December 22, 2023

Shanghai HeartCare Medical Technology Co., Ltd.
% Diana Hong
General Manager
Mid-Link Consulting Co., Ltd.
P.O. Box 120-119
Shanghai, 200120
China

Re: K233205
Trade/Device Name: Distal Access Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: QJP, DQY
Dated: September 25, 2023
Received: September 28, 2023

Dear Diana Hong:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Naira Muradyan -S

Naira Muradyan, Ph.D.
Assistant Director
DHT5A: Division of Neurosurgical,
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Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K233205

Device Name
Distal Access Catheter

Indications for Use *(Describe)*
The 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 Distal Access Catheter is also indicated for use as a conduit for retrieval devices.

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

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

CONTINUE ON A SEPARATE PAGE IF NEEDED.

510(k) Summary

This 510(k) Summary is being submitted in accordance with requirements of 21 CFR 807.92.

510(k) Number: K233205

Date of Preparation: 12/19/2023

1. Sponsor Identification

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2. Designated Submission Correspondent

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3. Identification of Proposed Device

Trade Name: Distal Access Catheter

Common Name: Percutaneous Catheter

Regulatory Information

Primary Product Code: QJP

Classification Name: Catheter, Percutaneous, Neurovasculature

Classification: II

Regulation Number: 21 CFR 870.1250

Review Panel: Neurology

Secondary Product Code: DQY
Classification Name: Catheter, Percutaneous

Classification: II
Regulation Number: 21 CFR 870.1250
Review Panel: Cardiovascular

4. Identification of Predicate and Reference Devices

Predicate Device: K151667
Device Name: AXS Catalyst™ Distal Access Catheter

Reference Device: K183463
Device Name: AXS Catalyst Distal Access Catheter (AXS Catalyst 7)

5. Device Description

The Distal Access Catheter is a sterile, single lumen, variable stiffness catheter designed for use in facilitating the insertion and guidance of appropriately sized interventional devices into a selected blood vessel in the peripheral and neurovascular systems. The catheter comes in Straight (with no shaping of the catheter tip) and Curved (curved catheter tip) models based on the shape of the distal end. The catheter shaft has a hydrophilic coating on the distal end of the shaft 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.

6. Indications for Use

The 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 Distal Access Catheter is also indicated for use as a conduit for retrieval devices.

7. Comparison of Technological Characteristics

Table 1: Comparison of Technological Characteristics

ITEM	Subject Device K233205 Distal Access Catheter	Predicate Device K151667 AXS Catalyst™ Distal Access Catheter	Reference Device K183463 AXS Catalyst Distal Access Catheter (AXS Catalyst 7)	Remark
Classification	II	II	II	Same
Regulation No.	21 CFR 870.1250	21 CFR 870.1250	21 CFR 870.1250	Same
Code	QJP, DQY	DQY	DQY	Same
Indication for Use	The 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 Distal Access Catheter is also indicated for use as a conduit for retrieval devices.	The AXS Catalyst Distal Access Catheter is indicated for use in facilitating the insertion and guidance of appropriately sized interventional devices into a selected blood vessel in the peripheral and neurovascular systems. The AXS Catalyst Distal Access Catheter is also indicated for use as a conduit for retrieval devices.	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.	Same
Inner Diameter (ID)	0.058 inch; 0.071 inch	0.058 inch; 0.060 inch	0.068 inch	Similar
Outer Diameter (OD)	5.4F (0.071 inch); 6.3F (0.083 inch)	Distal: 5.3F (0.069 inch); 5.4F (0.071 inch) Proximal: 5.6F (0.073 inch); 6F (0.079 ”)	Distal: 6.2F (0.082 inch) Proximal: 6.3F (0.0825 inch)	Similar
Effective Length	95 cm; 105 cm; 115 cm; 125 cm; 130 cm	115 cm; 132 cm	115 cm; 125 cm; 132 cm	Similar
Radiopaque Marker	Yes	Yes	Yes	Same
Single Use	Yes	Yes	Yes	Same
Accessories	None	Rotating Hemostasis Valve (RHV) Tuohy Borst valve with sideport Two peel away introducer sheaths	RHV Tuohy Borst valve with sideport Peel away introducer sheath	N/A
Maximum Guidewire OD	0.035 inch	0.038 inch	0.038 inch	Similar

Materials				
Shaft (Outer Surface)	Pebax; Nylon; Thermoplastic Urethanes (TPU)	Pebax; Nylon; Tecoflex	Pebax; Nylon; Tecoflex	The differences do not raise new questions of safety or effectiveness. The subject device has been evaluated through bench and biocompatibility testing.
Shaft (Metal Braid)	Nickel-Titanium alloy	Stainless steel, Nitinol wire, and polymer fiber	Nitinol wire and polymer fiber	
Shaft (Inner Lumen)	Polytetrafluoroethylene (PTFE)	PTFE	PTFE	
Hydrophilic Coating	Polyvinylpyrrolidone (PVP)	Hydrophilic coating	Hydrophilic coating	
Marker	Platinum-Tungsten alloy	Platinum/Iridium	Platinum/Iridium	
Hub	Polycarbonate (PC)	Nylon	Nylon	
Heat Shrink Tube and Stainless Steel Diffusion Tube	Polyolefin and 304 Stainless Steel	Thermoplastic rubber (Santoprene)	Thermoplastic rubber (Polyolefin)	
Sterilization				
Method	Ethylene Oxide (EO) sterilized	EO sterilized	EO sterilized	Same
Sterility Assurance Level (SAL)	10^{-6}	10^{-6}	10^{-6}	Same

8. Non-Clinical Performance Testing

The results of verification and validation testing conducted on the Distal Access Catheter demonstrate that it performs as designed and is substantially equivalent to the predicate. A summary of the tests performed is provided in the table below:

Test	Test Method / Applicable Standard	Test Results
Dimensional Verification	Verify dimensions using specified measurement tool.	Pass
Tip Configuration	Visually inspect distal tip at 10x magnification.	Pass
Surface Integrity	Inspect catheter surface. ISO 10555-1:2013	Pass
Tip Buckling	Use a testing apparatus to measure the maximum force required to cause a test sample to buckle at 5 mm, 10 mm and 20 mm from distal tip.	Pass
Luer Connector Tests	ISO 80369-7: 2021	Pass
Flexural Fatigue	After ten runs of the Distal Access Catheter with the accessories in the simulated use model, remove the test sample and inspect the sample for kinks or damage.	Pass
Trackability	Test the peak tracking force and the compatibility with the ancillary devices during insertion and retraction of the catheter in the simulated use model.	Pass
Catheter Lubricity and Durability	Use friction tester to measure the frictional force of the test samples when pulled between two clamped pads. Record the peak frictional force over 5 cycles.	Pass
Particulate and Coating Integrity Test	Measure the size and number of particulates generated during simulated use and conduct visual inspection at 50x and 200x magnification of the outer surface of the catheter after simulated use.	Pass
Tensile Strength Test	ISO 10555-1:2013	Pass
Air Leakage	ISO 10555-1:2013	Pass
Liquid Leakage	ISO 10555-1:2013	Pass
Torque Resistance	Fix the distal tip of the Distal Access Catheter and rotate the proximal end until the Distal Access Catheter shows kink or other signs of failure.	Pass
Kink Resistance Test	Visually inspect whether the Distal Access Catheter kinks or not when wrapped around mandrels with diameters 1 mm to 10 mm (in 1 mm increments).	Pass
Catheter Tip and Lumen Integrity	After simulated use, aspirate test sample for 10 sec using a 60 cc syringe during retrieval device withdrawal. Visually inspect the test sample to verify absence of tip or lumen collapse.	Pass

Corrosion Resistance Test	ISO 10555-1:2013	Pass
Tip Flexibility Test	Use a mechanical force meter to push the tip from left to right at 5 mm, 10 mm, and 20 mm from the distal tip.	Pass
Radiopacity	ASTM F640-12	Pass
Static Burst Pressure	ISO 10555-1:2013	Pass
Compatibility Test	The compatibility of the Distal Access Catheter with a marketed introducer sheath, guide catheter, guidewire, micro guidewire, microcatheter, and stent-retriever is evaluated.	Pass
Flow Rate	Use a flow rate tester to measure the flow rate of the Distal Access Catheter.	Pass

Biocompatibility

The Distal Access Catheter is categorized as Externally Communicating Device, Limited Contact (≤ 24 hours) with Circulating Blood, per ISO 10993-1, the following tests were conducted:

Test	**Standard Utilized / Section**	**Method**	**Acceptance Criteria**	**Test Results (Pass/Fail)**
Cytotoxicity	ISO 10993-5: 2009	MTT Method	Viability > 70%	Pass
Skin Sensitization	ISO 10993-10: 2010	Guinea Pig Maximization Test (GPMT)	Magnusson & Kligman grades < 1	Pass
Intracutaneous Reactivity Test	ISO 10993-10: 2010	Intracutaneous Reactivity Study (Dermal)	Score ≤ 1.0	Pass
Acute Toxicity	ISO 10993-11: 2017	Acute Toxicity in Mice	No acute toxicity	Pass
Rabbit Pyrogen	ISO 10993-11: 2017	Rabbit Pyrogen Study, Material Mediated	None of the animals showed a significantly greater reaction than the corresponding control animals.	Pass
Complement Activation	ISO 10993-4: 2017	In Vivo Thromboresistance Study in the Dog NAVI Mode	The thrombus formation score shall not be higher than control.	Pass
In Vivo Thromboresistance	ISO 10993-4: 2017	In Vivo Thromboresistance Study in the Dog NAVI Mode	The thrombus formation score shall not be higher than control.	Pass
ASTM Hemolysis	ASTM F756-2017	ASTM Hemolysis Study Direct Contact and Indirect Contact	Hemolytic Index 0 - < 2% Non-Hemolytic	Pass
Bacterial Reverse Mutation	ISO 10993-3: 2014	Bacterial Reverse Mutation Test	No mutation effects	Pass
In Vitro Mammalian Cell Mutation	ISO 10993-3: 2014	Thymidine Kinase Gene	No mutation effect	Pass
Partial Thromboplastin Time Study	ISO 10993-4: 2017 ASTM F2382-2018	Partial Thromboplastin Time Study	No statistically significant difference between test article and control article or the negative reference control.	Pass

Sterilization and Shelf Life

The Distal Access Catheter sterilization process using Ethylene Oxide (EO) has been validated in accordance with ISO 11135:2014 to achieve a sterility assurance level (SAL) of 10^{-6}. EO and Ethylene

Chlorohydrin (ECH) residuals were below the limits specified in ISO 10993-7:2008. Bacterial Endotoxin Levels were below the level of 2.15 EU/device in accordance with USP <85>. Both baseline and accelerated shelf-life testing were conducted demonstrating the device will perform as intended to support the proposed 2-year shelf-life.

9. Clinical Performance Testing

No clinical studies were necessary to demonstrate substantial equivalence.

10. Conclusion

The subject device, Distal Access Catheter, has similar technological characteristics and the same intended use as the predicate device, AXS Catalyst Distal Access Catheter (K151667). The differences in technological characteristics do not raise new or different questions of safety or effectiveness. The successful completion of bench performance, biocompatibility, and sterility testing demonstrates that the subject device performs as intended and is substantially equivalent to the predicate.