May 22, 2026

Suzhou Zenith Vascular SciTech Limited
Yexia Zhang
Senior Regulatory Affair Supervisor
Unit 101, Building 6, Block B, Phase 5, Biobay
No.21 Dongyanli Road, SIP Suzhou
Suzhou, Jiangsu 215123
China

Re: K253359
Trade/Device Name: Zenith Distal Access Long Sheath
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: QJP, DQY
Dated: April 20, 2026
Received: April 20, 2026

Dear Yexia Zhang:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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
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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)*
K253359

Device Name
Zenith Distal Access Long Sheath

Indications for Use *(Describe)*
The Zenith Distal Access 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.

510(k) Summary-K253359

Applicant	Suzhou Zenith Vascular SciTech Limited Unit 101, Building 6, Block B, Phase 5, Biobay, No.21 Dongyanli Road, SIP Suzhou, China 215123	
Contact Person	Yexia Zhang	Xiaoyu Wang
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Date Prepared	May 20, 2026	
Device Trade Name	Zenith Distal Access Long Sheath	
Regulation Number	21 CFR 870.1250	
Regulation Name	Percutaneous Catheter	
Product Code	QJP, DQY	
Device Classification	Class II	
Predicate Device	Neuron™ MAX System (K111380)	

Device Description

The Zenith Distal Access Long Sheath is a sterile, single-use, single-lumen, variable stiffness composite catheter. It has an inner diameter (ID) of 0.090", an outer diameter (OD) of 0.106” corresponding to 8 French (F), and is offered in five working lengths: 70 cm, 80 cm, 90 cm, 100 cm, and 105 cm. The device features two tip shapes: straight and curved (identified by the suffix “MP” in the model code). The device incorporates a radiopaque marker at the distal end for angiographic visualization. It is supplied with one Dilator, one Hemostasis Valve, and one Y-type valve.

The proximal end of each Zenith Distal Access Long Sheath incorporates a strain relief and a standard Luer adapter to facilitate the attachment of accessories. Graded shaft stiffness ranging from a flexible tip to a semi-rigid proximal section aids the physician in tracking the sheath over selectively placed catheters/guidewires.

Indications for Use

The Zenith Distal Access Long Sheath is indicated for the introduction of interventional devices into the peripheral, coronary, and neuro vasculature.

Predicate Device Comparison

The predicate device for the Zenith Distal Access Long Sheath is the Neuron™ MAX System (K111380). The table below describes the technological similarities and differences between them.

Table 1. Comparison of Subject and Predicate Devices

Attributes	Subject Device (K253359)	Predicate Device (K111380)
Device Name	Zenith Distal Access Long Sheath	Neuron™ MAX System
Indications for Use	The Zenith Distal Access Long Sheath is indicated for the introduction of interventional devices into the peripheral, coronary, and neuro vasculature.	The Neuron MAX System is indicated for the introduction of interventional devices into the peripheral, coronary, and neuro vasculature.
Regulation No.	21 CFR 870.1250	21 CFR 870.1250
Regulatory Class	II	II
Product Code	QJP, DQY	DQY
OD	0.106 inch (8 French)	0.110 inch (8 French)
ID	0.090 inch	0.088 inch
Effective Length	70-105 cm	70-100 cm
Tip shape	Straight/Curved	Straight/Curved
Dilator ID	0.040 inch	0.040 inch
Dilator OD	0.085 inch	0.084 inch
Dilator Effective Length	90-125 cm	90-125 cm
Inner Layer	Polytetrafluoroethylene (PTFE)	PTFE
Braid	Stainless steel	Stainless steel
Radiopaque Marker	Platinum-Iridium alloy	Platinum-Iridium alloy
Outer Jacket	Polyurethane, Polyamide, Nylon	Polyurethane, Polyether block amide materials
Coating	Hydrophilic	Hydrophilic
Hub	Polycarbonate	Polyamide
Strain Relief	Polyurethane	Stainless Steel
Accessories	Dilator, Hemostasis Valve, Y-type Valve	Dilator, Rotating Hemostasis Valve, 6F Select Catheter
Packaging Configuration	Placed into the Cardboard, protective tubes, Tyvek pouch, and box carton.	Placed into the Cardboard, protective tubes, Tyvek pouch, and box carton.
Sterilization Method	Ethylene Oxide (EO)	EO

Attributes	Subject Device (K253359)	Predicate Device (K111380)
Shelf Life	24 Months	36 Months

Performance Data

Non-clinical tests have been conducted to support substantial equivalence of the subject device to the predicate device and are summarized below.

Performance Testing-Bench

The following bench performance testing was performed to evaluate the Zenith Distal Access Long Sheath.

Table 2. Bench Performance Testing - Zenith Distal Access Long Sheath

Test	Test Method Summary	Results	Conclusion
Dimensional Verification	The dimensions (inner diameter, outer diameter, effective length, hydrophilic coating length, radiopaque marker width) of the Zenith Distal Access Long Sheath and Dilator were measured.	Pass	Zenith Distal Access Long Sheath and Dilator met the acceptance criteria.
Surface Inspection	The Zenith Distal Access Long Sheath and accessories were visually inspected under microscopy.	Pass	Zenith Distal Access Long Sheath met the acceptance criteria.
Distal Tip Inspection	The distal tip of the Zenith Distal Access Long Sheath and the Dilator were inspected for defects.	Pass	Distal tip met the acceptance criteria.
Corrosion Resistance	The Zenith Distal Access Long Sheath was tested according to ISO 10555-1, Annex A.	Pass	Zenith Distal Access Long Sheath showed no signs of corrosion.
Device Compatibility	Sheath-Dilator Compatibility, Dilator-Guidewire Compatibility, and Sheath-Catheter Compatibility were tested in the simulated use.	Pass	Device compatibility of Zenith Distal Access Long Sheath met the acceptance criteria
Simulated Use	The Zenith Distal Access Long Sheath and Dilator were evaluated in a simulated anatomical model with a 0.035” guidewire, a 6F guide catheter and a representative worst-case interventional device (neurovascular stent retriever retracted through the inner lumen of the Zenith Distal Access Long Sheath for 3 passes). Tracking, advancement force, withdrawal force, performance, and post-simulated use integrity were verified.	Pass	Zenith Distal Access Long Sheath met the acceptance criteria.
Peak Tensile Force	The Zenith Distal Access Long Sheath and Dilator were evaluated to verify the peak tensile force of the full system after preconditioning meets the minimum tensile strength requirement.	Pass	Zenith Distal Access Long Sheath and Dilator met the acceptance criteria.
Tip Pull Test	The Zenith Distal Access Long Sheath was evaluated via tip pull test after preconditioning with devices.	Pass	Zenith Distal Access Long Sheath met the acceptance criteria.
Flexibility and Kink Test	The Zenith Distal Access Long Sheath and Dilator were evaluated for resistance to kinking around bends with clinically relevant bend radii after preconditioning.	Pass	Zenith Distal Access Long Sheath met the acceptance criteria.
Torque Strength	The Zenith Distal Access Long Sheath and Dilator were evaluated for torque strength by rotating the test samples in an anatomical model with the distal tip fixed and recording the failure location, failure mode, and number of rotations to failure after preconditioning.	Pass	Zenith Distal Access Long Sheath and a cleared comparator showed a similar number of rotations to failure.

Coating Integrity	The Zenith Distal Access Long Sheath coating integrity was inspected pre- and post- simulated use in an anatomical model.	Pass	Zenith Distal Access Long Sheath met the acceptance criteria.
Coating Lubricity	The Zenith Distal Access Long Sheath was evaluated for frictional forces of the hydrophilic coated regions on a universal testing machine after preconditioning.	Pass	Zenith Distal Access Long Sheath and the predicate device showed similar frictional forces.
Particulate Evaluation	The Zenith Distal Access Long Sheath and Dilator were evaluated for particulate generation during simulated use with ancillary devices in an anatomical model.	Pass	Zenith Distal Access Long Sheath and the predicate device showed similar particle numbers.
Tip Stiffness	The distal tip of the Zenith Distal Access Long Sheath and Dilator were deflected on a universal testing machine to characterize bending forces before preconditioning.	Pass	The Zenith Distal Access Long Sheath and its dilator exhibited tip stiffness similar to that of the predicate device.
Hub Testing	The hub of the Zenith Distal Access Long Sheath and hub of Dilator were tested according to ISO 80369-7 and ISO 80369-20.	Pass	Zenith Distal Access Long Sheath hub and Dilator hub met the acceptance criteria.
Hemostasis Valve and Y-type Valve	The Hemostasis Valve and Y-type Valve were tested according to ISO 80369-7 and ISO 80369-20	Pass	The Hemostasis Valve and Y-type Valve met the acceptance criteria.
Static Burst Pressure	The Zenith Distal Access Long Sheath was tested for static burst pressure according to the methods specified in ISO 10555-1:2023, Annex F.	Pass	Zenith Distal Access Long Sheath met the acceptance criteria.
Liquid Leakage	The Zenith Distal Access Long Sheath and Dilator were tested according to ISO 10555-1, Annex C.	Pass	Zenith Distal Access Long Sheath and Dilator showed no leakage.
Air Leakage	The Zenith Distal Access Long Sheath and Dilator were tested according to ISO 10555-1, Annex D.	Pass	Zenith Distal Access Long Sheath and Dilator showed no leakage.
Radiopacity	The Zenith Distal Access Long Sheath was visualized under fluoroscopy.	Pass	Zenith Distal Access Long Sheath and the predicate device were imaged showing equivalence in terms of radiopacity.

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

Biocompatibility Test

Biocompatibility tests were conducted with the Zenith Distal Access Long Sheath in accordance with ISO 10993-1:2018, "*Biological evaluation of medical devices-Evaluation and testing within a risk management process*" and the FDA guidance, "Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process"." The tests performed 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	Non-sensitizer

		sensitization response in the guinea pigs.	
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 Zenith Distal Access Long Sheath is sterilized using ethylene oxide (EO) method. The sterilization cycle was verified to ensure a sterility assurance level (SAL) of 10^{-6} in accordance with ISO 11135, "Sterilization of Health-Care Products - Ethylene Oxide - Requirements for the Development, Validation and Routine Control of a Sterilization Process for Medical Devices."

Aging studies for the subject device have been conducted to support the 2 year shelf-life. Packaging 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, "Packaging for Terminally Sterilized Medical Devices - Part 2: Validation Requirements for Forming, Sealing and Assembly Processes."

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 Studies

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 similar technological characteristics. The

non-clinical testing demonstrates that the subject device 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.