February 27, 2020

Stryker Neurovascular
Shazia Hakim
Senior Staff Regulatory Affairs Specialist
47900 Bayside Parkway
Fremont, California 94538

Re: K200206
Trade/Device Name: AXS Vecta® Intermediate Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: QJP, DQY
Dated: January 27, 2020
Received: January 28, 2020

Dear Shazia Hakim:

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., M.S.
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)*
K200206

Device Name
AXS Vecta Intermediate Catheter

Indications for Use *(Describe)*
The AXS Vecta Intermediate 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 Vecta Intermediate Catheter is also indicated for use as a conduit for retrieval devices.

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

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

**CONTINUE ON A SEPARATE PAGE IF NEEDED.**

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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# 510(k) Summary

**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<br>47900 Bayside Parkway<br>Fremont, CA 94538-6515<br>(FDA Registration Number: 3008853977) |
| **Contact:** | **Shazia Hakim**<br>Sr. Staff Regulatory Affairs Specialist<br>Phone: 510-413-2636<br>Fax: 510-413-2588<br>Email: shazia.hakim@stryker.com |
| **Date Prepared:** | January 27, 2020 |
| **Trade/Proprietary Name:** | AXS Vecta® Intermediate Catheter |
| **Common Name:** | Percutaneous Catheter |
| **Classification Name:** | Percutaneous Catheter, 21CFR 870.1250 – Class II |
| **Product Code:** | **QJP and** DQY |

## Legally Marketed Predicate Devices

| Name of Predicate Device | Name of Manufacturer | 510(k) Number |
|---|---|---|
| AXS Vecta Intermediate Catheter | Stryker Neurovascular | K190833 |

## Device Description

The AXS Vecta Intermediate Catheter is a single lumen, flexible, variable stiffness catheter. It has a radiopaque marker band on the distal end and a Luer hub at the proximal end. The AXS Vecta Intermediate Catheter shaft has a lubricious hydrophilic coating at the distal end (distal 25cm) to reduce friction during use. It is packaged with one Scout Introducer, one hemostasis valve, and two peel-away introducers.

The Scout Introducer may be used in conjunction with the AXS Vecta Intermediate Catheter to facilitate in the introduction of the AXS Vecta Intermediate Catheter into distal vasculature and aid in navigation to distal anatomy. The Scout Introducer has a lubricious hydrophilic coating at the distal end to reduce friction during use. The inner lumen of the AXS Vecta Intermediate Catheter is compatible with the Scout Introducer, guide wires and microcatheters. The inner lumen of the Scout Introducer is compatible with guide wires and microcatheters of an outer diameter of less than 0.044in.

## Indications for Use

The AXS Vecta Intermediate 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 Vecta Intermediate Catheter is also indicated for use as a conduit for retrieval devices.

**Technological Characteristics and Product Feature Comparison**

Stryker Neurovascular has demonstrated the AXS Vecta® Intermediate Catheter (AXS Vecta® 71 & 74 Intermediate Catheters) is substantially equivalent to the Predicate device, AXS Vecta Intermediate Catheter (**K190833**) and Reference device (**K191768)** based on the same or similar materials, similar design, and the same fundamental operating principles. A comparison of the Subject device with the Predicate and Reference device is summarized in **Table 1**: Product Feature Comparison of Subject Device to Predicate and Reference Device below.

**Table 1. Product Feature Comparison of Subject Device to Predicate and Reference Device**

| Feature | Submission Subject Device | Predicate Device | Reference Device |
|---|---|---|---|
| Manufacturer | Stryker Neurovascular | Stryker Neurovascular | Stryker Neurovascular |
| 510(k) Number | **K200206** | **K190833** | **K191768** |
| Device Trade Name | **AXS Vecta® Intermediate Catheters (AXS Vecta® 71 & 74 Intermediate Catheters)** | **AXS Vecta® Intermediate Catheters (AXS Vecta® 71 & 74 Intermediate Catheters)** | **AXS Vecta® Aspiration System (AXS Vecta® 71 & 74 Aspiration Catheters)** |
| Regulation Number | 21 CFR 870.1250 | Same | Same |
| Regulation Name | Percutaneous Catheter | Same | Same |
| Classification | II | Same | Same |
| Product Code | QJP and DQY | DQY | NRY |
| Intended Use/Indication for Use | The AXS Vecta Intermediate 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 Vecta Intermediate | The AXS Vecta Intermediate 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 Vecta Intermediate | The AXS Vecta Aspiration Catheter, as part of the AXS Vecta Aspiration System is indicated in the revascularization of patients with acute ischemic stroke secondary to intracranial large vessel occlusive disease (within the |

| Feature | Submission Subject Device | Predicate Device | Reference Device |
|---|---|---|---|
| | Catheter is also indicated for use as a conduit for retrieval devices. | Catheter is also indicated for use as a conduit for retrieval devices. | 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. |
| Device Description | The AXS Vecta Intermediate Catheter is advanced into the neurovasculature by a physician trained interventional endovascular procedures using a compatible sheath or guide catheter, and over the appropriately sized microcatheter, guide wire, and/or the Scout Introducer. Two peel away introducer sheaths are provided in the package to provide support and facilitate the introduction of the AXS Vecta Intermediate Catheter tip into the sheath/guide catheter valve. Once the assembly is inserted, the peel-away introducer sheath can be removed. Under fluoroscopic guidance, | The AXS Vecta Intermediate Catheter is advanced into the neurovasculature by a physician trained interventional endovascular procedures using a compatible sheath or guide catheter, and over the appropriately sized microcatheter, guide wire, and/or the Scout Introducer. Two peel away introducer sheaths are provided in the package to provide support and facilitate the introduction of the AXS Vecta Intermediate Catheter tip into the sheath/guide catheter valve. Once the assembly is inserted, the peel-away introducer sheath can be removed. Under fluoroscopic guidance, | The AXS Vecta Aspiration Catheter is advanced into the neurovasculature by a physician trained in interventional endovascular procedures using a compatible sheath or guide catheter, and over an appropriately sized microcatheter, guide wire, and/or the Scout Introducer. Two peel-away introducer sheaths are provided in the package to provide support and facilitate the introduction of the AXS Vecta Aspiration Catheter tip into the sheath/guide catheter valve. Once the assembly is inserted, the peelaway introducer sheath can be removed. Under fluoroscopic |

| Feature | Submission Subject Device | Predicate Device | Reference Device |
|---|---|---|---|
| | the assembly can be advanced through the vasculature to the desired location. | the assembly can be advanced through the vasculature to the desired location. | guidance, the assembly can be advanced through the vasculature to the intended vascular site, with the distal end of the AXS Vecta Aspiration Catheter positioned proximal to the clot. The proximal end of the AXS Universal Aspiration Tubing is connected to the AXS Universal Liner Set. The AXS Universal Liner Set is connected to the Medela Dominant Flex Pump, and the Medela Dominant Flex Pump is turned ON. All devices inside of the AXS Vecta Aspiration Catheter are removed. The distal end of the AXS Universal Aspiration Tubing is attached to the proximal end of the AXS Vecta Aspiration Catheter. To start aspiration, the aspiration tubing clamp on the AXS Universal Aspiration Tubing is opened, and the clot is engaged with the AXS Vecta Aspiration Catheter. |
| Accessory Devices Provided (not in direct contact with patient) | Hemostasis Valve, 2 Peel-Away Introducers Scout Introducer | Same | Same |

| Feature | Submission Subject Device | Predicate Device | Reference Device |
|---|---|---|---|
| Outer Jacket | Polymeric catheter | Same | Same |
| Proximal Shaft | Vestamid/Pebax | Vestamid | Same as Subject device |
| Reinforcement | Stainless Steel/Nitinol | Same materials, but different wind pattern) | Same as Subject device |
| Strain Relief | Polyolefin | Same | Same |
| Inner Layer | PTFE | Same | Same |
| Catheter Hub | Nylon | Same | Same |
| Marker Band | Platinum/Iridium | Same | Same |
| Adhesive | Dymax | Cyanoacrylate | Same as Subject device |
| Outer Jacket Coating | Hydrophilic Coating | Same | Same |
| Labeled Shaft Outer Diameter | Distal OD:<br>Vecta 71: 0.082 in.<br>Vecta 74: 0.083 in.<br><br>Proximal OD:<br>Vecta 71: 0.085 in.<br>Vecta 74: 0.087 in. | Distal OD:<br>Same<br><br>Proximal OD:<br>Same | Distal OD:<br>Same<br><br>Proximal OD:<br>Same |
| Effective Lengths | 115, 125, 132 cm | Same | Same |
| Distal ID | 0.071 in.<br>0.074 in. | Same | Same |
| Proximal ID | 0.071 in.<br>0.074 in. | Same | Same |
| Packaging Materials and Configuration | Tyvek/Nylon Pouch, polyethylene support tube, packaging card, SBS carton | Same | Same |
| Sterilization Method | EO Sterilization | Same | Same |
| How Supplied | Single Use/Sterile | Same | Same |
| Principles of Operation | The AXS Vecta Intermediate Catheter is advanced into the neurovasculature by a physician trained in interventional endovascular procedures using a compatible sheath or | The AXS Vecta Intermediate Catheter is advanced into the neurovasculature by a physician trained in interventional endovascular procedures using a compatible sheath or | The AXS Vecta Aspiration Catheter is advanced into the neurovasculature by a physician trained in interventional endovascular procedures using a compatible sheath or |

| Feature | Submission Subject Device | Predicate Device | Reference Device |
|---|---|---|---|
| | guide catheter, and over an appropriately sized microcatheter, guide wire, and/or the Scout Introducer. Two peel-away introducer sheaths are provided in the package to provide support and facilitate the introduction of the AXS Vecta Intermediate Catheter tip and the Scout Introducer into the sheath/guide catheter valve. Once the assembly is inserted, the peel-away introducer can be removed. Under fluoroscopic guidance, the assembly can be advanced through the vasculature to the desired location. | guide catheter, and over an appropriately sized microcatheter, guide wire, and/or the Scout Introducer. Two peel-away introducer sheaths are provided in the package to provide support and facilitate the introduction of the AXS Vecta Intermediate Catheter tip and the Scout Introducer into the sheath/guide catheter valve. Once the assembly is inserted, the peel-away introducer can be removed. Under fluoroscopic guidance, the assembly can be advanced through the vasculature to the desired location. | guide catheter, and over an appropriately sized microcatheter, guide wire, and/or the Scout Introducer. Two peel-away introducer sheaths are provided in the package to provide support and facilitate the introduction of the AXS Vecta Aspiration Catheter tip into the sheath/guide catheter valve. Once the assembly is inserted, the peelaway introducer sheath can be removed. Under fluoroscopic guidance, the assembly can be advanced through the vasculature to the intended vascular site, with the distal end of the AXS Vecta Aspiration Catheter positioned proximal to the clot. The proximal end of the AXS Universal Aspiration Tubing is connected to the AXS Universal Liner Set. The AXS Universal Liner Set is connected to the Medela Dominant Flex Pump, and the Medela Dominant Flex Pump is turned ON. All devices inside of the AXS |

| Feature | Submission Subject Device | Predicate Device | Reference Device |
|---|---|---|---|
| | | | Vecta Aspiration Catheter are removed. The distal end of the AXS Universal Aspiration Tubing is attached to the proximal end of the AXS Vecta Aspiration Catheter. To start aspiration, the aspiration tubing clamp on the AXS Universal Aspiration Tubing is opened, and the clot is engaged with the AXS Vecta Aspiration Catheter. |
| Patient Contacting Components | AXS Vecta Intermediate Catheter and its Accessories | Same | Same |

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

**Design Verification – Bench Testing**

To demonstrate substantial equivalence between the Subject device, AXS Vecta Intermediate Catheter with proposed design changes and the currently cleared AXS Vecta Intermediate Catheter (Predicate device), performance testing was conducted. The tests were performed using standard test methods and pre-determined acceptance criteria and all samples passed. Therefore, this test data supports the argument that the AXS Vecta Intermediate Catheter has similar performance characteristics as the predicate device. All the testing conducted to demonstrate substantial equivalence are presented in **Table 2**: Performance Testing Summary below.

**Table 2. Performance Testing Summary**

| Test Method Summary | Conclusion |
|---|---|
| Visual Inspection (Packaging: Pouch Visual) | All units met the acceptance criteria and passed Packaging Visual Inspection |
| Visual Inspection (Packaging: Undamaged Product) | All units met the acceptance criteria and passed Packaging Visual Inspection |
| Tensile Strength | All units met the acceptance criteria and passed Tensile Strength testing. |
| PTFE Delamination | All units met the acceptance criteria and passed PTFE Delamination testing |
| Torque Strength | All samples met acceptance criteria and passed Torque Strength testing. |
| Catheter Burst | All samples met acceptance criteria and passed Catheter Burst testing |
| Leak (Liquid) | All samples met acceptance criteria and passed the Air and Liquid Leakage testing. |
| Leak | |
| Dimensional (ID, OD, & Working Length) | All samples met acceptance criteria and passed Dimensional testing. |
| Kink Reistance | All samples met acceptance criteria and passed Kink Resistance testing. |
| Visual Inspection (Transition & Tip) | All samples met acceptance criteria and passed both the transition and tip visual inspections. |
| Tip Flexibility | All samples met acceptance criteria and passed Tip Flexibility testing. |
| Friction Force | All samples met acceptance criteria and passed Friction Force testing. |

## Design Validation – Simulated-Use Testing

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

**Performance Data – Animal, Clinical**

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

**Shelf Life Testing**

Shelf life testing previously conducted for the AXS Vecta Aspiration System was used to support the changes to AXS Vecta Intermediate Catheters and can be found in **K172167** and **K181354**. Shelf life testing was not performed since it was determined that there is no impact on material degradation and the design changes do not impact the overall efficacy and safety of the device.

**Sterilization**

The subject device is sterilized by 100% EtO and has been adopted into a validated sterilization process in accordance with the principles of AAMI TIR 28:2016 *Product Adoption & Process Equivalence for Ethylene Oxide Sterilization* and per the requirements of ISO 11135:2014 *Sterilization of health-care products – Ethylene oxide – Requirements for the development, validation and routine control of a sterilization process for medical devices.*

**Biocompatibility**

Biocompatibility testing previously conducted for the AXS Vecta Aspiration System was used to support the changes to AXS Vecta Intermediate Catheters and can be found in **K172167** and **K181354**. Additionally, though no biological risks were identified, confirmatory tests (cytotoxicity, sensitization and irritation) were conducted to confirm that there is no impact on existing biocompatibility study. Based on the testing results, the AXS Vecta Intermediate Catheters with the design change is free from biological hazard per ISO 10993-1.

**Summary of Substantial Equivalence**

Based on the conclusions drawn from risk assessment and the bench testing results summarized above, the Subject device demonstrates substantial equivalence to the legally marketed Predicate device (**K190833**).