May 20, 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: K252707
Trade/Device Name: Zenith Aspiration Catheter; Disposable Aspiration Tubing Set
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: NRY
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, PhD
Assistant Director
DHT5A: Division of Neurosurgical,
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Neurodiagnostic Devices
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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)*
K252707

Device Name
Zenith Aspiration Catheter;
Disposable Aspiration Tubing Set

Indications for Use *(Describe)*
The Zenith Aspiration Catheter, with the Disposable Aspiration Tubing Set and a compatible aspiration pump, is indicated for use in the revascularization of patients with acute ischemic stroke secondary to intracranial large vessel occlusive disease (within the internal carotid, middle cerebral – M1 and M2 segments, basilar, and vertebral arteries) within 8 hours of symptom onset. Patients who are ineligible for thrombolytic drug therapy or who failed thrombolytic drug therapy are candidates for treatment.

The Disposable Aspiration Tubing Set is indicated to connect the Zenith Aspiration Catheter to a compatible aspiration pump.

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-K252707

Applicant	Suzhou Zenith Vascular SciTech Limited Unit 101, Building 6, Block B, Phase 5, Biobay, No.21 Dongyanli Road, SIP Suzhou, China 215123	
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Date Prepared	May 19, 2026	
Device Trade Name	Zenith Aspiration Catheter; Disposable Aspiration Tubing Set	
Common Name	Catheter, Thrombus Retriever	
Regulation Number	21 CFR 870.1250	
Regulation Name	Percutaneous Catheter	
Product Code	NRY	
Device Classification	Class II	
Predicate Devices	Penumbra System Max (K113163)	
	Penumbra Reperfusion Catheter 054 (K090752)	
	Penumbra System ACE 68 Reperfusion Catheter (K161640)	

Device Description

The Zenith Aspiration Catheter is a single-lumen, variable stiffness catheter. The device has a hydrophilic coating on the distal end. The device includes a radiopaque marker on the distal end for angiographic visualization. The Zenith Aspiration Catheter is supplied with one Metal Introducer Sheath, one Peelable Introducer Sheath, and one Shaping Mandrel.

The Disposable Aspiration Tubing Set consists of one piece of Distal Tubing, one Flow Control Switch, and one piece of Proximal Tubing. The Disposable Aspiration Tubing Set connects the aspiration catheter to the aspiration pump.

Indications for Use

The Zenith Aspiration Catheter, with the Disposable Aspiration Tubing Set and a compatible aspiration pump, is indicated for use in the revascularization of patients with acute ischemic stroke secondary to intracranial large vessel occlusive disease (within the internal carotid, middle cerebral – M1 and M2 segments, basilar, and vertebral arteries) within 8 hours of symptom onset. Patients who are ineligible for thrombolytic drug therapy or who failed thrombolytic drug therapy are candidates for treatment.

The Disposable Aspiration Tubing Set is indicated to connect the Zenith Aspiration Catheter to a compatible aspiration pump.

Predicate Device Comparison

The predicate devices for the Zenith Aspiration Catheters are the Penumbra 3MAX and 4MAX Reperfusion Catheters (K113163), the Penumbra Reperfusion Catheter 054 (K090752), and the Penumbra System ACE 68 Reperfusion Catheter (K161640), respectively. The table below describes the technological similarities and differences between them.

Table 1 . Comparison of the Subject Device and Predicate Devices

Attributes	**Subject Device (K252707)**	**Predicate Device (K113163)**	**Predicate Device (K090752)**	**Predicate Device (K161640)**
Device Name	Zenith Aspiration Catheter; Disposable Aspiration Tubing Set	Penumbra System® MAX	Penumbra Reperfusion Catheter 054	Penumbra System ACE 68 Reperfusion Catheter
Indications for Use	**The Zenith Aspiration Catheter**, with the Disposable Aspiration Tubing Set and a compatible aspiration pump, is indicated for use in the revascularization of patients with acute ischemic stroke secondary to intracranial large vessel occlusive disease (within the internal carotid, middle cerebral – M1 and M2 segments, basilar, and vertebral arteries) within	**The Penumbra System** is intended for use in the revascularization of patients with acute ischemic stroke secondary to intracranial large vessel occlusive disease (in the internal carotid, middle cerebral – M1 and M2 segments, basilar, and vertebral arteries) within 8 hours of symptom onset.	**The Penumbra System™** is intended for use in the revascularization of patients with acute ischemic stroke secondary to intracranial large vessel occlusive disease (within the internal carotid, middle cerebral – M1 and M2 segments, basilar, and vertebral arteries) within 8 hours of symptom onset.	**Penumbra Reperfusion Catheters and Separators:** As part of the Penumbra System, the Reperfusion Catheters and Separators are indicated for use in the revascularization of patients with acute ischemic stroke secondary to intracranial large vessel occlusive disease (within the internal carotid, middle cerebral – M1 and M2 segments, basilar, and vertebral arteries) within

	8 hours of symptom onset. Patients who are ineligible for thrombolytic drug therapy or who failed thrombolytic drug therapy are candidates for treatment.			8 hours of symptom onset. **Penumbra Pump MAX:** The Penumbra Pump MAX is indicated as a vacuum source for Penumbra Aspiration Systems.
	Disposable Aspiration Tubing Set: The Disposable Aspiration Tubing Set is indicated to connect the Zenith Aspiration Catheter to a compatible aspiration pump.	**Penumbra Aspiration Tubing:** As part of the Penumbra System, the Penumbra Sterile Aspiration Tubing is indicated to connect the Penumbra Reperfusion Catheters to the Penumbra Pump MAX.	**Penumbra Aspiration Tubing:** As part of the Penumbra System, the Penumbra Sterile Aspiration Tubing is indicated to connect the Penumbra Reperfusion Catheters to the Penumbra Pump MAX.	**Penumbra Aspiration Tubing:** As part of the Penumbra System, the Penumbra Sterile Aspiration Tubing is indicated to connect the Penumbra Reperfusion Catheters to the Penumbra Pump MAX.
Regulation Number	21 CFR 870.1250	21 CFR 870.1250	21 CFR 870.1250	21 CFR 870.1250
Regulatory Class	II	II	II	II
Product Code	NRY	NRY	NRY	NRY
Review Panel	Neurology	Neurology	Neurology	Neurology
Proximal OD	0.050, 0.060, 0.070, 0.084 inch	3MAX: 0.062 inch 4MAX: 0.080 inch	0.080 inch	0.084 inch
Proximal ID	0.035, 0.045, 0.058, 0.072 inch	3MAX: 0.043 inch 4MAX: 0.064 inch	0.064 inch	0.068 inch
Distal OD	0.050, 0.060, 0.070, 0.084 inch	3MAX: 0.050 inch 4MAX: 0.056 inch	0.065 inch	0.084 inch
Distal ID	0.035, 0.045, 0.058, 0.072 inch	3MAX: 0.035 inch 4MAX: 0.041 inch	0.054 inch	0.068 inch
Effective Length	105-155 cm	3MAX: 153 cm 4MAX: 139 cm	125-132 cm	115-132 cm
Tip Shape	Straight	Straight	Straight	Straight
Inner Layer	PTFE	PTFE	PTFE	PTFE
Braid	Stainless steel, Nitinol	Stainless steel, Nitinol	Stainless steel, Nitinol	Stainless steel, Nitinol
Marker Band	Platinum-Iridium alloy	Platinum-Iridium alloy	Platinum-Iridium alloy	Platinum-Iridium alloy

Outer Jacket	Polyblend 45A, Polyblend 55A, Polyblend 60A, Polyblend 75A, Polyblend 80A, Polyblend 90A, Pebax 40D, Pebax 55D, Pebax 63D, Pebax 72D, Nylon 12	Polymeric exterior	Tecoflex (thermoplastic polyurethane), Pellethane (thermoplastic polyurethane), Pebax (polyether block amide), Vestamid (polyamide)	Pebax 63D, Pebax 55D, Pebax 40D/55D Blend, Pebax 40D, Pebax 35D/40D Blend, Pebax 35D, Tecoflex 80A/Pebax 35D, Tecoflex 80A, Pellethane 80A, Vestamid, Pebax 72D
Coating	Hydrophilic	Hydrophilic	Hydrophilic	Hydrophilic
Hub	Polycarbonate	Grilamid (TR55)	Grilamid (TR55)	Grilamid (TR55-LX)
Strain Relief	Polyamide	Grilamid (TR55), 304 Stainless Steel	Grilamid (TR55), 304 Stainless Steel	Grilamid (TR55), 304 Stainless Steel
Accessories	Peelable Sheath	Peelable Sheath	Peelable Sheath	Peelable Sheath
	Shaping Mandrel	Shaping Mandrel	Shaping Mandrel	Shaping Mandrel
	Metal Introducer Sheath	Rotating Hemostasis Valve	Rotating Hemostasis Valve	Rotating Hemostasis Valve
Packaging Configuration	Placed into a packaging coil, Tyvek pouch, and box carton.	Placed into a packaging hoop, Tyvek pouch, and box carton.	Placed into a packaging hoop, Tyvek pouch, and box carton.	Placed into a packaging hoop, Tyvek pouch, and box carton.
Sterilization Method	EO	EO	EO	EO
Shelf Life	24 Months	36 Months	36 Months	36 Months

Performance Data

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

Performance Testing-Bench

The following bench performance testing was performed to evaluate the Zenith Aspiration Catheter and the Disposable Aspiration Tubing Set.

Table 2. Bench Performance Testing - Zenith Aspiration Catheter

Test	Test Method Summary	Results
Dimensional Verification	The dimensions (inner diameter, outer diameter, effective length, hydrophilic coating length, radiopaque maker width, length of radiopaque band to distal end) of the Zenith Aspiration Catheter were measured. The diameter of the peelable and metal introducer sheaths were measured. The outer diameter of the Shaping Mandrel was measured.	Zenith Aspiration Catheter and accessories met the acceptance criteria.
Surface Inspection	The Zenith Aspiration Catheter was visually inspected under microscopy.	Zenith Aspiration Catheter met the acceptance criteria.

Distal Tip Inspection	The distal tip of the Zenith Aspiration Catheter was inspected for defects.	Distal tip met the acceptance criteria.
Corrosion Resistance	The Zenith Aspiration Catheter was tested according to ISO 10555-1, Annex A.	Zenith Aspiration Catheter showed no signs of corrosion.
Compatibility Tests	The Zenith Aspiration Catheter was inspected for damage post simulated use testing with compatible interventional devices in a neurovascular model.	Zenith Aspiration Catheter met the acceptance criteria.
Tip Shapeability	The distal tip of the Zenith Aspiration Catheter was shaped using the Shaping Mandrel supplied with the Zenith Aspiration Catheter.	Distal tip met the acceptance criteria.
Simulated Use	The Zenith Aspiration 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 guide catheter, guidewire and micro catheter, pushability, trackability, thrombus aspiration, catheter withdrawal, lubricity, and durability of the hydrophilic coating, and tip shape retention rate.	Zenith Aspiration Catheter met the acceptance criteria.
Resistance to Lumen Collapse	The Zenith Aspiration Catheter was inspected for deformation under aspiration.	Zenith Aspiration Catheter met the acceptance criteria.
Tensile Strength and Tip Pull Test	The Zenith Aspiration Catheter was evaluated to verify the tensile strength and tip pull test meet the minimum tensile strength requirement.	Zenith Aspiration Catheter met the acceptance criteria.
Kink Resistance	The Zenith Aspiration Catheter was evaluated for resistance to kinking around bends with clinically relevant radii.	Zenith Aspiration Catheter met the acceptance criteria.
Torque Strength	The Zenith Aspiration Catheter was 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.	Zenith Aspiration Catheter and a cleared comparator showed a similar number of rotations to failure.
Torqueability	After tip shaping, the Zenith Aspiration Catheter was tracked in the vascular model during simulated use and evaluated the steerability and torque response.	Zenith Aspiration Catheter met the acceptance criteria.
Coating Integrity	The Zenith Aspiration Catheter coating integrity was inspected pre- and post- simulated use in an anatomical model.	Zenith Aspiration Catheter met the acceptance criteria.
Coating Lubricity	The Zenith Aspiration Catheter was evaluated for frictional forces on a universal testing machine.	Zenith Aspiration Catheter and the predicate showed similar frictional forces.
Particulate Evaluation	The Zenith Aspiration Catheter was evaluated for particulate generation during simulated use in an anatomical model.	Zenith Aspiration Catheter and the predicate showed similar particle numbers.
Static Burst Pressure	The Zenith Aspiration Catheter was tested according to ISO 10555-1, Annex F.	Zenith Aspiration Catheter met the acceptance criteria.
Dynamic Burst Pressure	The Zenith Aspiration Catheter was tested according to ISO 10555-1, Annex G.	Zenith Aspiration Catheter met the acceptance criteria.

Flowrate	The Zenith Aspiration Catheter was tested according to ISO 10555-1, Annex E.	Zenith Aspiration Catheter met the acceptance criteria.
Vacuum Flowrate	The vacuum flowrate was tested by connecting to a compatible vacuum pump.	Zenith Aspiration Catheter met the acceptance criteria.
Tip Stiffness	The distal tip of the Zenith Aspiration Catheter was deflected on a universal testing machine.	Zenith Aspiration Catheter and the predicate showed similar tip stiffness.
Hub Testing	The hub was tested according to ISO 80369-7 and ISO 80369-20.	Zenith Aspiration Catheter hub met the acceptance criteria.
Liquid Leakage	The Zenith Aspiration Catheter was tested according to ISO 10555-1, Annex C.	Zenith Aspiration Catheter showed no leakage.
Air Leakage	The Zenith Aspiration Catheter was tested according to ISO 10555-1, Annex D.	Zenith Aspiration Catheter showed no leakage.
Lumen Collapse	The force needed to collapse the catheter at the tip and along the Zenith Aspiration Catheter shaft was measured using a universal testing machine.	Zenith Aspiration Catheter met all acceptance criteria for lumen collapse resistance. Collapse forces were comparable to the predicate.
Radiopacity	The catheter was visualized under fluoroscopy.	Zenith Aspiration Catheter and the predicate device were imaged showing equivalence in terms of radiopacity.

Table 3. Bench Performance Testing – Disposable Aspiration Tubing Set

Test	Test Method Summary	Results
Dimensional Verification	The dimensions (inner diameter, outer diameter, effective length) of the Disposable Aspiration Tubing Set were measured.	The Disposable Aspiration Tubing Set met the acceptance criteria.
Surface Inspection	The Disposable Aspiration Tubing Set was visually inspected under microscopy.	The Disposable Aspiration Tubing Set met the acceptance criteria.
Aspiration Resistance	The Disposable Aspiration Tubing Set was subjected to -95 kPa vacuum for 390 seconds repeated five times and the change in outer diameter relative to inner diameter was calculated.	The Disposable Aspiration Tubing Set met the acceptance criteria.
Tensile Strength	The Disposable Aspiration Tubing Set was evaluated to verify the tensile strength meets the minimum tensile strength requirement.	The Disposable Aspiration Tubing Set met the acceptance criteria.
Tip Vacuum Force	The vacuum pressure delivered at the distal tip of the Disposable Aspiration Tubing Set was measured using a vacuum gauge when connected to a vacuum pump.	The Disposable Aspiration Tubing Set met the acceptance criteria.
Freedom from Leakage	The Disposable Aspiration Tubing Set was subjected to -95 kPa continuous negative pressure for 390 seconds repeated five times and inspected for leakage.	The Disposable Aspiration Tubing Set met the acceptance criteria.
Connector Compatibility	The Disposable Aspiration Tubing Set was connected to both a vacuum/suction device and a thrombus aspiration catheter, subjected to -95 kPa for 390 seconds repeated five times with each connection submerged in water, and inspected for leakage.	The Disposable Aspiration Tubing Set met the acceptance criteria.

Switch Performance	The Flow Control Switch of the Disposable Aspiration Tubing Set was cycled between the ON and OFF positions for 30 consecutive cycles under -95 kPa vacuum to verify fluid flow and complete interruption of flow.	The Disposable Aspiration Tubing Set met the acceptance criteria.

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

Biocompatibility Test

Biocompatibility tests were conducted with the Zenith Aspiration Catheter and the Disposable Aspiration Tubing Set in accordance with ISO 10993-1:2018, "*Biological evaluation of medical devices-Evaluation and testing within a risk management process*" and the FDA biocompatibility guidance. The tests performed are listed in Table 4.

Table 4. Biocompatibility Testing

Test	Standards	Results	Conclusion
Zenith Aspiration Catheter			
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
Disposable Aspiration Tubing Set			
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	ISO 10993-10	The saline and sesame oil test article extracts	Non-sensitizer

Maximization Sensitization Test (2 Extracts)		did not show evidence of causing delayed dermal contact 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

Sterilization and Shelf Life

The Zenith Aspiration Catheter and Disposable Aspiration Tubing Set are 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 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 the requirements of ISO 11607-2.

Animal Study

A good laboratory practices (GLP) animal study was conducted to evaluate the safety and performance of the Zenith Aspiration Catheter and Disposable Aspiration Tubing Set in comparison to a marketed control aspiration system in a porcine model. Catheters were compared to appropriate controls at subacute (Day 4) and chronic (Day 29) timepoints through hard and mixed autologous clot aspiration and empty aspiration procedures. Device usability, angiographic safety evaluations using mTICI scoring, and comprehensive histopathological examination were performed.

The test devices performed comparably to controls with successful clot aspiration in all cases and no significant differences in vascular injury patterns between test and control groups. Histopathological evaluation revealed vascular changes consistent with expected mechanical injury from aspiration catheter procedures. The animal study demonstrated that the Zenith Aspiration Catheters have substantially equivalent safety and performance compared to the predicate devices.

Clinical Studies

Clinical testing was not deemed necessary to support the substantial equivalence of the subject device to the predicate devices. 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 devices. The differences in technological characteristics do not raise new questions of safety and effectiveness.