January 19, 2024

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

Re: K231218
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: December 21, 2023
Received: December 22, 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.
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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)*
K231218

Device Name
Distal Access Catheter

Indications for Use *(Describe)*
The Distal Access Catheter is indicated for the introduction of interventional devices into the peripheral and neurovasculature.

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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K231218 510(k) Summary

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

1. Date of Preparation: 01/19/2024

2. Sponsor Identification

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3. Designated Submission Correspondent

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4. Identification of Proposed Device

Trade Name: Distal Access Catheter
Common Name: Percutaneous Catheter

Regulatory Information
Classification Name: Catheter, Percutaneous, Neurovasculature
Classification: II
Primary Product Code: QJP
Regulation Number: 21 CFR 870.1250
Review Panel: Neurology

Classification Name: Catheter, Percutaneous
Classification: II
Secondary Product Code: DQY

Regulation Number: 21 CFR 870.1250
Review Panel: Cardiovascular

5. Indications for Use

The Distal Access Catheter is indicated for the introduction of interventional devices into the peripheral and neurovasculature.

6. Device Description

The Distal Access Catheter is a single lumen, flexible, variable stiffness composite catheter which has a luer hub on the proximal end. The catheter shaft has a hydrophilic coating to reduce friction during use. The Distal Access Catheter has a radiopaque marker on the distal tip that is visible under fluoroscopy. The Distal Access Catheter inner lumen can accommodate guidewires up to 0.038 inches in diameter to aid in placement of the catheter system. The catheter has a straight tip. The catheter is offered in various lengths to accommodate physician preferences and anatomical variations. The catheter is provided sterile, nonpyrogenic, and is intended for single use only.

7. Identification of the Predicate Device

510(k) Number: K161152
Device Name: Navien™ Intracranial Support Catheter

8. Comparison of Technological Characteristics

Item		Subject Device (K231218) Distal Access Catheter	Predicate Device (K161152) Navien Intracranial Support Catheter
Classification		II	II
Product Code		QJP, DQY	DQY
Regulation Number		21 CFR 870.1250	21 CFR 870.1250
Indications for Use		The Distal Access Catheter is indicated for the introduction of interventional devices into the peripheral and neurovasculature.	The Navien™ Intracranial Support Catheter is indicated for the introduction of interventional devices into the peripheral and neurovasculature.
Accessories		Shaping Mandrel Two Peelable Introducer Sheaths	None
Distal Inner Diameter (ID)		1.80 mm (0.071")	0.046" – 0.072"
Distal Outer Diameter (OD)		2.13 mm (0.084")	0.058"– 0.084" max
Proximal ID		1.80 mm (0.071")	0.046" – 0.072"
Proximal OD		2.13 mm (0.084")	0.058"– 0.084" max
Effective Length		90 - 138 cm	90 - 130 cm
Maximum Guidewire OD		0.038 inch	0.038 inch
Radiopaque Marker		Yes	Yes
Tip Configuration		Single, straight flexible tip	Single, straight flexible tip
Coating		Hydrophilic coating	Hydrophilic coating
Single Use		Yes	Yes
Sterilization		Ethylene oxide	Ethylene oxide
Sterility Assurance Level		10^{-6}	10^{-6}
Packaging		Catheter in packaging coil attached to packaging card inside PET/ LDPE/ Tyvek pouch inside white card carton.	Catheter in polyethylene hoop attached to packaging card inside PET/PE/Tyvek pouch inside SBS carton.
Shelf-Life		1 year	2 years
Materials:			
Catheter Shaft	Outer Layer	TPU, Pebax, Polyamide	PTFE lined polymeric catheter. Catheter shaft support - Nitinol.
	Inner Layer	PTFE	
Hub		Polyamide	Unknown
Shaping Mandrel		304 Stainless Steel	None
Peelable Introducer Sheath		PTFE	None
Strain Relief		Pebax	Unknown

9. Non-Clinical Performance Testing

Bench Testing

Bench performance testing was conducted to verify that the Distal Access Catheter meets all design specifications and to support substantial equivalence to the predicate.

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

Test	Test Method Summary	Result
Dimensional Verification	The effective length of the catheter shaft, the inner diameter of the proximal and distal ends of the catheter shaft, and the maximum outer diameter of the entire catheter shaft was measured.	Device met the dimensional specifications.
Visual Inspection	The catheter was inspected for structural or mechanical damage.	Device met the visual specifications.
Simulated Use and Compatibility Testing	Clinical use was simulated with compatible devices in a tortuous anatomical bench test model to test compatibility.	Device performed as intended under simulated use conditions.
Delivery and Retrieval	The maximum forces to deliver and retrieve the device through a tortuous anatomical bench test model were measured.	Device met the delivery and retrieval force specifications.
Tensile Strength	Devices were pre-conditioned by simulated use. The peak tensile force of all bonding points of the catheter was tested using a universal tensile machine per methods defined in ISO 10555-1.	Device met acceptance criteria determined with delivery and retrieval force testing.
Torque Strength	Devices were pre-conditioned by simulated use and torqued to failure inside tortuous anatomical model with distal tip held fixed.	Device torque strength is similar to the predicate.
Burst Pressure	The catheter was evaluated per methods defined in ISO 10555-1:2013 following pre-conditioning by simulated use.	Device resistance to burst pressure is similar to the predicate.
Kink Resistance	Devices were pre-conditioned by simulated use and all bonding points of the distal access catheter were wrapped around varying size pin gauges until failure.	Device kink resistance is similar to the predicate.
Coating Integrity	Hydrophilic coating on the catheter surface was evaluated after particulate testing for defects.	Device coating integrity is similar to the predicate.

Corrosion Resistance	The subject device was evaluated per ISO 10555-1:2013 to demonstrate that the device meets the corrosion resistance requirements.	Device met corrosion resistance specification.
Air Leakage	The subject device was evaluated per methods and criteria defined in ISO 10555-1:2013 following pre-conditioning by simulated use.	Device integrity is suitable for intended clinical use and met requirements of ISO 10555-1.
Liquid Leakage	The subject device was evaluated per methods and criteria defined in ISO 10555-1:2013 following pre-conditioning by simulated use.	Device integrity is suitable for intended clinical use and met requirements of ISO 10555-1.
Radiopacity	Visibility of the distal marker band and catheter body were evaluated under X-ray.	Device radiopacity comparable to the predicate device.
Particulate Testing	Test articles were tracked multiple times through a tortuous anatomical model with ancillary devices and all generated particulates were collected.	Particulate generation of the subject device was comparable to the predicate device.
Luer Connector Testing	The subject device was evaluated per ISO 80369-7 and ISO 80369-20 to demonstrate that the device meets the requirements.	Device met the establish acceptance criteria.
Tip Flexibility and Tip Buckling Testing	The catheter distal tip was evaluated following simulated use testing.	Tip flexibility and tip buckling of the subject device are similar to the predicate device.

Biocompatibility

The Distal Access Catheter is categorized as Externally Communicating Device, Circulating Blood, Limited Contact (≤ 24 hours). The introducer sheath and shaping mandrel are considered to have indirect blood contact for a limited (≤ 24 hours) duration, via the fluid path and solid-to-solid contact, respectively. Per ISO 10993-1, the following tests were conducted on the final, finished device based on the nature and duration of tissue contact:

Test	Test Method Summary	Conclusion
Cytotoxicity	ISO 10993-5:2009 MTT Method	The Distal Access Catheter, introducer sheath, and shaping mandrel were non-cytotoxic.
Skin Sensitization	ISO 10993-10:2021 Guinea Pig Maximization Test	The Distal Access Catheter, introducer sheath, and shaping mandrel were non-sensitizers.

Irritation	ISO 10993-23:2021 Intracutaneous Reactivity Test	The Distal Access Catheter, introducer sheath, and shaping mandrel were non-irritant.
Acute Systemic Toxicity	ISO 10993-11:2017 Acute Systemic Toxicity Study in Mice	No mortality or evidence of acute systemic toxicity with the Distal Access Catheter, introducer sheath, and shaping mandrel test articles.
Material-Mediated Pyrogenicity	USP <151>, ISO 10993-11:2017 Rabbit Pyrogen Study	The Distal Access Catheter, introducer sheath, and shaping mandrel were non-pyrogenic.
Hemocompatibility	ASTM F756-2017, ISO 10993-4:2017 ASTM Hemolysis Study (Direct and Indirect Contact)	The Distal Access Catheter was non-hemolytic (direct and indirect contact). The introducer sheath and shaping mandrel were non-hemolytic (indirect contact).
	ISO 10993-4:2017 Complement Activation, SC5b-9	The Distal Access Catheter results were similar to the negative control group.
	ISO 10993-4:2017, ASTM F2382-2018 Partial Thromboplastin Time Study	The Distal Access Catheter results were similar to the negative control group.
	ISO 10993-4:2017 In Vivo Vein Thromboresistance Study	The Distal Access Catheter results were similar to the control and had no evidence of thrombosis.
Genotoxicity	ISO 10993-3:2014 Bacterial Reverse Mutation Test	No backward mutation in Salmonella typhimurium with the Distal Access Catheter test article.
	ISO 10993-3:2014 Mouse Lymphoma TK Assay	The Distal Access Catheter was non-mutagenic to mouse lymphoma cells (L5178Y $TK^{+/-}$—3.7.2C).
	ISO 10993-3:2014 In vitro Mammalian Chromosome Aberration Test	The Distal Access Catheter results were similar to the negative control group.

Sterility 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 1-year shelf-life.

10. Clinical Performance Testing

No clinical studies were deemed necessary to demonstrate substantial equivalence.

11. Conclusion

The subject device, Distal Access Catheter, has similar technological characteristics and the same intended use as the predicate device, Navien Intracranial Support Catheter (K161152). The differences in technological characteristics do not raise new or different questions of safety or effectiveness. Based on the completed bench performance, biocompatibility, and sterility testing, and the comparison and analysis above, the subject device performs as intended and is determined to be substantially equivalent to the predicate device.