November 29, 2019

Stryker Neurovascular
Shivani Patel
Senior Staff Regulatory Affairs Specialist
47900 Bayside Parkway
Fremont, California 94538

Re: K193034
Trade/Device Name: AXS Infinity LS Plus Long Sheath
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: DQY
Dated: October 30, 2019
Received: October 31, 2019

Dear Shivani Patel:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's

requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Xiaolin Zheng, Ph.D.
Director
DHT5A: Division of Neurosurgical,
Neurointerventional
and Neurodiagnostic Devices
OHT5: Office of Neurological
and Physical Medicine Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K193034

Device Name
AXS Infinity LS Plus Long Sheath

Indications for Use *(Describe)*
The AXS Infinity LS Plus Long Sheath is indicated for the introduction of interventional devices into the peripheral, coronary, and neuro vasculature.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary
(K193034)

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 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:	**Shivani Patel** Senior Staff Regulatory Affairs Specialist Phone: 510-413-2772 Email: shivani.patel2@stryker.com

Date Prepared:	November 27, 2019

Device Name and Classification:

Trade/Proprietary Name:	AXS Infinity LS™ Plus Long Sheath
Common Name:	Percutaneous Catheter
Classification Name:	Catheter, Percutaneous
Classification Regulation:	21CFR 870.1250
Class:	Class II
Product Code:	DQY

Legally Marketed Predicate Device:

Table 5-1: Legally Marketed Predicate Device		
Name of Predicate Device	**Name of Manufacturer**	**510(k) Number**
AXS Infinity LS™ Plus Long Sheath	Stryker Neurovascular	K172468

Device Description:

The AXS Infinity LS Plus Long Sheath is a variable stiffness catheter that has a catheter shaft reinforced with a stainless-steel mixed coil design (single wind and cross coil wind). It has a radiopaque Platinum/Iridium marker band on the distal end. The distal 10 cm of the AXS Infinity LS Plus Long Sheath has a hydrophilic coating which reduces the insertion force and allows the catheter to traverse the vasculature more easily. The catheter has a maximum average outer diameter of 0.109", where no point is > 0.112" and a nominal inner diameter of 0.091". It is available in three working lengths: 70 cm, 80 cm, and 90 cm. The AXS Infinity LS Plus Long Sheath has a PTFE-lined lumen. The AXS Infinity LS Plus Long Sheath is inserted at a vascular access point to provide access to the target site and once in place, provides a reinforcing conduit for other intravascular devices. Accessories included with the device are a Tuohy-Borst Hemostasis Valve and a Vessel Dilator. The accessories are identical to those in the previous clearance (**K172468**). The AXS Infinity LS Plus Long Sheath is supplied sterile, non-pyrogenic, and intended for single use only.

Indications for Use

The AXS Infinity LS™ Plus Long Sheath is indicated for the introduction of interventional devices into the peripheral, coronary, and neuro vasculature.

Technological Characteristics and Product Feature Comparison

The AXS Infinity LS Plus Long Sheath is composed of a PTFE inner liner, a reinforcing stainless-steel single and cross-coil wind middle layer, and a polymer jacket outer layer. A polycarbonate Luer hub is bonded onto the proximal end. The device features segmented, progressively softer distal segments with a soft tip, designed to minimize vessel trauma, which contains a radiopaque platinum iridium marker band to provide visualization by fluoroscope. Stryker Neurovascular has demonstrated that the AXS Infinity LS Plus Long Sheath (modified) is substantially equivalent to the Predicate device (**K172468**), based on same or similar materials, same intended use, similar design and the same fundamental operating principles. A comparison of the Subject device with the Predicate device is summarized in **Table 5-2,** below.

Table 5-2: Product Feature Comparison of Subject Device to Predicate Device		
Detail	**Submission Subject Device** AXS Infinity LS Plus Long Sheath	**Predicate Device** AXS Infinity LS Plus Long Sheath
Legal Manufacturer	Stryker Neurovascular	Same
510(k) Number	K193034	K172468
Device Trade Name	AXS Infinity LS Plus Long Sheath	Same
Regulation Number	21 CFR 870.1250	Same
Regulation Name	Percutaneous Catheter	Same
Classification	II	Same
Product Code	DQY	Same
Intended Use/Indication for Use	The AXS Infinity LS Plus Long Sheath is indicated for the introduction of interventional devices into the peripheral, coronary and neuro vasculature.	Same
Components Supplied	Sheath, Vessel Dilator, Hemostasis Valve	Same
Catheter Distal and Mid-Shaft Material	Polyether Block Amide (PEBAX) and Chronoflex	Same
Proximal Shaft Material	Coextrusion of Grilamid (outer layer) and Pebax 55D (inner layer)	Single extrusion of Vestamid
Catheter Shaft Reinforcement	Mixed Coil Winding (Single and cross coil)	Cross-Coil winding
Adhesive	Adhesive with light cure process	Adhesive with humidity cure process
Inner Liner	PTFE	Same
Hub Material	Polycarbonate	Same
Strain Relief	Polyolefin	Same
Lubricious Coating	Harland Hydrophilic Coating	Same
Radiopaque Marker Band	Platinum/Iridium	Same
Packaging	Tyvek/Nylon Pouch, polyethylene support tube,	Same

Table 5-2: Product Feature Comparison of Subject Device to Predicate Device		
Detail	**Submission Subject Device** AXS Infinity LS Plus Long Sheath	**Predicate Device** AXS Infinity LS Plus Long Sheath
	packaging card, SBS Carton	
Sterilization	Ethylene Oxide	Same
Pyrogenicity	Nonpyrogenic	Same
Working Lengths	70, 80, 90 cm	Same
Internal Diameter	0.91 in	Same
Outer Diameter	.109	Same
Accessories	• Tuohy-Borst Hemostasis Valve • Vessel Dilator	Same

Risk Assessment

A Risk Assessment of the AXS Infinity LS Plus Long Sheath with design changes has been conducted in accordance with EN ISO 14971:2012 *Medical devices- Application of risk management to medical devices*. Based on the similarity in design and identical intended use of the AXS Infinity LS Plus Long Sheath, the same risk and risk mitigation activities were applied. There were no changes in functionality. Additionally, a risk analysis was conducted at several points throughout the design process and documented throughout the process in updates to the DHF, and where necessary, updates to risk documentation. An impact assessment was also performed to analyze the effect of the proposed modifications to the existing AXS Infinity LS Plus Long

Sheath. Results of testing are appropriate for determining that the AXS Infinity LS Plus Long Sheath is substantially equivalent to the legally marketed Predicate device.

Summary of Non-Clinical Data

Testing was conducted for the specifications that were impacted by the changes to the AXS Infinity LS Plus Long Sheath: Proximal shaft material (coextrusion); mixed coil winding pattern and pitch; modifications to the wall thickness and lengths of different polymer sections along the catheter shaft; modification to the outer diameter and use of a different adhesive to secure the marker band. Summary descriptions of the testing, which substantiates the safe and effective performance of the subject device and its substantial equivalence to the Predicate device is provided below.

- Biocompatibility
- Design Verification (Benchtop Testing)
- Sterilization
- Design Validation (Simulated-Use Testing)

Biocompatibility

Biocompatibility testing was conducted on the Subject device, the modified AXS Infinity LS Plus Long Sheath. The studies were selected in accordance with ISO 10993-1:2018 guidelines, based on the classification as an External Communication Device used within the circulating blood for a limited (<24 hour) duration. The results of biocompatibility testing are presented below:

Table 5-3: Summary of Biocompatibility Test Results

#	Tests	Acceptance Criteria	Results (Pass/Fail/Other)
1	MEM elution, 48 hr. inc., triplicate L929, 24 hr. ext. (non-implant)	Replicate results from negative and media controls must all receive a in. 2in. reactive grade and replicate positive controls must all receive a 3-4 reactivity grade.	Pass. All test method acceptance criteria were met. No cytotoxicity or cell lysis, Score: 0

Table 5-3: Summary of Biocompatibility Test Results			
#	**Tests**	**Acceptance Criteria**	**Results (Pass/Fail/Other)**
2	Magnusson-Kligman Method, 2 extracts	Replicate results from negative and media controls must all receive a in. 2in. reactive grade and replicate positive controls must all receive a 3-4 reactivity grade	Pass. 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. The test article is classified as a non-sensitizer.
3	Intracutaneous Toxicity (ISO), 2 extracts	The test article extracts must not produce a significantly greater biological reaction than the control.	Pass. The test article (device) sites did not show a significantly greater biological reaction than the sites injected with the control article.
4	Material Mediated Pyrogen	The test article extract must not produce a pyrogenic response.	Pass. The test article (device) is considered non-pyrogenic.
5	Systemic Injection (ISO), 2 extracts	The test article extracts must not produce a significantly greater biological reaction than the control.	Pass. The test article (device) extracts did not cause acute adverse effects under the conditions of this assay.
6	Hemolysis, ASTM Method, indirect contact (human blood)	The negative control must produce a corrected hemolytic index of less than 2%. The positive control must produce a corrected hemolytic index of greater than 5% above the negative control. The hemolytic index of the test article must be rated 0-2 (Non-Hemolytic) when corrected with a negative control.	Pass. The difference between the hemolytic indexes of the test article and the negative control is 0.00 percent for direct contact, and 0.44 for extract; this places the test article in the non-hemolytic range.
7	Hemolysis, ASTM Method, direct contact (human blood)	The concentration of SC5b-9 in the test article should be comparable to the predicate and the negative control.	

Table 5-3: Summary of Biocompatibility Test Results			
#	**Tests**	**Acceptance Criteria**	**Results (Pass/Fail/Other)**
8	Complement Activation, SC5b-9	Clotting times are evaluated using analysis of variance and compared to the clotting time of the negative control. When a predicate product is tested, the results of the test article are compared to predicate values.	Pass. The SCb5-9 results for the test article were statistically similar to the predicate device after 30 minutes exposure and only marginally higher than the predicate device for 60 and 90 minutes exposure. The SCb5-9 results for the test article were statistically similar to the negative control after 30- and 90-minutes exposure and only marginally higher than the negative control following 60 minutes exposure.
9	Partial Thromboplastin Time (PTT), Human Plasma	Clotting times are evaluated using analysis of variance and compared to the clotting time of the negative control. When a predicate product is tested, the results of the test article are compared to predicate values. The positive control should show a significantly shortened clotting time when compared to the negative control. A p value of less than 0.050 demonstrates a statistically significant difference.	Pass. The average clotting time for the test article was compared to the predicate and negative control and was deemed similar when p values of clotting times were compared. Hence, this result is considered acceptable
10	Dog Thrombogenicity	The thrombogenic potential of test article will be comparable or less than the Predicate device.	Pass. The test article thrombogenic potential was less than and comparable to the Predicate device.

Design Verification-Bench Testing

Performance testing was conducted to demonstrate substantial equivalence between the Subject device, AXS Infinity LS Plus Long Sheath (modified), and the currently cleared AXS Infinity LS Plus Long Sheath (Predicate device). The tests were performed using standard test methods and pre-determined acceptance criteria, and all samples passed. Therefore, the data provided herein supports the argument that the AXS Infinity LS Plus Long Sheath has similar performance characteristics as the Predicate device. The packaging and accessories are unchanged from the predicate device and no additional testing was needed. All the testing conducted to demonstrate equivalence is presented in **Table 5-4**, which follows.

Table 5-4: Summary of Design Verification (Bench Testing)

Design Requirement/ Test Name		Acceptance Criteria	Results
7	Tensile Strength	Peak tensile force shall be ≥ 15N at all joints	Pass. Two deviations were identified. The deviations did not impact the outcome of Tensile Strength testing. Refer to the summary of the deviations provided below. In all cases, the 90/95 confidence/reliability was higher than the specification of 15N.
7	PTFE Delamination	PTFE liner shall not delaminate. Any observed delamination within 1 mm of the cut is not considered a failure.	Pass. All samples did not exhibit any PTFE delamination.
7	Torque Strength	Catheter shall withstand at least one 360 degree turn of the hub	Pass. A reliability analysis was completed at 85% reliability and 95% confidence (8.50 turns minimum torque strength).

Table 5-4: Summary of Design Verification (Bench Testing)			
Design Requirement/ Test Name		**Acceptance Criteria**	**Results**
8	Catheter Burst	Product shall not burst below 44 psi	Pass. The minimum catheter burst pressure recorded was 119.7 psi. In addition, the 85%/95% lower bound value at 117.28 psi is greater than the lower specification limit of 44 psi.
10	Leak (Liquid)	No liquid leaking from hub and catheter shaft at 44 psi for 30 second duration	Pass. All units passed the liquid leak test.
10	Leak (Air)	No air shall leak into the catheter assembly during manual aspiration	Pass. All units passed air leakage testing.
11, 12, 17	Catheter Dimensional Testing (ID, OD, and Working Lengths)	The ID of the catheters shall be ≥ 0.090''	Pass. 95% confidence lower bound is 0.0914". which is greater than the lower specification limit of 0.090".
		The average OD of the catheter shall be ≤ 0.110'' over the length of the catheter where no point measured shall be > 0.112'' maximum	Pass. The average OD, the 95% confidence, 90% reliability upper bound is 0.109886" which is less than 0.110". For max OD, the 95% confidence, 90% reliability upper bound is 0.0110" which is less than 0.112" , max OD.
		The catheter working length shall be within 2 cm of nominal	Pass. For catheter working length, the 95% confidence, 90% reliability lower bound is 89.72 cm and the upper bound is 90.23 cm, which is within 2 cm of nominal (90 cm).
13	Chemical Compatibility	Product shall withstand exposure to the following chemicals without degradation: • Saline • Dextrose • Heparin	Pass. All units passed chemical compatibility.

Table 5-4: Summary of Design Verification (Bench Testing)			
Design Requirement/ Test Name		**Acceptance Criteria**	**Results**
		• Contrast	
17	Kink Resistance	The kink resistance shall be: • ≤ 0.215" at the distal most material • ≤ 2" at the proximal most material	Pass. All units passed kink resistance.
17 & 18	Visual Inspection (Transitions and Tip)	The catheter shall have progressively lower durometer moving from proximal end to distal tip with smooth transition points to facilitate navigation through tortuous vascular anatomy. -The catheter's distal tip shall be visibly tapered	Pass. Units were inspected for smooth transitions and rounded tip. All units met the acceptance criteria and passed the transitions and tip visual inspection.

Shelf Life

Performance testing was conducted to demonstrate that the Subject device maintains functionality throughout the 3-year shelf life. The tests were performed using standard test methods and pre-determined acceptance criteria, and all samples passed. Therefore, the data provided herein supports the argument that the AXS Infinity LS Plus Long Sheath has similar performance characteristics as the Predicate device. All the testing conducted to demonstrate equivalence is presented in **Table 5-5**, which follows.

Table 5-5: Summary of 3-Year Accelerated Aging			
Design Requirement/ Test Name		**Acceptance Criteria**	**Results**
7	Tensile Strength	Peak tensile force shall be ≥ 15N at all joints	Pass. All samples had a peak tensile force of less than 15N.
7	PTFE Delamination	PTFE liner shall not delaminate. Any observed delamination within 1 mm of the cut is not considered a failure.	Pass. All samples did not exhibit any PTFE delamination.
7	Torque Strength	Catheter shall withstand at least one 360 degree turn of the hub	Pass. All samples withstood at least one 360 degree turn of the hub.
8	Catheter Burst	Product shall not burst below 44 psi	Pass. All samples had a burst rate greater than the lower specification limit of 44 psi.
10	Leak (Liquid)	No liquid leaking from hub and catheter shaft at 44 psi for 30 second duration	Pass. All units passed the liquid leak test.

Table 5-5: Summary of 3-Year Accelerated Aging			
Design Requirement/ Test Name		**Acceptance Criteria**	**Results**
10	Leak (Air)	No air shall leak into the catheter assembly during manual aspiration	Pass. All units passed air leakage testing.
11, 12, 17	Catheter Dimensional Testing (ID, OD, and Working Lengths)	The ID of the catheters shall be ≥ 0.090''	Pass. The ID of all catheters was greater than the lower specification limit of 0.090".
		The average OD of the catheter shall be ≤ 0.110'' over the length of the catheter where no point measured shall be > 0.112'' maximum	Pass. The average OD of all catheters was less than 0.110". The max OD of all catheters was less than 0.112".
		The catheter working length shall be within 2 cm of nominal	Pass. The working length of all catheters was within 2 cm of nominal.
17	Kink Resistance	The kink resistance shall be: • ≤ 0.215" at the distal most material • ≤ 2" at the proximal most material	Pass. All units passed kink resistance.
17 & 18	Visual Inspection (Transitions and Tip)	The catheter shall have progressively lower durometer moving from proximal end to distal tip with smooth transition points to facilitate navigation through tortuous vascular anatomy. -The catheter's distal tip shall be visibly tapered	Pass. Units were inspected for smooth transitions and rounded tip. All units met the acceptance criteria and passed the transitions and tip visual inspection.

Sterilization

Testing was conducted to assess the impact of the proposed design and process changes on sterilization which included Bioburden, EO Residuals and Pyrogenicity testing. Results confirmed there was no adverse impact due to the proposed changes, Refer to **Table 5-6**, below, for a summary of sterilization testing results.

Table 5-6: Summary of Sterilization Testing Results

Test Name	Acceptance Criteria	Results
EO Residuals Testing	The total EO content of the AXS Infinity LS Plus was no more than 4 mg and the ECH level no more than 9 mg following 12 hours heated aeration for 1X product and 2X product	Pass.
Bioburden Testing	The average corrected bioburden count should be less than 111 CFU/ product unit. The types/groupings of microorganisms present in the bioburden should be similar to those observed with the exiting products.	Pass.
LAL Testing	LAL results were < 2.15 EU/ device (0.06 EU/ml).	Pass.

Design Validation- Simulated-Use Testing

The modified AXS Infinity LS Plus Long Sheath (Subject device) was evaluated through simulated use testing using standard bench top models which included tortuosity of worst-case pathways in which the AXS Infinity LS Plus Long Sheath would traverse. The modified AXS Infinity LS Plus Long sheath met all relevant user needs.

Performance Data- Animal Testing

Animal testing previously conducted for the AXS Infinity LS Plus Long Sheath was used to support the changes to the AXS Infinity LS Plus Long Sheath. Prior to design changes, Simulated Use- Animal Testing was performed to support the previously cleared AXS Infinity LS Plus Long Sheath and can be found in **K172468** (cleared as 091 Long Sheath). Additional testing was not performed because the proposed design changes do not impact the overall safety and efficacy of the device.

Performance Data – Clinical

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

Summary of Substantial Equivalence

Stryker Neurovascular has demonstrated the AXS Infinity LS™ Plus Long Sheath is substantially equivalent to the Predicate device, AXS Infinity LS Plus Long Sheath (**K172468)**, based on same intended use / indications for use, same or similar materials, same fundamental design, and the same operating principles. The conclusions drawn from risk assessments and the bench testing conducted using the Subject device demonstrate that the Subject device is suitable for the indication for use. Additionally, the testing results summarized above along with the risk assessment demonstrate that the benefits of the device outweigh any residual risks when used in accordance with device Instructions for Use.

Stryker Neurovascular has demonstrated that the AXS Infinity LS™ Plus Long Sheath is as safe, as effective, and performs as well as the legally marketed Predicate device.