July 30, 2025

Suzhou Zenith Vascular SciTech Limited
Jie Xia
Chief Executive Officer
Building 6, Block B, Phase 5, Biobay,
No.21 Dongyanli Road,
SIP Suzhou 215123
China

Re: K243534
Trade/Device Name: Micro Catheter
Regulation Number: 21 CFR 870.1210
Regulation Name: Continuous Flush Catheter
Regulatory Class: Class II
Product Code: KRA, QJP
Dated: June 26, 2025
Received: June 26, 2025

Dear Jie Xia:

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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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,
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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K243534

Device Name
Micro Catheter

Indications for Use *(Describe)*
The Micro Catheter is intended for the delivery of interventional devices or contrast media into the vasculature of the peripheral and neuro anatomy.

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-K243534

Applicant	Suzhou Zenith Vascular SciTech Limited Building 6, Block B, Phase 5, Biobay, No.21 Dongyanli Road, SIP Suzhou, China 215123	
Contact Person	Jie Xia	
Contact Telephone	+86-18051093308	
Date Prepared	July 28, 2025	
Device Trade Name	Micro Catheter	
Common Name	Percutaneous Catheter	
Regulation Number	21 CFR 870.1210	21 CFR 870.1250
Regulation Name	Continuous Flush Catheter	Percutaneous Catheter, Neurovasculature
Product Code	KRA	QJP
Device Classification	Class II	
Predicate Device	Rebar™ Micro Catheter (K210114)	

Device Description

The Micro Catheter is a sterile, single-use, single lumen, variable stiffness, composite catheter. The Micro Catheter is available in three inner diameters (0.017″, 0.021″ and 0.027″), and two working lengths (150cm and 155cm). All models are designed with a straight tip, and are steam shapeable by the user. Single or dual radiopaque markers at the distal end facilitate fluoroscopic visualization. The outer surface of the catheter is coated with a hydrophilic coating to increase lubricity. The proximal end of Micro Catheter incorporates a standard luer adapter to facilitate the attachment of accessories. The catheter body has a semi-rigid proximal end which transitions into the flexible distal end to facilitate the advancement of the catheter in the tortuous vasculature. The Micro Catheter is compatible with ≤ 0.014″ guidewires and 5F or larger guide catheters.

Indications for Use

The Micro Catheter is intended for the delivery of interventional devices or contrast media into the vasculature of the peripheral and neuro anatomy.

Predicate Device Comparison

The predicate device for the Micro Catheter is the Rebar™ Micro Catheter (K210114). The table below describes the differences between the subject and predicate device.

Table 1. Comparison of the Subject Device and Predicate Device

Characteristics	**Subject Device-** **Micro Catheter(K243534)**			**Predicate Device-** **Rebar Micro Catheter(K210114)**		**Justification of Substantial Equivalence**
Product Code	KRA, QJP			KRA, QJP		Same
Indications for Use	The Micro Catheter is intended for the delivery of interventional devices or contrast media into the vasculature of the peripheral and neuro anatomy.			The Rebar™ Micro Catheter is intended for the delivery of interventional devices or contrast media into the vasculature of the peripheral and neuro anatomy.		Same
Materials						
Inner Layer	PTFE			PTFE		Same
Middle Layer	Stainless steel			Stainless steel		Same
Outer Jacket	Pebax			Pebax		Same
Coating	Hydrophilic coating			Hydrophilic coating		Same
Radiopaque Marker	Platinum-Iridium Alloy			Platinum-Iridium Alloy		Same
Strain Relief	Polyurethane/PU			Elvax and Dynaflex		Different. The subject device was evaluated via bench and biocompatibility testing with passing or acceptable results.
Hub	Polycarbonate			Polypropylene		
Specification						
Model	200017150/ 200017155	200021150/ 200021155	200027150/ 200027155	Rebar 18	Rebar 27	N/A
Proximal OD	0.81 mm	0.91 mm	0.93 mm	0.89 mm Max	1.09 mm Max	Similar. The design validation testing has demonstrated the subject device performs as intended.
Distal OD	0.66 mm	0.81 mm	0.93 mm	0.93 mm Max	1.09 mm Max	
Inner Diameter	0.017 inch	0.021 inch	0.027 inch	0.020 inch Min	0.026 inch Min	
Effective Length	150 cm and 155 cm			130 cm and 153 cm	130 cm and 145cm	
Coating Length	80 cm			100 cm	95 cm	
Tip Configuration	Straight, shapeable			Straight, shapeable		Same
Sterilization Method	Ethylene Oxide			Ethylene Oxide		Same
How Supplied	Sterile, non-pyrogenic.			Sterile, non-pyrogenic.		Same
Shelf-Life	2 years			2 years		Same

Performance Data

The Micro Catheter was evaluated via the following non-clinical testing.

Performance Testing-Bench

The following bench performance testing was performed to characterize the Micro Catheter.

Table 2. Bench Performance Testing

Test	Test Method Summary	Results
Dimensional Verification	The dimensions (Inner Diameter, Outer Diameter, Effective Length) of the catheter were measured. The inner diameter of the introducer sheath was measured. The outer diameter of the shaping mandrel was measured.	Micro Catheter and accessories met the acceptance criteria.
Radiopacity	The catheter was visualized under fluoroscopy.	Micro Catheter and the predicate device were imaged showing equivalence in terms of radiopacity.
Surface Inspection	The catheter was visually inspected under microscopy.	Micro Catheter met the acceptance criteria.
Corrosion Resistance	The catheter was tested according to ISO 10555-1, Annex A.	Micro Catheter showed no signs of corrosion.
Peak Tensile Force/Bond Strength	The catheter was evaluated to verify the peak tensile force/bond strength of the full system meets the minimum tensile strength requirement.	Micro Catheter met the acceptance criteria.
Liquid Leakage	The catheter was tested according to ISO 10555-1, Annex C.	Micro Catheter showed no leakage.
Air Leakage	The catheter was tested according to ISO 10555-1, Annex I.	Micro Catheter showed no leakage.
Hub Testing	The hub was tested according to ISO 80369-20.	Micro Catheter hub met the acceptance criteria.
Flowrate at Maximum Rated Infusion Pressure	The flow rate at the maximum rated infusion pressure was measured using saline, 50:50 saline: contrast, and 100% contrast.	Micro Catheter met the acceptance criteria. The mean flow rate values for the subject device and predicate device are comparable for the injectate media tested.
Dynamic Burst Pressure	The catheter was tested according to ISO 10555-1, Annex G.	Micro Catheter met the acceptance criteria.
Static Burst Pressure	The catheter was tested according to ISO 10555-1, Annex F.	Micro Catheter met the acceptance criteria.
Simulated Use	The catheter was evaluated in a simulated anatomical model for the preparation and ease of assembly, introducer sheath compatibility and peel away, ancillary device compatibility with a guidewire and guide catheter, trackability, lubricity and durability of the hydrophilic coating, and kink resistance.	Micro Catheter met the acceptance criteria.
Flexibility and Kink Test	The catheter was evaluated for resistance to kinking around bends with clinically relevant radii.	Micro Catheter met the acceptance criteria.
Torque Strength	The catheter was evaluated for torque strength by rotating the test samples in an anatomical model with the distal tip fixed	Micro Catheter and a cleared comparator showed a similar number of rotations to

	and recording the number of rotations to failure.	failure.
Coating Integrity	The catheter coating integrity was inspected pre- and post-simulated use in an anatomical model.	Micro Catheter met the acceptance criteria.
Coating Lubricity	The catheter was evaluated for frictional forces on a universal testing machine.	Micro Catheter and the predicate showed similar frictional forces.
Particulate Evaluation	The catheter was evaluated for particulate generation during simulated use in an anatomical model.	Micro Catheter and the predicate showed similar particle numbers.
Tip Stiffness	The distal tip of the catheter was deflected on a universal testing machine.	Micro Catheter and a cleared comparator showed a similar tip stiffness.
Distal Tip Inspection	The distal tip of the catheter was inspected for defects.	Distal tip met the acceptance criteria.
Tip Shapeability	The distal tip of the catheter was shaped using the shaping mandrel supplied with Micro Catheter.	Distal tip met the acceptance criteria.
Lumen Collapse	The force needed to collapse the catheter at the tip and along the catheter shaft was measured using a universal testing machine.	Micro Catheter and the predicate showed similar forces to collapse the catheter.
Compatibility tests	The catheter was inspected for damage post simulated use testing with compatible interventional devices in a neurovascular model.	Micro Catheter met the acceptance criteria.

The performance data demonstrate that the subject device is substantially equivalent to the predicate devices.

Biocompatibility Testing

Biocompatibility tests were conducted with the Micro Catheter in accordance with ISO 10993-1:2018, "*Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process",* and the FDA biological evaluation guidance. The performed tests are listed in Table 3.

Table 3. Biocompatibility Testing

Test	Standards	Results	Conclusion
ISO MEM Elution Test with L-929 Cells	ISO 10993-5	The test article had a reactivity grade of ≤2 under the conditions of this study.	Non-cytotoxic
ISO Guinea Pig Maximization Sensitization Test (2 Extracts)	ISO 10993-10	The saline and sesame oil test article extracts did not show evidence of causing delayed dermal contact sensitization response in the guinea pigs.	Non-sensitizer
Intracutaneous Reactivity Test in Rabbits (2 Extracts)	ISO 10993-23	The differences between the test extracts and their respective control mean scores were less than 1.0.	Non-irritant
Acute Systemic Toxicity Study in Mice (2 Extracts)	ISO 10993-11	There was no mortality or evidence of acute systemic toxicity from the extracts.	No evidence of acute systemic toxicity
Material-Mediated Pyrogenicity Test in Rabbits (Saline Extract)	ISO 10993-11	None of the test rabbits exhibited a temperature rise greater than or equal to 0.5°C.	Non-pyrogenic
ASTM Hemolysis Test - Direct Contact and Extract Methods	ISO 10993-4	The test article hemolytic index was above the negative control and was less than 2% for both direct contact and extract methods under the conditions of this study.	Non-hemolytic

Complement Activation SC5b-9 Assay (with Comparator Control Article)	ISO 10993-4	The concentration of SC5b-9 activated by the test article was statistically lower than that activated by the negative reference material and comparator control article.	Not an activator
Non-anticoagulated Venous Implant Study in Canines for Evaluation of Thromboresistance	ISO 10993-4	The extent of thrombus formation on the test article was not greater than the comparator control article.	Non-thrombogenic

Sterilization and Shelf Life

The Micro Catheter is sterilized using ethylene oxide. The sterilization cycle was verified to ensure a sterility assurance level (SAL) of 10^{-6} in accordance with ISO 11135.

Aging studies for subject device have been conducted and demonstrated a 2 year shelf-life. Packaging aging tests were also conducted and the results met all acceptance criteria.

Packaging

Each package consists of a Sterile Barrier System (SBS) and protective packaging. SBS validation was conducted per requirements of ISO 11607-2.

Animal Study

An animal study was not deemed necessary to support the substantial equivalence of the subject device to the predicate device. Non-clinical testing described above was determined to be sufficient to support substantial equivalence.

Clinical Study

Clinical testing was not deemed necessary to support the substantial equivalence of the subject device to the predicate device. Non-clinical testing described above was determined to be sufficient to support substantial equivalence.

Conclusion

The subject and predicate devices have the same intended use and the same or similar technological characteristics. The non-clinical testing demonstrates that the subject Micro Catheter performs as intended and supports substantial equivalence to the predicate device. The differences in technological characteristics do not raise new questions of safety and effectiveness.