps for the interactive review of K173481.

Kind regards,

Angelica Beckmann

Director Regulatory Affairs

Stryker Neurovascular

47900 Bayside Pkwy

Fremont, CA 94538

510-413-2900 Office

(b)(6) Mobile

angelica.beckmann@stryker.com

From: [Zheng, Xiaolin](#)
To: [Williams, Dhanya K](#)
Subject: RE: K173841 - Interactive request #1 - Updated (b)(5)
Date: Thursday, March 08, 2018 9:04:36 AM
Attachments: [image004.png](#)

Hi Dhanya:

(b)(5)

Thanks,
Lin

From: Williams, Dhanya K
Sent: Thursday, March 08, 2018 6:31 AM
To: Zheng, Xiaolin <Xiaolin.Zheng@fda.hhs.gov>
Cc: Williams, Dhanya K <Dhanya.Kumar@fda.hhs.gov>
Subject: FW: K173841 - Interactive request #1 - Updated (b)(5)

Hi Lin,

(b)(5)

(b)(5)

Thanks,
Dhanya

From: Beckmann, Angelica [<mailto:angelica.beckmann@stryker.com>]

Sent: Wednesday, March 07, 2018 11:41 PM

To: Williams, Dhanya K <Dhanya.Kumar@fda.hhs.gov>

Cc: Allison, John <John.Allison@stryker.com>; Mateus, Jennifer <Jennifer.Mateus@stryker.com>;
K173841@docs.fda.gov; Ellis, Kristin (Contractor) <kristin.ellis@stryker.com>

Subject: RE: K173841 - Interactive request #1 - Updated (b)(4)

Dear Ms. Williams,

(b)(4)

Best regards,

Angelica Beckmann

Director Regulatory Affairs
Stryker Neurovascular
47900 Bayside Pkwy
Fremont, CA 94538
510-413-2900 Office
(b)(6) Mobile
angelica.beckmann@stryker.com

From: Williams, Dhanya K [<mailto:Dhanya.Kumar@fda.hhs.gov>]
Sent: Wednesday, March 7, 2018 6:02 AM
To: Beckmann, Angelica <angelica.beckmann@stryker.com>
Cc: Allison, John <John.Allison@stryker.com>; Mateus, Jennifer <Jennifer.Mateus@stryker.com>;
K173841@docs.fda.gov; Williams, Dhanya K <Dhanya.Kumar@fda.hhs.gov>
Subject: K173841 - Interactive request #1 - Updated (b)(4)

Hello Ms. Beckmann,

Thank you for your email. As Ms. Anderson noted, I am the lead reviewer for your submission, K173841, and we are still in the process of reviewing your deficiency responses. I will be in touch with you in the next day or two regarding any additional items that need to be addressed as we continue our review, however in the meantime, please address the following:

(b)(4)

(b)(4)

Thank you,

Dhanya Williams, M.S.
Biologist/Scientific Reviewer
Center for Devices and Radiological Health (CDRH)
Office of Device Evaluation (ODE)
U.S. Food and Drug Administration
Tel: 301-796-6498
dhanya.williams@fda.hhs.gov



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From: Anderson, Leigh
Sent: Wednesday, March 07, 2018 7:30 AM
To: 'Beckmann, Angelica' <angelica.beckmann@stryker.com>
Cc: Allison, John <John.Allison@stryker.com>; Mateus, Jennifer <Jennifer.Mateus@stryker.com>; Zheng, Xiaolin <Xiaolin.Zheng@fda.hhs.gov>; Williams, Dhanya K <Dhanya.Kumar@fda.hhs.gov>
Subject: RE: K173841-A1 - Updated (b)(4)

Dear Ms. Beckmann,

Thank you for your email.

Ms. Dhanya Williams is the Lead Reviewer for K173841, and I have forwarded the email to her, as well as copied her on this reply. Ms. Williams can assist with questions specific to K173841 and review of the submission.

Regards,

Leigh Anderson
Biomedical Engineer
Neurointerventional Devices Branch (NIDB)
Division of Neurological and Physical Medicine Devices (DNPMD)
Center for Devices and Radiological Health (CDRH)
Office of Device Evaluation (ODE)
U.S. Food and Drug Administration
Tel: 301-796-5613
leigh.anderson@fda.hhs.gov

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From: Beckmann, Angelica [<mailto:angelica.beckmann@stryker.com>]

Sent: Tuesday, March 06, 2018 6:04 PM

To: Anderson, Leigh <Leigh.Anderson@fda.hhs.gov>

Cc: Allison, John <John.Allison@stryker.com>; Mateus, Jennifer <Jennifer.Mateus@stryker.com>; Zheng, Xiaolin <Xiaolin.Zheng@fda.hhs.gov>

Subject: K173841-A1 - Updated (b)(4)

Importance: High

Dear Ms. Anderson,

I hope this e-mail finds you well.

(b)(4)

(b)(4)

I would also like to understand the next steps for the interactive review of K173481.

Kind regards,

Angelica Beckmann

Director Regulatory Affairs

Stryker Neurovascular

47900 Bayside Pkwy

Fremont, CA 94538

510-413-2900 Office

(b)(6) Mobile

angelica.beckmann@stryker.com

From: Zheng, Xiaolin
To: Williams, Dhanya K
Subject: RE: K173841 - Interactive request #1 - Updated (b)(5)
Date: Thursday, March 08, 2018 9:15:32 AM
Attachments: image004.png

(b)(5)

-Lin

From: Williams, Dhanya K
Sent: Thursday, March 08, 2018 9:15 AM
To: Zheng, Xiaolin <Xiaolin.Zheng@fda.hhs.gov>
Subject: RE: K173841 - Interactive request #1 - Updated (b)(5)

Hi Lin,

(b)(5)

Thanks,
Dhanya

From: Zheng, Xiaolin
Sent: Thursday, March 08, 2018 9:05 AM
To: Williams, Dhanya K <Dhanya.Kumar@fda.hhs.gov>
Subject: RE: K173841 - Interactive request #1 - Updated (b)(5)

Hi Dhanya:

(b)(5)

Thanks,
Lin

From: Williams, Dhanya K
Sent: Thursday, March 08, 2018 6:31 AM
To: Zheng, Xiaolin <Xiaolin.Zheng@fda.hhs.gov>
Cc: Williams, Dhanya K <Dhanya.Kumar@fda.hhs.gov>
Subject: FW: K173841 - Interactive request #1 - Updated (b)(5)

Hi Lin,

(b)(5)

Thanks,
Dhanya

From: Beckmann, Angelica [<mailto:angelica.beckmann@stryker.com>]

Sent: Wednesday, March 07, 2018 11:41 PM

To: Williams, Dhanya K <Dhanya.Kumar@fda.hhs.gov>

Cc: Allison, John <John.Allison@stryker.com>; Mateus, Jennifer <Jennifer.Mateus@stryker.com>; K173841@docs.fda.gov; Ellis, Kristin (Contractor) <kristin.ellis@stryker.com>
Subject: RE: K173841 - Interactive request #1 - Updated (b)(4)

Dear Ms. Williams,

(b)(4)

Best regards,

Angelica Beckmann

Director Regulatory Affairs

Stryker Neurovascular

47900 Bayside Pkwy

Fremont, CA 94538

510-413-2900 Office

(b)(6) Mobile

angelica.beckmann@stryker.com

From: Williams, Dhanya K [<mailto:Dhanya.Kumar@fda.hhs.gov>]

Sent: Wednesday, March 7, 2018 6:02 AM

To: Beckmann, Angelica <angelica.beckmann@stryker.com>

Cc: Allison, John <John.Allison@stryker.com>; Mateus, Jennifer <Jennifer.Mateus@stryker.com>; K173841@docs.fda.gov; Williams, Dhanya K <Dhanya.Kumar@fda.hhs.gov>

Subject: K173841 - Interactive request #1 - Updated (b)(4)

Hello Ms. Beckmann,

Thank you for your email. As Ms. Anderson noted, I am the lead reviewer for your submission, K173841, and we are still in the process of reviewing your deficiency responses. I will be in touch with you in the next day or two regarding any additional items that need to be addressed as we continue our review, however in the meantime, please address the following:

(b)(4)

(b)(4)

Thank you,

Dhanya Williams, M.S.
Biologist/Scientific Reviewer
Center for Devices and Radiological Health (CDRH)
Office of Device Evaluation (ODE)
U.S. Food and Drug Administration
Tel: 301-796-6498

dhanya.williams@fda.hhs.gov



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From: Anderson, Leigh

Sent: Wednesday, March 07, 2018 7:30 AM

To: 'Beckmann, Angelica' <angelica.beckmann@stryker.com>

Cc: Allison, John <John.Allison@stryker.com>; Mateus, Jennifer <Jennifer.Mateus@stryker.com>; Zheng, Xiaolin <Xiaolin.Zheng@fda.hhs.gov>; Williams, Dhanya K <Dhanya.Kumar@fda.hhs.gov>

Subject: RE: K173841-A1 - Updated (b)(4)

Dear Ms. Beckmann,

Thank you for your email.

Ms. Dhanya Williams is the Lead Reviewer for K173841, and I have forwarded the email to her, as well as copied her on this reply. Ms. Williams can assist with questions specific to K173841 and review of the submission.

Regards,

Leigh Anderson

Biomedical Engineer

Neurointerventional Devices Branch (NIDB)

Division of Neurological and Physical Medicine Devices (DNPMD)

Center for Devices and Radiological Health (CDRH)

Office of Device Evaluation (ODE)

U.S. Food and Drug Administration

Tel: 301-796-5613

leigh.anderson@fda.hhs.gov

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From: Beckmann, Angelica [<mailto:angelica.beckmann@stryker.com>]

Sent: Tuesday, March 06, 2018 6:04 PM

To: Anderson, Leigh <Leigh.Anderson@fda.hhs.gov>

Cc: Allison, John <John.Allison@stryker.com>; Mateus, Jennifer <Jennifer.Mateus@stryker.com>; Zheng, Xiaolin <Xiaolin.Zheng@fda.hhs.gov>

Subject: K173841-A1 - Updated (b)(4)

Importance: High

Dear Ms. Anderson,

I hope this e-mail finds you well.

(b)(4)

(b)(4)

I would also like to understand the next steps for the interactive review of K173481.

Kind regards,

Angelica Beckmann

Director Regulatory Affairs

Stryker Neurovascular

47900 Bayside Pkwy

Fremont, CA 94538

510-413-2900 Office

(b)(6) Mobile

angelica.beckmann@stryker.com

From: [Herrmann, Robert](#)
To: [Williams, Dhanya K](#)
Subject: RE: K173841 - Interactive request #2 (b)(5)
Date: Tuesday, March 13, 2018 5:08:47 PM
Attachments: [image007.png](#)

Hi Dhanya,

(b)(5)

Robert

From: Williams, Dhanya K
Sent: Tuesday, March 13, 2018 12:17 PM
To: Herrmann, Robert <Robert.Herrmann@fda.hhs.gov>
Cc: Williams, Dhanya K <Dhanya.Kumar@fda.hhs.gov>
Subject: FW: K173841 - Interactive request #2 (b)(5)
Importance: High

Hi Robert,

(b)(5)

Thanks,
Dhanya

From: Beckmann, Angelica [<mailto:angelica.beckmann@stryker.com>]
Sent: Tuesday, March 13, 2018 11:57 AM
To: Williams, Dhanya K <Dhanya.Kumar@fda.hhs.gov>
Cc: K173841@docs.fda.gov
Subject: RE: K173841 - Interactive request #2 - (b)(4)
Importance: High

Dear Ms. Williams,

Thank you for your e-mail.

Enclosed are the responses to FDA's Interactive Request regarding additional information needed.
The requested information is contained within the attached pdf file.

Please feel free to call me or send email with any additional requests.

Best regards,

Angelica Beckmann

Director Regulatory Affairs
Stryker Neurovascular
47900 Bayside Pkwy
Fremont, CA 94538
(b)(6) Mobile
angelica.beckmann@stryker.com

From: Williams, Dhanya K [<mailto:Dhanya.Kumar@fda.hhs.gov>]
Sent: Monday, March 12, 2018 11:24 AM
To: Beckmann, Angelica <angelica.beckmann@stryker.com>
Cc: K173841@docs.fda.gov; Williams, Dhanya K <Dhanya.Kumar@fda.hhs.gov>
Subject: K173841 - Interactive request #2 - (b)(4)
Importance: High

Hello Ms. Beckmann,

We are nearing the completion of our review, however after reviewing your (b)(4) (b)(4) "Response to FDA Interactive Request #1 Rev 2 (002)" that you provided interactively on 3/8/18, we have identified two items that need to be addressed:

(b)(4)

(b)(4)

Please feel free to email me or call me at 301-796-6498 if you need any clarification.

(b)(4)

Thank you,

Dhanya Williams, M.S.
Biologist/Scientific Reviewer
Center for Devices and Radiological Health (CDRH)
Office of Device Evaluation (ODE)
U.S. Food and Drug Administration
Tel: 301-796-6498
dhanya.williams@fda.hhs.gov



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From: Zheng, Xiaolin
To: Williams, Dhanya K
Subject: RE: K173841-S001 - Interactive request #1 rev 2
Date: Friday, March 09, 2018 9:05:25 AM

Hi Dhanya:

(b)(5)

Thanks,
Lin

From: Williams, Dhanya K
Sent: Thursday, March 08, 2018 11:57 PM
To: Zheng, Xiaolin <Xiaolin.Zheng@fda.hhs.gov>
Cc: Williams, Dhanya K <Dhanya.Kumar@fda.hhs.gov>
Subject: FW: K173841-S001 - Interactive request #1 rev 2

Hi Lin,

(b)(5)

Thanks,
Dhanya

From: Beckmann, Angelica [<mailto:angelica.beckmann@stryker.com>]
Sent: Thursday, March 08, 2018 11:52 PM
To: Williams, Dhanya K <Dhanya.Kumar@fda.hhs.gov>
Cc: Mateus, Jennifer <Jennifer.Mateus@stryker.com>; K173841@docs.fda.gov; Zheng, Xiaolin <Xiaolin.Zheng@fda.hhs.gov>; Allison, John <John.Allison@stryker.com>
Subject: K173841-S001 - Interactive request #1 rev 2

Dear Ms. Williams,

(b)(4)

Please feel free to call me or send email with any additional requests.

Best regards,

Angelica Beckmann
Director Regulatory Affairs
Stryker Neurovascular
47900 Bayside Pkwy
Fremont, CA 94538

(b)(6) Mobile

angelica.beckmann@stryker.com

From: [Herrmann, Robert](#)
To: [Williams, Dhanya K](#)
Subject: RE: Please review (b)(5) K173841 - Engineering consult request
Date: Monday, March 12, 2018 11:53:07 AM
Attachments: [K173841.Proceed Interactively.Engineering Consult.Herrmann.pdf](#)
[image008.png](#)

Hi Dhanya,

(b)(5)

Let me know if you have any questions,

Robert

From: Williams, Dhanya K
Sent: Monday, March 12, 2018 7:02 AM
To: Herrmann, Robert <Robert.Herrmann@fda.hhs.gov>
Subject: Please review (b)(5): K173841 - Engineering consult request
Importance: High

Hi Robert,

(b)(5)

Thanks,
Dhanya

From: Williams, Dhanya K
Sent: Wednesday, January 03, 2018 4:03 PM
To: Herrmann, Robert <Robert.Herrmann@fda.hhs.gov>
Subject: K173841 - Engineering consult request

Hello Robert,

(b)(5)

(b)(5)

I appreciate your help!!

Thanks,

Dhanya Williams, M.S.
Biologist/Scientific Reviewer
Center for Devices and Radiological Health (CDRH)
Office of Device Evaluation (ODE)
U.S. Food and Drug Administration
Tel: 301-796-6498
dhanya.williams@fda.hhs.gov



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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration

Memorandum**Engineering Review**

Date:	March 12, 2018
To:	Dhanya Williams, Ph.D. ODE/DNPMD/NIDB
From:	Robert Herrmann, Ph.D., Sr. Reviewer, ODE/DNPMD/NIDB
Reviewer Electronic Signature:	Robert Herrmann -S 2018.03.12 11:48:15 -04'00'
Sponsor:	Angelica Beckmann Director, Regulatory Affairs Stryker 47900 Bayside Parkway Fremont, CA 94538 Tel: (510) 413-2900 angelica.beckmann@stryker.com
Device:	AXS Catalyst Distal Access Catheter
Subject:	K173841

(b)(5)

(b)(5)

(b)(5)

(b)(5)

(b)(5)

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(b)(5)

(b)(5)

(b)(5)

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(b)(5)

(b)(5)

(b)(5)

(b)(5)

(b)(5)

(b)(5)

(b)(5)

(b)(5)

(b)(5)

From: [Fusco, Matthew](#)
To: [Williams, Dhanya K](#)
Subject: RE: Urgent question - UPDATE with full response doc: Follow-up: K173841 - Clinical consult request
Date: Monday, March 12, 2018 6:56:24 PM
Attachments: [image010.png](#)
[image011.png](#)

Dhanya,

(b)(5)

Thanks,

Matt

From: Williams, Dhanya K
Sent: Monday, March 12, 2018 11:49 AM
To: Fusco, Matthew <Matthew.Fusco@fda.hhs.gov>
Cc: Williams, Dhanya K <Dhanya.Kumar@fda.hhs.gov>
Subject: Urgent question - UPDATE with full response doc: Follow-up: K173841 - Clinical consult request
Importance: High

Hi Matt,

(b)(5)

Thanks!
Dhanya
301-633-9090

From: Williams, Dhanya K
Sent: Monday, March 12, 2018 12:29 PM

To: Fusco, Matthew <Matthew.Fusco@fda.hhs.gov>

Cc: Williams, Dhanya K <Dhanya.Kumar@fda.hhs.gov>

Subject: Urgent question: Follow-up: K173841 - Clinical consult request

Importance: High

Hi Matt,

(b)(5)

Thanks!

(b)(5)

(b)(5)

(b)(5)

From: Fusco, Matthew
Sent: Monday, February 19, 2018 5:31 PM
To: Williams, Dhanya K <Dhanya.Kumar@fda.hhs.gov>
Subject: RE: Follow-up: K173841 - Clinical consult request

Dhanya,

(b)(5)

Thanks again for your understanding of the timing issues recently.

Let me know if there are any issues.

Thanks,

Matt

From: Williams, Dhanya K
Sent: Monday, February 5, 2018 9:23 AM
To: Fusco, Matthew <Matthew.Fusco@fda.hhs.gov>
Subject: Follow-up: K173841 - Clinical consult request
Importance: High

Hello Matt,

(b)(5)

Thank you,

Dhanya

From: Williams, Dhanya K
Sent: Wednesday, January 03, 2018 4:04 PM
To: Fusco, Matthew <Matthew.Fusco@fda.hhs.gov>
Subject: K173841 - Clinical consult request

Hello Matt,

(b)(5)

(b)(5)

I appreciate your help!!

Thanks,

Dhanya Williams, M.S.
Biologist/Scientific Reviewer
Center for Devices and Radiological Health (CDRH)
Office of Device Evaluation (ODE)

U.S. Food and Drug Administration

Tel: 301-796-6498

dhanya.williams@fda.hhs.gov



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From: [Williams, Dhanya K](#)
To: [Fusco, Matthew](#)
Cc: [Williams, Dhanya K](#)
Subject: RE: Urgent question - UPDATE with full response doc: Follow-up: K173841 - Clinical consult request
Date: Monday, March 12, 2018 9:11:55 PM
Attachments: [image004.png](#)
[image005.png](#)

(b)(5)

Thanks again!
Dhanya

From: Fusco, Matthew
Sent: Monday, March 12, 2018 6:56 PM
To: Williams, Dhanya K <Dhanya.Kumar@fda.hhs.gov>
Subject: RE: Urgent question - UPDATE with full response doc: Follow-up: K173841 - Clinical consult request

Dhanya,

(b)(5)

I hope that is sufficient, if not or there are other issues please let me know.

Thanks,

Matt

From: Williams, Dhanya K

Sent: Monday, March 12, 2018 11:49 AM

To: Fusco, Matthew <Matthew.Fusco@fda.hhs.gov>

Cc: Williams, Dhanya K <Dhanya.Kumar@fda.hhs.gov>

Subject: Urgent question - UPDATE with full response doc: Follow-up: K173841 - Clinical consult request

Importance: High

Hi Matt,

(b)(5)

Thanks!

Dhanya

301-633-9090

From: Williams, Dhanya K

Sent: Monday, March 12, 2018 12:29 PM

To: Fusco, Matthew <Matthew.Fusco@fda.hhs.gov>

Cc: Williams, Dhanya K <Dhanya.Kumar@fda.hhs.gov>

Subject: Urgent question: Follow-up: K173841 - Clinical consult request

Importance: High

Hi Matt,

(b)(5)

Thanks!

(b)(5)

(b)(5)

(b)(5)

From: Fusco, Matthew
Sent: Monday, February 19, 2018 5:31 PM
To: Williams, Dhanya K <Dhanya.Kumar@fda.hhs.gov>
Subject: RE: Follow-up: K173841 - Clinical consult request

Dhanya,

(b)(5)

Thanks again for your understanding of the timing issues recently.

Let me know if there are any issues.

Thanks,

Matt

From: Williams, Dhanya K
Sent: Monday, February 5, 2018 9:23 AM
To: Fusco, Matthew <Matthew.Fusco@fda.hhs.gov>
Subject: Follow-up: K173841 - Clinical consult request
Importance: High

Hello Matt,

(b)(5)

Thank you,

Dhanya

From: Williams, Dhanya K
Sent: Wednesday, January 03, 2018 4:04 PM
To: Fusco, Matthew <Matthew.Fusco@fda.hhs.gov>
Subject: K173841 - Clinical consult request

Hello Matt,

(b)(5)

(b)(5)

I appreciate your help!!

Thanks,

Dhanya Williams, M.S.
Biologist/Scientific Reviewer
Center for Devices and Radiological Health (CDRH)
Office of Device Evaluation (ODE)

U.S. Food and Drug Administration

Tel: 301-796-6498

dhanya.williams@fda.hhs.gov



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From: Katz, Elizabeth
To: Noonan, Patrick
Cc: Williams, Dhanya K
Subject: RE: animal review for K173841 - (b)(5)
Date: Monday, January 29, 2018 10:07:08 AM
Attachments: image002.png
image008.png
image009.png

(b)(5)

Elizabeth Katz, PhD, DABT

Biologist
FDA, Center for Devices and Radiological Health
Office of Device Evaluation
Respiratory Devices Branch
10903 New Hampshire Avenue, WO66, Rm 2606
Silver Spring, MD 20993
301-796-2495



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From: Katz, Elizabeth
Sent: Monday, January 29, 2018 9:58 AM
To: Noonan, Patrick <Patrick.Noonan@fda.hhs.gov>
Cc: Williams, Dhanya K <Dhanya.Kumar@fda.hhs.gov>
Subject: animal review for K173841 - (b)(5)

Hi Patrick,

(b)(5)

(b)(5)

Best,

Elizabeth Katz, PhD, DABT

Biologist

FDA, Center for Devices and Radiological Health

Office of Device Evaluation

Respiratory Devices Branch

10903 New Hampshire Avenue, WO66, Rm 2606

Silver Spring, MD 20993

301-796-2495



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From: Katz, Elizabeth
To: Williams, Dhanya K
Subject: RE: animal review for K173841 - (b)(5)
Date: Monday, January 29, 2018 10:06:25 AM
Attachments: image002.png
image009.png
image010.png

OK, thank you for your insight.



Elizabeth Katz, PhD, DABT

Biologist
FDA, Center for Devices and Radiological Health
Office of Device Evaluation
Respiratory Devices Branch
10903 New Hampshire Avenue, WO66, Rm 2606
Silver Spring, MD 20993
301-796-2495



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From: Williams, Dhanya K
Sent: Monday, January 29, 2018 10:05 AM
To: Katz, Elizabeth <ELIZABETH.KATZ@fda.hhs.gov>; Noonan, Patrick <Patrick.Noonan@fda.hhs.gov>
Cc: Williams, Dhanya K <Dhanya.Kumar@fda.hhs.gov>
Subject: RE: animal review for K173841 - (b)(5)

Hi Liz,

(b)(5)

Thanks,
Dhanya

From: Katz, Elizabeth
Sent: Monday, January 29, 2018 9:58 AM
To: Noonan, Patrick <Patrick.Noonan@fda.hhs.gov>
Cc: Williams, Dhanya K <Dhanya.Kumar@fda.hhs.gov>

Subject: animal review for K173841 - (b)(5)

Hi Patrick,

(b)(5)

Best,

Elizabeth Katz, PhD, DABT

Biologist

FDA, Center for Devices and Radiological Health

Office of Device Evaluation

Respiratory Devices Branch

10903 New Hampshire Avenue, WO66, Rm 2606

Silver Spring, MD 20993

301-796-2495



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From: [Williams, Dhanya K](#)
To: [Katz, Elizabeth](#); [Noonan, Patrick](#)
Cc: [Williams, Dhanya K](#)
Subject: RE: animal review for K173841 - (b)(5)
Date: Monday, January 29, 2018 10:05:22 AM
Attachments: [image001.png](#)
[image008.png](#)
[image009.png](#)

Hi Liz,

(b)(5)

Thanks,
Dhanya

From: Katz, Elizabeth
Sent: Monday, January 29, 2018 9:58 AM
To: Noonan, Patrick <Patrick.Noonan@fda.hhs.gov>
Cc: Williams, Dhanya K <Dhanya.Kumar@fda.hhs.gov>
Subject: animal review for K173841 - (b)(5)

Hi Patrick,

(b)(5)

(b)(5)

Best,

Elizabeth Katz, PhD, DABT

Biologist

FDA, Center for Devices and Radiological Health

Office of Device Evaluation

Respiratory Devices Branch

10903 New Hampshire Avenue, WO66, Rm 2606

Silver Spring, MD 20993

301-796-2495



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From: Noonan, Patrick
To: Williams, Dhanya K
Subject: RE: animal review for K173841 - (b)(5)
Date: Monday, January 29, 2018 10:44:03 AM
Attachments: image001.png
image002.png
image003.png

(b)(5)

From: Williams, Dhanya K
Sent: Monday, January 29, 2018 10:05 AM
To: Katz, Elizabeth <ELIZABETH.KATZ@fda.hhs.gov>; Noonan, Patrick <Patrick.Noonan@fda.hhs.gov>
Cc: Williams, Dhanya K <Dhanya.Kumar@fda.hhs.gov>
Subject: RE: animal review for K173841 - (b)(5)

Hi Liz,

(b)(5)

Thanks,
Dhanya

From: Katz, Elizabeth
Sent: Monday, January 29, 2018 9:58 AM
To: Noonan, Patrick <Patrick.Noonan@fda.hhs.gov>
Cc: Williams, Dhanya K <Dhanya.Kumar@fda.hhs.gov>
Subject: animal review for K173841 (b)(5)

Hi Patrick,

(b)(5)

(b)(5)

Best,

Elizabeth Katz, PhD, DABT

Biologist

FDA, Center for Devices and Radiological Health

Office of Device Evaluation

Respiratory Devices Branch

10903 New Hampshire Avenue, WO66, Rm 2606

Silver Spring, MD 20993

301-796-2495



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From: Zheng, Xiaolin
To: Anderson, Leigh; Williams, Dhanya K
Subject: Re: K173841-A1 - Updated (b)(5)
Date: Wednesday, March 07, 2018 7:31:27 AM

Hi Leigh and Dhanya,

(b)(5)

Lin

From: Anderson, Leigh <Leigh.Anderson@fda.hhs.gov>
Date: March 7, 2018 at 7:23:56 AM EST
To: Williams, Dhanya K <Dhanya.Kumar@fda.hhs.gov>
Cc: Zheng, Xiaolin <Xiaolin.Zheng@fda.hhs.gov>
Subject: FW: K173841-A1 - Updated (b)(5)
Importance: High

Hi Dhanya,

I received this email from Angelica Beckmann from Stryker last night.

I haven't replied yet, but I can let her know that I've forwarded to the email to you and you are Lead Reviewer for K173841, and CC you in my reply.

Thanks
Leigh

From: Beckmann, Angelica [mailto:angelica.beckmann@stryker.com]
Sent: Tuesday, March 06, 2018 6:04 PM
To: Anderson, Leigh <Leigh.Anderson@fda.hhs.gov>
Cc: Allison, John <John.Allison@stryker.com>; Mateus, Jennifer <Jennifer.Mateus@stryker.com>; Zheng, Xiaolin <Xiaolin.Zheng@fda.hhs.gov>
Subject: K173841-A1 - Updated (b)(4)
Importance: High

Dear Ms. Anderson,
I hope this e-mail finds you well.

(b)(4)

(b)(4)

I would also like to understand the next steps for the interactive review of K173481.

Kind regards,

Angelica Beckmann

Director Regulatory Affairs

Stryker Neurovascular

47900 Bayside Pkwy

Fremont, CA 94538

510-413-2900 Office

(b)(6) Mobile

angelica.beckmann@stryker.com

From: [Williams, Dhanya K](#)
To: [Fusco, Matthew](#)
Cc: [Williams, Dhanya K](#)
Subject: Urgent question - UPDATE with full response doc: Follow-up: K173841 - Clinical consult request
Date: Monday, March 12, 2018 12:49:26 PM
Attachments: [image001.png](#)
[K173841, CLINICAL REVIEW, FUSCO.pdf](#)
[image010.png](#)
(b)(5)
Importance: High

Hi Matt,

(b)(5)

Thanks!
Dhanya
301-633-9090

From: Williams, Dhanya K
Sent: Monday, March 12, 2018 12:29 PM
To: Fusco, Matthew <Matthew.Fusco@fda.hhs.gov>
Cc: Williams, Dhanya K <Dhanya.Kumar@fda.hhs.gov>
Subject: Urgent question: Follow-up: K173841 - Clinical consult request
Importance: High

Hi Matt,

(b)(5)

(b)(5)

(b)(5)

(b)(5)

From: Fusco, Matthew
Sent: Monday, February 19, 2018 5:31 PM
To: Williams, Dhanya K <Dhanya.Kumar@fda.hhs.gov>
Subject: RE: Follow-up: K173841 - Clinical consult request

Dhanya,

(b)(5)

Thanks again for your understanding of the timing issues recently.

Let me know if there are any issues.

Thanks,

Matt

From: Williams, Dhanya K
Sent: Monday, February 5, 2018 9:23 AM
To: Fusco, Matthew <Matthew.Fusco@fda.hhs.gov>
Subject: Follow-up: K173841 - Clinical consult request
Importance: High

Hello Matt,

(b)(5)

(b)(5)

Thank you,

Dhanya

From: Williams, Dhanya K

Sent: Wednesday, January 03, 2018 4:04 PM

To: Fusco, Matthew <Matthew.Fusco@fda.hhs.gov>

Subject: K173841 - Clinical consult request

Hello Matt,

(b)(5)

(b)(5)

I appreciate your help!!

Thanks,

Dhanya Williams, M.S.
Biologist/Scientific Reviewer
Center for Devices and Radiological Health (CDRH)
Office of Device Evaluation (ODE)
U.S. Food and Drug Administration
Tel: 301-796-6498
dhanya.williams@fda.hhs.gov



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on the content of this communication is not authorized. If you have received this document in error, please immediately notify the sender immediately by e-mail or phone.

From: [Williams, Dhanya K](#)
To: [Fusco, Matthew](#)
Cc: [Williams, Dhanya K](#)
Subject: Urgent question: Follow-up: K173841 - Clinical consult request
Date: Monday, March 12, 2018 12:28:51 PM
Attachments: [image001.png](#)
[K173841, CLINICAL REVIEW, FUSCO.pdf](#)
[image010.png](#)
Importance: High

Hi Matt,

(b)(5)

Thanks!

(b)(5)

(b)(5)

(b)(5)

From: Fusco, Matthew
Sent: Monday, February 19, 2018 5:31 PM
To: Williams, Dhanya K <Dhanya.Kumar@fda.hhs.gov>
Subject: RE: Follow-up: K173841 - Clinical consult request

Dhanya,

(b)(5)

Thanks again for your understanding of the timing issues recently.

Let me know if there are any issues.

Thanks,

Matt

From: Williams, Dhanya K
Sent: Monday, February 5, 2018 9:23 AM
To: Fusco, Matthew <Matthew.Fusco@fda.hhs.gov>
Subject: Follow-up: K173841 - Clinical consult request
Importance: High

Hello Matt,

(b)(5)

Thank you,

Dhanya

From: Williams, Dhanya K
Sent: Wednesday, January 03, 2018 4:04 PM
To: Fusco, Matthew <Matthew.Fusco@fda.hhs.gov>
Subject: K173841 - Clinical consult request

Hello Matt,

(b)(5)

(b)(5)

I appreciate your help!!

Thanks,

Dhanya Williams, M.S.
Biologist/Scientific Reviewer
Center for Devices and Radiological Health (CDRH)
Office of Device Evaluation (ODE)

U.S. Food and Drug Administration

Tel: 301-796-6498

dhanya.williams@fda.hhs.gov



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From: Katz, Elizabeth
To: Noonan, Patrick
Cc: Williams, Dhanya K
Subject: animal review for K173841 - (b)(5)
Date: Monday, January 29, 2018 9:58:05 AM
Attachments: image001.png
image002.png
image009.png

Hi Patrick,

(b)(5)

(b)(5)

Best,

Elizabeth Katz, PhD, DABT

Biologist

FDA, Center for Devices and Radiological Health

Office of Device Evaluation

Respiratory Devices Branch

10903 New Hampshire Avenue, WO66, Rm 2606

Silver Spring, MD 20993

301-796-2495



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Hello Ms. Beckmann,

I recently sent you an email responding to your questions, with a couple of additional interactive requests and a time to set up a call later today. It may be possible that our emails crossed each other, but please let me know if you still haven't received it and I can resend.

Thank you,

Dhanya Williams, M.S.
Biologist/Scientific Reviewer
Center for Devices and Radiological Health (CDRH)
Office of Device Evaluation (ODE)
U.S. Food and Drug Administration
Tel: 301-796-6498
dhanya.williams@fda.hhs.gov

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1CE7E DEAA22AA

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From: Beckmann, Angelica [mailto:angelica.beckmann@stryker.com]
Sent: Wednesday, March 07, 2018 9:02 AM
To: Anderson, Leigh <Leigh.Anderson@fda.hhs.gov>
Cc: Allison, John <John.Allison@stryker.com>; Mateus, Jennifer <Jennifer.Mateus@stryker.com>; Zheng, Xiaolin <Xiaolin.Zheng@fda.hhs.gov>; Williams, Dhanya K <Dhanya.Kumar@fda.hhs.gov>
Subject: RE: K173841-A1 - Updated (b)(4)

Ms. Leigh,
Thank you for your e-mail and for taking my call this morning.
As I mentioned during the call, I thought that Ms. Williams was responsible for this review only during the week you were out of the office.

Ms. Williams,

(b)(4)

Best regards,

Angelica Beckmann
Director Regulatory Affairs
Stryker Neurovascular
47900 Bayside Pkwy
Fremont, CA 94538
510-413-2900 Office
(b)(6) Mobile
angelica.beckmann@stryker.com

From: Anderson, Leigh [mailto:Leigh.Anderson@fda.hhs.gov]
Sent: Wednesday, March 7, 2018 4:30 AM
To: Beckmann, Angelica <angelica.beckmann@stryker.com>
Cc: Allison, John <John.Allison@stryker.com>; Mateus, Jennifer <Jennifer.Mateus@stryker.com>; Zheng, Xiaolin <Xiaolin.Zheng@fda.hhs.gov>; Williams, Dhanya K <Dhanya.Kumar@fda.hhs.gov>
Subject: RE: K173841-A1 - Updated (b)(4)

Dear Ms. Beckmann,

Thank you for your email.

Ms. Dhanya Williams is the Lead Reviewer for K173841, and I have forwarded the email to her, as well as copied her on this reply. Ms. Williams can assist with questions specific to K173841 and review of the submission.

Regards,

Leigh Anderson
Biomedical Engineer
Neurointerventional Devices Branch (NIDB)
Division of Neurological and Physical Medicine Devices (DNPMD)
Center for Devices and Radiological Health (CDRH)
Office of Device Evaluation (ODE)
U.S. Food and Drug Administration
Tel: 301-796-5613
leigh.anderson@fda.hhs.gov

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From: Beckmann, Angelica [<mailto:angelica.beckmann@stryker.com>]
Sent: Tuesday, March 06, 2018 6:04 PM
To: Anderson, Leigh <Leigh.Anderson@fda.hhs.gov>
Cc: Allison, John <john.Allison@stryker.com>; Mateus, Jennifer <Jennifer.Mateus@stryker.com>; Zheng, Xiaolin <Xiaolin.Zheng@fda.hhs.gov>
Subject: K173841-A1 - Updated (b)(4)
Importance: High

Dear Ms. Anderson,
I hope this e-mail finds you well.

(b)(4)

I would also like to understand the next steps for the interactive review of K173481.

Kind regards,

Angelica Beckmann
Director Regulatory Affairs
Stryker Neurovascular
47900 Bayside Pkwy
Fremont, CA 94538
510-413-2900 Office
(b)(6) Mobile
angelica.beckmann@stryker.com



Response to Interactive Request for K173841-S001, Traditional 510(k)

AXS Catalyst™ Distal Access Catheter

March 8, 2018

Stryker Neurovascular
47900 Bayside Parkway
Fremont, CA 94538

Stryker Neurovascular

Submission Date:

Response to Interactive Request for K173841-S001, Traditional 510(k)

December 17, 2017

AXS Catalyst Distal Access Catheter

Table of Contents

Section 1	Response to Question #1 from FDA Interactive Request	4
Section 2	Response to Question #2 from FDA Interactive Request	5
Section 3	Response to Question #3 from FDA Interactive Request	6
Section 4	Response to Question #4 from FDA Interactive Request	7

Stryker Neurovascular

Submission Date:

Response to Interactive Request for K173841-S001, Traditional 510(k)

December 17, 2017

AXS Catalyst Distal Access Catheter

List of Appendices

Appendix 1 (b)(4) AXS Catalyst DFU redline

Appendix 2 (b)(4) AXS Catalyst DFU clean

Appendix 3 510(k) Summary

Appendix 4 Indications For Use

Stryker Neurovascular

Response to Interactive Request for K173841-S001, Traditional 510(k)

AXS Catalyst Distal Access Catheter

Submission Date:

December 17, 2017

Section 1 Response to Question #1 from FDA Interactive Request

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Stryker Neurovascular

Submission Date:

Response to Interactive Request for K173841-S001, Traditional 510(k)

December 17, 2017

AXS Catalyst Distal Access Catheter

Appendix 1

(b)(4) AXS Catalyst DFU redline

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Stryker Neurovascular

Response to Interactive Request for K173841-S001, Traditional 510(k)

AXS Catalyst Distal Access Catheter

Submission Date:

December 17, 2017

Appendix 2

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AXS Catalyst DFU clean

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Stryker Neurovascular

Submission Date:

Response to Interactive Request for K173841-S001, Traditional 510(k)

December 17, 2017

AXS Catalyst Distal Access Catheter

Appendix 3
510(k) Summary

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Indications for Use

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Food and Drug Administration
CDRH/ODE/DNPMD/NIDB
WO66 RM2664
10903 New Hampshire Ave
Silver Spring, MD 20993-0002
301-796-6498

Premarket Notification 510(k) Review

Date: March 14, 2018

Reviewer: Dhanya K Williams

Subject: Traditional 510(k)# K173841

Applicant: Stryker

Device Trade Name: AXS Catalyst Distal Access Catheter 058 x 115cm; AXS Catalyst Distal Access Catheter 058 x 132cm; AXS Catalyst Distal Access Catheter 060 x 132cm

Contact Name: Angelica Beckmann

Contact Title: Director, Regulatory Affairs

Correspondent Firm: Stryker

Phone: (510) 413-2900 **Email:** angelica.beckmann@stryker.com

Received Date: December 18, 2017

Due Date: March 18, 2018

Pro Code(s): NRY **Class:** II **Reg #:** 870.1250

Reg Name: Percutaneous Catheter

Pro Code(s): DQY **Class:** II **Reg #:** 870.1250

Reg Name: Percutaneous catheter

Predicate Devices:

Submission #	Pro Code	Device Trade Name	Applicant
K090752	NRY	Penumbra System (penumbra Reperfusion Catheter 054), Model Psc054; (penumbra Separator 054), Model Pss054	Penumbra, Inc.
K151667	DQY	Axs Catalyst Distal Access Catheter 058x115cm, Axs Catalyst Distal Access Catheter 058x132cm, Axs Catalyst Distal Access Catheter 060x132cm	Stryker

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Digital Signature Concurrence Table (Doc ID: 04500.12.14)

This document represents a high-level summary of the Agency's determination on whether the applicant's device is substantially equivalent to a legally marketed predicate device. In determining whether the subject device is substantially equivalent to a predicate device, we carefully considered the relevant regulatory and statutory criteria for Agency decision-making under 21 CFR part 807 and section 513(i) of the Federal Food, Drug and Cosmetic Act (FD&C Act). We considered the burden that may be incurred by the applicant's attempt to follow the premarket notification process. The deficiencies provided in this review, if any, represent the required minimum information necessary to support a substantial equivalence determination. Therefore, we believe that we have considered the least burdensome requirements, under section 513(i)(1)(D) of the FD&C Act, for a 510(k) determination of substantial equivalence.

Reviewer Sign-Off

Dhanya K. Williams -S
2018.03.15 09:49:03 -04'00'

Hello Ms. Beckmann,

Sorry I was unable to respond to your email on Friday but I was out of the office due to an unexpected family matter. By now you should have received notification of the clearance of K173841. We appreciate your quick responses to the additional information that was needed during the review period. Please let me know if you have any questions.

Thank you,

Dhanya Williams, M.S.

Biologist/Scientific Reviewer

Center for Devices and Radiological Health (CDRH)

Office of Device Evaluation (ODE)

U.S. Food and Drug Administration

Tel: 301-796-6498

dhanya.williams@fda.hhs.gov

[cid:image001.png@01D1C57E.DFA022A0]<<http://www.fda.gov/>>

[cid:image002.jpg@01D1C57E.DFA022A0]<<https://www.facebook.com/FDA>>

[cid:image003.jpg@01D1C57E.DFA022A0] <https://twitter.com/US_FDA>

[cid:image004.jpg@01D1C57E.DFA022A0] <<http://www.youtube.com/user/USFoodandDrugAdmin>>

[cid:image005.jpg@01D1C57E.DFA022A0] <<http://www.flickr.com/photos/fdaphotos/>>

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From: Beckmann, Angelica [mailto:angelica.beckmann@stryker.com]

Sent: Friday, March 16, 2018 5:37 PM

To: Williams, Dhanya K <Dhanya.Kumar@fda.hhs.gov>

Subject: K173841

Hi Dhanya,

Sorry for bothering you on a Friday afternoon.

But I would like to know if we should expect to hear from FDA about the clearance today.

I appreciate it if you can let me know.

Best regards

Angelica Beckmann

Director Regulatory Affairs

Stryker Neurovascular

47900 Bayside Pkwy

Fremont, CA 94538

(b)(6)

Mobile

angelica.beckmann@stryker.com<mailto:angelica.beckmann@stryker.com>