



April 16, 2026

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

Re: K252317

Trade/Device Name: Zenith Micro Guidewire
Regulation Number: 21 CFR 870.1330
Regulation Name: Catheter Guide Wire
Regulatory Class: Class II
Product Code: MOF, DQX
Dated: July 15, 2025
Received: July 25, 2025

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,

JAIME RABEN -S

for Naira Muradyan
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

Indications for Use

510(k) Number (if known)
K252317

Device Name
Zenith Micro Guidewire

Indications for Use (Describe)

Zenith Micro Guidewire is indicated for general intravascular use, including the neuro and peripheral vasculature. The guidewire can be steered to facilitate the selective placement of diagnostic or therapeutic catheters. This device is not intended for use in coronary arteries.

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.

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510(k) Summary-K252317

Applicant	Suzhou Zenith Vascular SciTech Limited Building 6, Block B, Phase 5, Biobay, No.21 Dongyanli Road, SIP Suzhou, China 215123	
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Date Prepared	April 16, 2026	
Device Trade Name	Zenith Micro Guidewire	
Device Regulation Rule	21CFR 870.1330	
Device Regulation Name	Catheter Guide Wire	
Product Code	MOF	DQX
Device Class	Class II	
Predicate Device	Traxcess 14 Guidewire (K133725)	
	Aristotle 18 Guidewire (K243938)	

Device Description

The Micro Guidewire is a non-active, surgically invasive device intended for limited duration use within the vasculature, which is manufactured by Suzhou Zenith Vascular SciTech Limited.

The four series of Micro Guidewire: Zenith 12 Micro Guidewire, 13 Micro Guidewire, 16 Micro Guidewire and 18 Micro Guidewire ("the Micro Guidewires") are steerable guidewires with a shapeable tip to aid in accessing the neuro and peripheral vasculatures. The guidewires are supplied sterile, for single use only. The distal portion of each Micro Guidewire's tip includes a radiopaque platinum spring marker coil to facilitate fluoroscopic visualization. All guidewires have a hydrophilic polymer coating on the distal portion and a hydrophobic (PTFE) coating on the proximal portion to reduce friction during manipulation in vessels.

The guidewires are provided with an accessory kit consisting of an introducer (to aid with the insertion of the guidewire into a catheter hub and/or a hemostasis valve), a torque device (to attach to the proximal portion of the guidewire to facilitate gripping and manipulation of the guidewire during use), and a shaping mandrel (to aid in shaping the flexible tip of the guidewire). These accessory devices are included to facilitate use of the guidewires and are not intended to contact the patient's body.

Indications for Use

Zenith Micro Guidewire is indicated for general intravascular use, including the neuro and peripheral vasculature. The guidewire can be steered to facilitate the selective placement of diagnostic or therapeutic catheters. This device is not intended for use in coronary arteries.

Predicate Device Comparison

The predicate devices for the Micro Guidewire are the Traxcess 14 Guidewire (K133725) and the Aristotle 18 Guidewire (K243938). The table below describes the technological differences between them.

Attributes	Subject Device (K252317)	Predicate Device (K133725)	Predicate Device (K243938)	Difference Analysis
Device Name	Zenith Micro Guidewire	Traxcess 14 Guidewire	Aristotle 18 Guidewire	N.A.
Indications for use	Zenith Micro Guidewire is indicated for general intravascular use, including the neuro and peripheral vasculature. The guidewire can be steered to facilitate the selective placement of diagnostic or therapeutic catheters. This device is not intended for use in coronary arteries.	The Traxcess 14 Guidewire is indicated for general intravascular use, including the neuro and peripheral vasculature. The guidewire can be steered to facilitate the selective placement of diagnostic or therapeutic catheters. This device is not intended for use in coronary arteries.	The Aristotle 18 Guidewire is intended for general vascular use within the neuro and peripheral vasculature to introduce and position catheters and other interventional devices. The guidewire is not intended for use in the coronary vasculature.	Same
Regulation No.	21CFR 870.1330	21CFR 870.1330	21CFR 870.1330	Same
Regulatory Class	II	II	II	Same
Product Code	MOF, DQX	MOF, DQX	MOF, DQX	Same
Review Panel	Neurology	Neurology	Neurology	Same
Dimensional				
Wire Diameter	0.012" (Proximal 0.013", Distal 0.012"); 0.013"; 0.016"; 0.018".	0.014" (Proximal 0.014", Distal 0.012").	0.018".	Same
Device Length	110 cm -320 cm	200 cm	200 cm, 300 cm	Similar, and the device performance has been verified.

Table 1. Technological Comparison to Subject Device and Predicate Devices

Attributes	Subject Device (K252317)	Predicate Device (K133725)	Predicate Device (K243938)	Difference Analysis
Radiopaque Coil Length	30 mm; 85 mm	Coil Length 40 cm Radiopaque Length 3 cm	Undisclosed	Similar.
Woven Jacket length	80 mm; 335 mm	Undisclosed	Undisclosed	Similar, and the device performance has been verified.
Shapeable Tip Length	1 cm	1.4 cm	35 cm	Similar, and the device performance has been verified.
Hydrophilic Coating Length	10 cm, 35.5 cm	40 cm	46 cm	Similar, and the coating performance has been verified.
Hydrophobic Coating Length	95 cm - 285 cm	160 cm	Undisclosed	Similar, and the coating performance has been verified.
Tip shape	Straight and Shapeable	Straight and Shapeable	Straight and Shapeable	Same
Coil Wire Type	Integrated	Undisclosed	Undisclosed	Similar
Raw Material				
Core Wire Material	Stainless steel	Proximal: Stainless steel; Distal: Nickel titanium alloy.	Stainless steel	Same
Jacket	Woven jacket: Nitinol Protective jacket: TPU	NA	Undisclosed	Different, but the biological safety has been validated.
Radiopaque coil	Platinum nickel alloy	Stainless steel and platinum nickel alloy	Platinum	Similar
Coating	Distal end: Hydrophilic Proximal end: PTFE	Distal: Hydrophilic Proximal: PTFE/Silicone	Distal end: Hydrophilic Proximal end: PTFE	Different, but the biological safety has been validated.
Accessories	Shaping Mandrel, Guidewire Introducer and Torque Device	Shaping Mandrel, Insertion tool and Torque Device	Shaping Mandrel, Guidewire Introducer and Torque Device	Same
Packaging Configuration	Placed into a packaging coil, Tyvek pouch, and box carton.	Placed into a dispenser hoop, Tyvek pouch, and box carton.	Placed into a dispenser hoop, Tyvek pouch, and box carton.	Same
Sterilization Method	EO	EO	EO	Same
Shelf Life	2 years	3 years	1 year	Different, but the shelf-life period has been verified.

Performance Data

Non-clinical tests have been conducted to support substantial equivalence of the device to the predicate devices and are summarized as follows.

Performance Testing-Bench

The results of the bench testing conducted on the subject device demonstrate that it performs as intended and meets design specifications. Bench performance testing included the following:

Test	Test Method Summary	Conclusion
Dimensional and Visual Inspection	Testing completed per FDA guidance document "Coronary, Peripheral, and Neurovascular Guidewires – Performance Tests and Recommended Labeling" (2019). Verified key dimensions and surface of the Guidewire.	Acceptance criteria were met.
Corrosion Resistance	Testing completed per FDA guidance document "Coronary, Peripheral, and Neurovascular Guidewires – Performance Tests and Recommended Labeling" (2019).	Acceptance criteria were met.
Tensile Strength	Testing completed per FDA guidance document "Coronary, Peripheral, and Neurovascular Guidewires – Performance Tests and Recommended Labeling" (2019). Measured the force required to break at each bond, including the distal tip.	Acceptance criteria were met.
Simulated Use	Testing completed per FDA guidance document "Coronary, Peripheral, and Neurovascular Guidewires – Performance Tests and Recommended Labeling" (2019). Guidewires were tested for use with a micro catheter, the Guidewire Introducer, and Torque Device while navigating to target locations in the vascular model.	Acceptance criteria were met.
Tip Shaping	Shaped the Guidewire tip for a total of 5 times per labeling.	Acceptance criteria were met.
Tip Shape Retention	Measured the tip shape retention rate after tip shaping and simulated use in the vascular model.	Acceptance criteria were met.
Coating Integrity	Testing completed per FDA guidance document "Coronary, Peripheral, and Neurovascular Guidewires – Performance Tests and Recommended Labeling" (2019). Coating integrity was inspected before and after simulated use tracking with comparison to predicate.	Coating integrity was reported and considered acceptable.
Coating Lubricity (Friction Force, Durability)	Testing completed per FDA guidance document "Coronary, Peripheral, and Neurovascular Guidewires – Performance Tests and Recommended Labeling" (2019). The coating lubricity and durability of the Guidewire was evaluated for frictional forces on a universal testing machine after multiple pull cycles.	Acceptance criteria were met.
Kink Resistance	Testing completed per FDA guidance document "Coronary, Peripheral, and Neurovascular Guidewires – Performance Tests and Recommended Labeling" (2019). Wrapped the	Acceptance criteria were met.

	Guidewire around a test fixture with a clinically relevant radius.	
Torque Strength	Testing completed per FDA guidance document "Coronary, Peripheral, and Neurovascular Guidewires – Performance Tests and Recommended Labeling" (2019). Recorded the number of times the distal end of the Guidewire can be rotated until it exceeds its maximum rotations and fails after tip shaping and simulated use.	Acceptance criteria were met.
Torqueability	Testing completed per FDA guidance document "Coronary, Peripheral, and Neurovascular Guidewires – Performance Tests and Recommended Labeling" (2019). After tip shaping, the Guidewire was tracked in the vascular model during simulated use and evaluated the steerability and torque response.	Acceptance criteria were met.
Tip Flexibility/Stiffness	Testing completed per FDA guidance document "Coronary, Peripheral, and Neurovascular Guidewires – Performance Tests and Recommended Labeling" (2019). Measured the force required to deflect the Guidewire tip when held at 5 mm, 10 mm and 20 mm gauge lengths. Forces were compared to the predicate device.	Acceptance criteria were met.
Flexing Test	Testing completed per ISO 11070:2014 "Sterile single-use intravascular introducers, dilators and guidewires".	Acceptance criteria were met.
Fracture Test	Testing completed per ISO 11070:2014 "Sterile single-use intravascular introducers, dilators and guidewires".	Acceptance criteria were met.
Particulate Evaluation	Testing completed per FDA guidance document "Coronary, Peripheral, and Neurovascular Guidewires – Performance Tests and Recommended Labeling" (2019).	Particulate counts were reported and considered acceptable.
Compatibility tests	After tip shaping, the Guidewires were inserted into compatible micro catheters and subjected to simulated use.	Acceptance criteria were met.
Radiopacity	Subject and predicate guidewires were evaluated under fluoroscopy.	Zenith Micro Guidewire demonstrated acceptable radiopacity. The radiopacity of the subject device was comparable to that of the predicate device.

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

Biocompatibility Test

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

Test	Standards	Conclusion
Cytotoxicity- MEM Elution	ISO 10993-5	Pass: Non-cytotoxic
Sensitization	ISO 10993-10	Pass: Non-sensitizing

Intracutaneous Reactivity	ISO 10993-23	Pass: Non-reactive
Acute Systemic Toxicity	ISO 10993-11	Pass: No evidence of acute systemic toxicity
Pyrogenicity	ISO 10993-11	Pass: Non-pyrogenic
Hemolysis (direct and indirect)	ISO 10993-4	Pass: Non-hemolytic
Complement Activation	ISO 10993-4	Pass: Not an activator
In Vivo Thrombogenicity	ISO 10993-4	Pass: Non-thrombogenic

Sterilization and Shelf Life

The Zenith Micro Guidewire is sterilized using the 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 subject device have been conducted and demonstrated for 2 year shelf-life. Packaging aging tests were also conducted and the results met all acceptance criteria.

Packaging

Each package consists of SBS (Sterile Barrier System) and protective packaging. SBS type is a flexible peel pouch, materials are UF 1250 and Tyvek Paper 1073B. All of the materials are subjected to EO sterilization with good compatibility, and the sterilization validation proves this.

Shipping container is a logistic unit. Corrugated case is used as packaging material for transportation.

Animal Study

An animal study was not deemed necessary to support the substantial equivalence of the subject device to the predicate device. Bench testing was determined sufficient to support substantial equivalence

Clinical Studies

This pre-market submission did not rely on the assessment of clinical data to demonstrate device performance and equivalence. Non-clinical testing described above was determined to be sufficient to support substantial equivalence.

Conclusion

The conclusions of the performance data demonstrate that the subject device - Zenith Micro Guidewire performs substantially equivalent to the predicate devices and does not raise new questions of safety and effectiveness.