September 20, 2023

Scientia Vascular, Inc.
Thomas Lippert
Regulatory Affairs Associate
3487 West 2100 South Suite 100
West Valley City, Utah 84119

Re: K223913
Trade/Device Name: Socrates Aspiration System
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: NRY
Dated: August 22, 2023
Received: August 23, 2023

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 (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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K223913

Device Name
Socrates™ Aspiration System

Indications for Use *(Describe)*

As part of the Socrates Aspiration System, the Socrates 38 Aspiration Catheter with a compatible suction 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 intravenous tissue plasminogen activator (IV t-PA) or who fail IV t-PA therapy are candidates for treatment.

As part of the Socrates Aspiration System, the Socrates Aspiration Tubing is indicated to connect the Socrates 38 Aspiration Catheter to a compatible suction pump.

Type of Use *(Select one or both, as applicable)*

[X] 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 K223913
(Per 21 CFR 807.92)

SCIENTIA VASCULAR, INC
Socrates™ Aspiration System

SUBMITTER

Submitter Name and Address
Scientia Vascular, Inc.
3487 West 2100 South Suite 100
West Valley City, UT 84119

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

Date Prepared
September 20, 2023

DEVICE

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

PREDICATE DEVICE

Predicate Device

Trade Name:	Penumbra System® MAX
Predicate 510(k) Number:	K113163
Device Models:	Reperfusion Catheters 3MAX and 4MAX

DEVICE DESCRIPTION

The Scientia Vascular Socrates Aspiration System is composed of two components: the Socrates 38 Aspiration Catheter, 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. Both components are supplied sterile for single use only.

The Socrates 38 Aspiration Catheter 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).

The Socrates Aspiration Tubing is designed to connect the Socrates 38 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 Aspiration System with a compatible suction pump is intended for use in the revascularization of patients with acute ischemic stroke.

INDICATIONS FOR USE

As part of the Socrates Aspiration System, the Socrates 38 Aspiration Catheter with a compatible suction 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 intravenous tissue plasminogen activator (IV t-PA) or who fail IV t-PA therapy are candidates for treatment.

As part of the Socrates Aspiration System, the Socrates Aspiration Tubing is indicated to connect the Socrates 38 Aspiration Catheter to a compatible suction pump.

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS

The technological characteristics of the Socrates Aspiration System are compared to those of the predicate device, the Penumbra System® MAX (K113163) in Table 1, below.

Table 1. Comparison between Subject & Predicate Device Technological Characteristics
Note: Differences are bolded

Characteristic	Subject Device Socrates Aspiration System (K223913)	Predicate Device Penumbra System® MAX (K113163) Reperfusion Catheter 3MAX unless otherwise noted	Comparison Analysis
Indications for Use	**As part of** the Socrates Aspiration System, the Socrates 38 Aspiration Catheter **with a compatible suction pump** is **indicated** for use in the revascularization of patients with acute ischemic stroke secondary to intracranial large vessel occlusive disease (**with**in 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 fail IV t-PA therapy are candidates for treatment.** **As part of the Socrates Aspiration System, the Socrates Aspiration Tubing is indicated to connect the Socrates 38 Aspiration Catheter to a compatible suction pump.**	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 differences reflect that the subject device does not include a suction pump and the more current wording regarding IV t-PA therapy.

Intended Use	Revascularization of patients with acute ischemic stroke.	Revascularization of patients with acute ischemic stroke.	Same
Catheter Materials	Hub Polycarbonate Strain Relief Stainless Steel Catheter Shaft PEBAX, **Polyurethane**, Nitinol, and PTFE Radiopaque Marker **Tantalum**	Hub Polycarbonate Strain Relief Stainless Steel Catheter Shaft Polyether Block Amide (PEBAX), Urethane, Nylon, Stainless Steel/Nitinol, and PTFE Radiopaque Marker Platinum/Iridium	The differences have been evaluated via non-clinical testing.
Catheter Dimensions	Outer Diameter Proximal: **0.053"** Distal: **0.053"** Inner Diameter Proximal: **0.038"** Distal: **0.038"** Effective Lengths **115 cm and 156 cm** Hydrophilic Coating length **90 cm**	Outer Diameter (3MAX) Proximal: 0.062" Distal: 0.050" Outer Diameter (4MAX) Proximal: 0.080" Distal: 0.056" Inner Diameter (3MAX) Proximal: 0.043" Distal: 0.035" Inner Diameter (4MAX) Proximal: 0.064" Distal: 0.041" Effective Lengths (3MAX) 153 cm Hydrophilic Coating length 95 cm Effective Lengths (4MAX) 139 cm Hydrophilic Coating length Unknown	The differences have been evaluated via non-clinical testing.

Coating	Hydrophilic	Hydrophilic	Same
Tip Shape	Straight	Straight	Same
Radiopaque Markers	1 Distally Located Radiopaque Marker	1 Distally Located Radiopaque Marker	Same
Condition Supplied	Sterile, Single Use	Sterile, Single Use	Same
Sterilization Method	Ethylene Oxide (EO)	EO	Same
Packaged Accessories	Rotating Hemostasis Valve (RHV)	RHV **and Shaping Mandrel**	Similar
Aspiration Tubing Set Features	Length: **100 in (254 cm)** Inner Diameter (ID): 0.110 in Vacuum control: **Clamp**	Length: 112 in. ID: 0.110 in Vacuum control: Flow Switch	The differences have been evaluated via non-clinical testing.
Aspiration Pump Features	Pressure: -20 inHg to -29inHg	Pressure: -20 inHg to -29inHg	Same

The subject device, Socrates Aspiration System, has technological characteristic differences as shown in Table 1 above when compared to the predicate device. These differences do not raise new questions of safety and effectiveness for the subject device. Evaluation of the risks for the subject device in the form of failure modes and effect analysis (FMEA) was conducted along with testing of the subject device to demonstrate the substantial equivalence to the predicate.

NON-CLINICAL PERFORMANCE DATA

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

- Biocompatibility
- Functional Testing
- Animal Study

Biocompatibility Testing

The biocompatibility evaluation of the subject device, Socrates Aspiration System, was performed in accordance with ISO 10993-1: 2018, and is summarized in Table 2 below.

Table 2. Summary of Subject Device Biocompatibility Testing Performed		
Test	**Test Summary**	**Conclusion of Testing**
Socrates 38 Aspiration Catheter		
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
Partial Thromboplastin Time (PTT)	The clotting time was observed for both the subject device and the predicate.	The two samples are considered similar.
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.
Hemocompatibility: In Vitro Blood Loop	The catheters are placed in an in-vitro blood loop for three runs. The thrombus score for the subject device and predicate device is observed.	Thromboresistant
Socrates Aspiration Tubing		
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 (Extract Method Testing)	The difference between the hemolytic indexes of the subject device and the negative control was evaluated.	Non-hemolytic

Functional Testing

Following a risk assessment performed per ISO 14971:2012 Medical Devices – Application of Risk Management to Medical Devices, the functional testing summarized in Table 3 was performed in accordance with the following standards:

- ISO 10555-1:2013 (corrected 2014) Intravascular catheters – Sterile and single-use catheters – Part 1: General requirements,
- ISO 80369-7:2016 Small bore connectors for liquids and gases in healthcare applications – Connectors for intravascular or hypodermic applications,
- ISO 80369-20:2015 Small bore connectors for liquids and gases in healthcare applications - Common test methods,
- AAMI TIR 42: 2021 – Evaluation of Particulates Associated with Vascular Medical Devices.

As well as the FDA Guidance Documents:

- Intravascular Catheters, Wires, and Delivery Systems with Lubricious Coatings - Labeling Considerations (October 2019),
- Non-Clinical Engineering Tests and Recommended Labeling for Intravascular Stents and Associated Delivery Systems (April 2010).

Table 3. Summary of Subject Device Functional Testing

Socrates 38 Aspiration Catheter		
Test	**Test Method Summary**	**Results**
Visual & Dimensional	Test per ISO-10555-1:2014. Dimensional inspection per engineering drawings.	Pass
Dynamic Flow	Reference ISO-10555-1:2014. Dynamic flow rate was characterized.	Pass
Liquid Leak / Static Burst	Test Per ISO-10555-1:2014.	Pass
Torque - Turns to Failure	Torque - turns to failure were evaluated in an anatomical model with comparison to the predicate.	Pass
Simulated Clot Retrieval and Compatibility Testing (System)	An anatomical model designed to simulate the tortuous neurovasculature was used for performance (including simulated thrombectomy) testing with the aspiration system (tubing and RHV) attached to a vacuum pump.	Pass
Tensile/Elongation	Reference ISO-10555-1:2014. Peak tensile force and elongation measured by displacement at break.	Pass

Flexural Fatigue	The catheter was flexed for multiple cycles and inspected for damage.	Pass
Particulate	Particulates of various size ranges were counted after simulated use in a tortuous path model with comparison to the predicate.	Pass
Coating Integrity	Frictional force of the coated catheter portion was determined after simulated use in a tortuous path model. Coating integrity was visually inspected pre- and post-simulated use.	Pass
Suction Flow Rate (System)	Measured the suction flow rate at maximum pressure while the catheter is connected to the aspiration tubing.	Pass
Tip Stiffness	Measured the cantilever bending stiffness of the catheter tip.	Pass
Delivery and Retrieval	Measured the forces required to deliver and retrieve the catheter in a tortuous pathway with ancillary devices.	Pass
Air Ingress/Negative Collapse	Test per ISO-10555-1:2014 for air ingress through the catheter hub. Negative collapse testing checks for catheter lumen integrity while being subjected to a worst-case vacuum pressure.	Pass
Kink Radius	The catheter is wrapped around mandrels of descending sizes to determine minimum kink radius.	Pass
Hub Luer Design Verification	Test per ISO-80369-7.	Pass
Corrosion Resistance	Test Per ISO-10555-1:2014.	Pass

Compatibility with Agents	The catheters were inspected and functionally tested post exposure to agents (contrast media and saline) used during test procedures.	Pass
Usability and Radiopacity Validation	Physicians evaluated subject and predicate catheters for various performance characteristics, including radiopacity, in a human cadaver.	Pass
Socrates Aspiration Tubing		
Visual & Dimensional	Visual and dimensional inspection per engineering drawing.	Pass
Vacuum Drop	The aspiration tubing was evaluated for ability to hold a vacuum over a specified time period.	Pass
Leakage	The ability of the clamp to prevent leakage after a specified number of cycles was evaluated.	Pass
Negative Collapse (Degree of Collapse)	Test per ISO 10079-4.	Pass
Joint Tensile	Peak tensile force measured at break.	Pass
Simulated Clot Retrieval and Compatibility Testing (System)	An anatomical model designed to simulate the tortuous neurovasculature was used for performance (including simulated thrombectomy) testing with the aspiration system (tubing and RHV) attached to a vacuum pump.	Pass
Suction Flow Rate (System)	Measured the suction flow rate at maximum pressure while the catheter is connected to the aspiration tubing.	Pass

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

Animal Study

The safety and effectiveness of the Socrates Aspiration System was evaluated in a comparative animal study conducted under Good Laboratory Practices (GLP) in a porcine model against a control (the Penumbra System with the ACE 68 Reperfusion Catheter). Assessments included aspiration of experimental soft and firm clots and application of maximum vacuum with the device in a wedged position against the vessel wall. Both the subject and control systems were evaluated at subacute (3 day) and chronic (30 day) time points. 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.

CLINICAL PERFORMANCE DATA

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

CONCLUSION

The subject device, Socrates Aspiration System, 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 testing and the resulting data demonstrate that the subject device, Socrates Aspiration System, is substantially equivalent to the predicate.