July 16, 2026

Scientia Vascular, Inc.
Thomas Lippert
Regulatory Affairs Specialist
2460 South 3270 West
West Valley City, Utah 84119

Re: K260002
Trade/Device Name: Socrates Aspiration System (Socrates 70 Aspiration Catheter)
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: NRY
Dated: June 17, 2026
Received: June 17, 2026

Dear Thomas Lippert:

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,
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)*
K260002

Device Name
Socrates Aspiration System (Socrates 70 Aspiration Catheter)

Indications for Use *(Describe)*

Socrates Aspiration Catheters

As part of the Socrates Aspiration System, the Socrates Aspiration Catheters with a compatible suction pump 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 intravenous thrombolytic drug therapy or who failed thrombolytic drug therapy are candidates for treatment.

Socrates Aspiration Tubing

As part of the Socrates Aspiration System, the Socrates Aspiration Tubing is indicated to connect the Socrates Aspiration Catheters to a compatible suction 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(K) SUMMARY
K260002
(Per 21 CFR 807.92)

SCIENTIA VASCULAR, INC
Socrates® Aspiration System (Socrates 70 Aspiration Catheter)

Submitter Name and Address
Scientia Vascular, Inc.
2460 South 3270 West
West Valley City, UT 84119

Contact Person
Thomas Lippert
Regulatory Affairs Specialist
Phone: 1 (888) 385-9016
Email: regulatory@scientiavascular.com

Date Prepared
17 June 2026

SUBJECT DEVICE

Trade Name:	Socrates® Aspiration System (Socrates 70 Aspiration Catheter)
Common Name:	Catheter, Thrombus Retriever
Classification Name:	Percutaneous Catheter
Regulation:	21 CFR 870.1250
Product Code:	NRY
Review Panel:	Neurology
Device Class:	Class II

PREDICATE DEVICE
Trade Name: Penumbra System ACE 68 Reperfusion Catheter
Predicate 510(k) Number: K161640

REFERENCE DEVICE
Trade Name: AXS Vecta Aspiration System
Reference Device 510(k) Number: K191768

DEVICE DESCRIPTION

The Scientia Vascular Socrates Aspiration System is composed of three components: the Socrates 38 and 70 Aspiration Catheters, designed to aid in accessing vasculature, and the Socrates Aspiration Tubing, designed to connect the aspiration catheter to a compatible suction pump and control flow between them. When used with a compatible vacuum pump, these components facilitate the aspiration and removal of thrombus from the neurovasculature. All components are supplied sterile for single use only.

The Socrates 70 Aspiration Catheter, a component in the Socrates Aspiration System, is a single lumen, variable stiffness catheter designed to be advanced over a steerable guidewire. The catheter shaft design includes nitinol, polymers of varying durometer, and an internal lubricious liner. To reduce friction during manipulation, a hydrophilic coating is applied to the distal exterior section of the catheter shaft. A single radiopaque tip marker provides visualization under fluoroscopy. The proximal end of the catheter includes a clear hub with Luer lock and a stainless-steel strain relief. The catheter is supplied sterile, for single use only and is packaged with a rotating hemostasis valve (RHV) and three peel-away introducers.

The Socrates Aspiration Tubing is designed to connect the Socrates 38 or Socrates 70 Aspiration Catheter to a compatible vacuum pump and control flow between them. The aspiration tubing consists of tubing attached to a suction connector on one end and a male Luer lock on the other with an intermediate on/off fluid flow control device and is supplied sterile and for single use only.

INTENDED USE

The Socrates System with the Socrates 70 Aspiration Catheter is intended for use in revascularization of patients with acute ischemic stroke.

INDICATIONS FOR USE

Socrates Aspiration Catheters

As part of the Socrates Aspiration System, the Socrates Aspiration Catheters with a compatible suction pump 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 intravenous thrombolytic drug therapy or who failed thrombolytic drug therapy are candidates for treatment.

Socrates® Aspiration Tubing

As part of the Socrates Aspiration System, the Socrates Aspiration Tubing is indicated to connect the Socrates Aspiration Catheters to a compatible suction pump.

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS

The technological characteristics of the Socrates Aspiration System Socrates™ 70 Aspiration Catheter are compared to those of the predicate device, Penumbra System ACE 68 Reperfusion Catheter below. Differences are indicated in **bold.**

Characteristic	**Subject Device Socrates Aspiration System (Socrates 70 Aspiration Catheter)**	**Predicate Device** Penumbra System ACE 68 Reperfusion Catheter (K161640)	**Reference Device** AXS Vecta Aspiration System (K191768)
Indications for Use	As part of the Socrates Aspiration System, the Socrates Aspiration Catheters **with a**	As part of the **Penumbra** System, the **Reperfusion** Catheters **and Separators** are	The AXS Vecta Aspiration Catheter, as part of the AXS Vecta Aspiration System, is

	compatible suction pump 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 intravenous thrombolytic drug therapy or who failed thrombolytic drug therapy are candidates for treatment.** As part of the Socrates Aspiration System, the Socrates Aspiration Tubing is indicated to connect the Socrates Aspiration Catheters to a compatible suction pump.	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. As part of the **Penumbra** System, the **Penumbra Sterile** Aspiration Tubing is indicated to connect the **Penumbra Reperfusion** Catheters to **the Penumbra Pump MAX.** **The Penumbra Pump MAX is indicated as a vacuum source for Penumbra Aspiration Systems.**	indicated 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 intravenous tissue plasminogen activator (IV t-PA) or who failed IV t-PA therapy are candidates for treatment.
Intended Use	Revascularization of patients with acute ischemic stroke.	Revascularization of patients with acute ischemic stroke.	Revascularization of patients with acute ischemic stroke.
Catheter Materials	<u>Hub</u> **Polycarbonate** <u>Strain Relief</u> Stainless Steel <u>Catheter Shaft</u> PEBAX, **Polyurethane**, Nitinol, and PTFE <u>Radiopaque Marker</u> **Tantalum**	<u>Hub</u> Grilamid <u>Strain Relief</u> Stainless Steel, **[hub sleeve] Grilamid** <u>Catheter Shaft</u> PTFE, **Stainless Steel**, Nitinol, **Vestamid,** Pebax**, Tecoflex, Pellathane,** <u>Radiopaque Marker</u> Platinum/ Iridium	<u>Hub</u> **Nylon** <u>Strain Relief</u> **Polyolefin** <u>Catheter Shaft</u> Polymer, Stainless Steel/Nitinol <u>Radiopaque Marker</u> Platinum/Iridium <u>Colorants</u> Not Publicly Available

	Colorants Clear/Natural	Colorants Clear/Natural or **Purple colorants,** **PET yellow, black ink** ID Band **Polyolefin**	
Catheter Dimensions	Outer Diameter **Proximal: 0.085"** **Distal: 0.085"** Inner Diameter **Proximal: 0.070"** **Distal: 0.070"** Effective Lengths 115cm, 132cm, **138cm** Hydrophilic Coating Length **90cm**	Outer Diameter: Proximal: 0.084" Distal: 0.084" Inner Diameter Proximal: 0.068" Distal: 0.068" Effective Lengths 115cm, 120cm, 125cm, 127cm, 132cm Hydrophilic Coating Length 30cm	Outer Diameter: Proximal: 0.087" Distal: 0.083" Inner Diameter Proximal: 0.074" Distal: 0.074" Effective Lengths 115cm, 125cm, 132cm Hydrophilic Coating length 25cm
Coating	Hydrophilic	Hydrophilic	Hyrdrophilic
Tip Shape	Straight	Straight	Straight
Radiopaque Markers	1 distally located radiopaque marker	1 distally located radiopaque marker	1 distally located radiopaque marker
Condition Supplied	Sterile, single use	Sterile, single use	Sterile, single use
Sterilization Method	Ethylene oxide (EO)	EO	EO
Packaged Accessories	Rotating hemostasis valve (RHV), three (3) **peel-away introducers**	RHV, peelable sheath, **shaping mandrel**	RHV, two (2) **peel-away introducers**

When compared with the predicate device, the subject Socrates™ 70 Aspiration Catheter has the technological characteristic differences shown in the table above. These differences do not raise new questions of safety and effectiveness for the subject device.

NON-CLINICAL PERFORMANCE DATA

The following non-clinical performance data were provided in support of the substantial equivalence determination:

- Biocompatibility
- Functional Testing
- Animal Study
- Sterilization, Shelf Life, and Residuals

Biocompatibility

The following biocompatibility evaluations were performed in support of the substantial equivalence determination.

Test	Test Summary	Conclusion of Testing
Cytotoxicity (MEM Elution)	Cell culture was observed for cytotoxic reactivity.	Non-cytotoxic

Sensitization	The study animals with subject device were observed for dermal sensitization.	No sensitization reaction.
Intracutaneous Reactivity	The study animals with subject device were observed for dermal reaction.	No significant dermal reactions at the injected site.
Acute Systemic Toxicity	The study animals with the subject device were observed for abnormal clinical signs indicative of toxicity during the 72-hour test period.	No signs of toxicity.
Material-Mediated Pyrogenicity	The study animals were observed for individual temperature rise.	Non-pyrogenic
Hemolysis (Direct Contact and Extract Method Testing)	The difference between the hemolytic indexes of the subject device and the negative control was evaluated.	Non-hemolytic
Complement Activation of SC5b-9	Comparison of the subject device SC5b-9 value to the predicate device for all exposure times was performed.	The two samples are considered similar.
Thrombogenicity	Hemocompatibility: In Vitro Blood Loop Partial Thromboplastin Time (PTT) Platelet and Leukocyte Count (PLC) Comparative Surface Assessment	Considered similar to the predicate.

Functional Testing

The following functional tests were conducted in support of the substantial equivalence determination:

Test	Test Method Summary	Results
Tensile and Elongation	Reference ISO-10555-1:2013. Peak tensile force and elongation measured by displacement at break.	Pass
Tip Stiffness	The cantilever bending stiffness of the catheter tip was measured.	Pass
Kink Radius	Minimum kink radius was measured by wrapping the catheter around mandrels of varying size.	Pass
Liquid Leak and Static Burst	Per ISO-10555-1:2013.	Pass
Positive Flow Rate	Reference ISO-10555-1:2013. Dynamic flow rate was characterized. Dynamic leak and burst were evaluated.	Pass
Compatibility with Agents	Compatibility was evaluated by functionally testing catheters following exposure to contrast media and saline.	Pass
Torque Turns to Failure	Torque turns to failure were evaluated in an anatomical model.	Pass
Visual and Dimensional Inspections	Test per ISO-10555-1:2013. Dimensional inspection per engineering drawings.	Pass
Flexural Fatigue	The catheter was flexed for multiple cycles and inspected for damage.	Pass
Air Ingress	Tested for air ingress through catheter hub per ISO-10555-1:2013.	Pass
Negative Collapse	Negative collapse measures catheter lumen integrity while the catheter is subjected to a worst-case vacuum pressure.	Pass
Hub Luer Design Verification	Test per ISO-80369-7.	Pass
Usability and Radiopacity Validation	Physicians evaluated various performance characteristics of the subject and predicate catheters, including radiopacity, in a human cadaver.	Pass
Coating Lubricity, Durability, and Integrity	Frictional force of the coated catheter portion was determined after simulated use in a tortuous path model. Hydrophilic coating of the catheter was inspected before and after simulated use in a tortuous path model with interfacing ancillary devices.	Pass

Test	Test Method Summary	Results
Corrosion Resistance	Per ISO-10555-1:2013	Pass
Particulate Characterization	Particulates of various size ranges were counted after simulated use in a tortuous path model with comparison to the predicate.	Pass
Model and Product Compatibility Testing	Catheters were advanced through a representative neurovascular anatomical model with the use of interfacing ancillary devices and compared with the predicate device.	Pass
Delivery and Retrieval Testing	Measured the forces required to deliver and retrieve the catheter in a tortuous pathway with ancillary devices.	Pass
Suction Flow Rate	Measured the suction flow rate at maximum pressure while the catheter is connected to the aspiration tubing.	Pass

Animal Study

The safety and effectiveness of the Socrates Aspiration System (including the Socrates 70 Aspiration Catheter) was evaluated in a comparative porcine study conducted under Good Laboratory Practices (GLP) against a cleared control system. Both the subject and control systems were evaluated at subacute (3 day) and chronic (30 day) time points, with three animals evaluated at each time point. Assessments included aspiration of experimental soft clots from the left or right ascending pharyngeal arteries, firm clots from the left or right renal arteries, and application of maximum vacuum with the device in a wedged position against the vessel wall in the left or right lingual artery.

Modified TICI (Thrombolysis in Cerebral Infarction) scores were assigned after clot aspiration. Following treatment, in-life monitoring, necropsy, angiography, histopathological and downstream organ assessments were conducted. Clot aspiration and wedge assessment results were comparable between the test and control systems. Angiographic and histological evaluations concluded the systems were comparable at all time points. There were no significant gross or histological findings suggestive of significant vascular injury (lesions, dissection, perforation, infarction, etc.) in the test or control treated vessels at either time point. Additionally, there were no gross or histological findings in nontarget organs which were attributable to the test or control articles at either time point. Therefore, the study endpoints support equivalent safety and performance of the Socrates Aspiration System when compared with the reference device.

Sterilization, Shelf-Life, and Residuals

Additionally, the subject device and its packaging were evaluated for the proposed shelf-life, packaging integrity and sterilization including ethylene oxide (EO), ethylene chlorohydrin (ECH) residuals, and bacterial endotoxin levels. The subject device met the predetermined acceptance criteria.

CLINICAL PERFORMANCE DATA

The non-clinical performance data presented were determined to be sufficient to support the substantial equivalence of the Socrates Aspiration System (Socrates 70 Aspiration Catheter) to the predicate. Therefore, no clinical study was conducted.

CONCLUSION

The subject device, Socrates Aspiration System (Socrates 70 Aspiration Catheter), has the same intended use and similar indications for use as the predicate device. The differences in technological characteristics do not raise new questions of safety or effectiveness and have been evaluated through non-clinical performance testing. The resulting data demonstrate that the subject device is substantially equivalent to the predicate.