December 4, 2024

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

Re: K242301
Trade/Device Name: Socrates™ 38 Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: QJP, DQY
Dated: November 1, 2024
Received: November 1, 2024

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 System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 systems (QS) regulation (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,

Michael Mcknight -S

for 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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K242301

Device Name
Socrates™ 38 Catheter

Indications for Use *(Describe)*
The Socrates™ 38 Catheter is indicated for use in facilitating the insertion and guidance of an appropriate microcatheter or diagnostic agents into a selected blood vessel in the peripheral or neuro vasculature. The Socrates™ 38 Catheter is not intended for use in the coronary vasculature.

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

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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

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510(K) SUMMARY
K242301
(Per 21 CFR 807.92)

SCIENTIA VASCULAR INC
Socrates 38 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
4 December 2024

SUBJECT DEVICE

Trade Name:	Socrates™ 38 Catheter
Common Name:	Catheter, percutaneous, neurovasculature
Classification Name:	Percutaneous catheter
Regulation:	21 CFR 870.1250
Primary Product Code:	QJP
Secondary Product Code:	DQY
Review Panel:	Neurology
Device Class:	Class II device per 21 CFR 870.1250

PREDICATE DEVICE
Trade Name: Modified HD Guide Catheter
Predicate 510(k) Number: K133177

REFERENCE DEVICE
Trade Name: Socrates Aspiration System
Predicate 510(k) Number: K223913
Device Models: Socrates™ 38 Aspiration Catheter

DEVICE DESCRIPTION

Scientia Vascular's Socrates™ 38 Catheter is a single lumen, variable stiffness, open-ended catheter designed to track through a guide catheter using a steerable guidewire and microcatheter. 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).

INTENDED USE

The Socrates™ 38 Catheter is intended to provide access to the neuro and peripheral vasculatures.

INDICATIONS FOR USE

The Socrates™ 38 Catheter is indicated for use in facilitating the insertion and guidance of an appropriate microcatheter or diagnostic agents into a selected blood vessel in the peripheral or neuro vasculature. The Socrates™ 38 Catheter is not intended for use in the coronary vasculature.

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS

The technological characteristics of the Socrates™ 38 Catheter are compared to those of the predicate device, the Modified HD Guide Catheter below. Differences are indicated in **bold.**

Characteristic	Subject Device Socrates 38 Catheter	Predicate Device Modified HD Guide Catheter (K133177)	**Reference Device (comparisons vs subject)** The Socrates Aspiration System (K223913)	Comparison analysis (subject device vs predicate device)
Indications for Use	The **Socrates™ 38 Catheter** is indicated for use in facilitating the insertion and guidance of **an appropriate microcatheter or diagnostic agents** into a selected blood vessel in the peripheral or neuro **vasculature**. **The Socrates™ 38 Catheter is not intended for use in the coronary vasculature.**	The modified HD guide catheter is indicated for use in facilitating the insertion and guidance of an occlusion catheter, infusion catheter or other appropriate microcatheter into a selected blood vessel in the peripheral, **coronary**, and neuro vascular systems. It may also be used as a diagnostic angiographic catheter and as a conduit for retrieval devices	**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**	Different

			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.**	
Intended Use	Vascular access	Vascular access	**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 PEBAX Strain Relief Polyolefin Catheter Shaft PEBAX, Stainless Steel, **Acrylic** and PTFE Radiopaque Marker Platinum/ Iridium	Same	Different
Catheter Dimensions	Outer Diameter Proximal: **0.053"** Distal: **0.053"** Inner Diameter Proximal: 0.038" Distal: 0.038" Effective Lengths 115 cm, 127cm, and **156 cm**	Outer Diameter: Proximal: 0.051" Distal: 0.051" Inner Diameter Proximal: 0.038" Distal: 0.038" Effective Lengths 105-136 cm	Same	Different

	Hydrophilic Coating length 90 cm	Hydrophilic Coating length Unknown		
Coating	Hydrophilic	Hydrophilic	Same	Same
Tip Shape	Straight	Straight	Same	Same
Radiopaque Markers	1 distally located radiopaque marker	1 distally located radiopaque marker	Same	Same
Condition Supplied	Sterile, Single Use	Sterile, Single Use	Same	Same
Sterilization Method	Ethylene Oxide (EO)	Ethylene Oxide (EO)	Same	Same
Packaged Accessories	Rotating Hemostasis Valve (RHV)	Rotating Hemostasis Valve (RHV)	Same	Same

When compared with the predicate device, the subject Socrates™ 38 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. To evaluate the effects of these characteristic differences on safety and effectiveness, performance testing was conducted.

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

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

Performance Data – Biocompatibility
Performance data demonstrating the biocompatibility of the subject Socrates™ 38 Catheter per ISO 10993-1:2018 are leveraged from evaluations supporting the reference Socrates™ 38 Aspiration Catheter (K223913), which has the same design, components, materials, and manufacturing process as the subject device. No further required biocompatibility assessments were identifed.

Performance Data – Functional Testing
Non-clinical functional testing was leveraged and conducted in support of the substantial equivalence determination.

The following functional tests were leveraged for the Socrates™ 38 Catheter from K223913:

Test	Test Method Summary	Results
Tensile and Elongation	Reference ISO-10555-1:2014. 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-10555-1:2014.	Pass

Test	Test Method Summary	Results
Dynamic Flow	Reference ISO-10555-1:2014. Dynamic flow rate was characterized.	Pass
Agent Compatibility	Compatibility was measured 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 and compared with the predicate.	Pass
Visual and Dimensional Inspections	Test per ISO-10555-1:2014. Dimensional inspection per engineering drawings.	Pass
Flexural Fatigue	The catheter was flexed for multiple cycles and inspected for damage.	Pass
Air Ingress and Negative Collapse	Air ingress through catheter hub per ISO-10555-1:2014. Negative collapse measures catheter lumen integrity while the catheter is subjected to a worst-case vacuum pressure.	Pass
Model and Compatibility Testing	An anatomical model designed to simulate the tortuous neurovasculature was used for performance with ancillary devices.	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 catheter, including radiopacity in a human cadaver.	Pass
Lubricity and Durability	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
Corrosion Resistance	Per ISO-10555-1:2014	Pass

The following functional tests were conducted for the Socrates™ 38 Catheter:

Test	Test Method Summary	Results
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 Evaluation	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
Coating Integrity	Hydrophilic coating of catheter was inspected before and after simulated use in a tortuous path model with interfacing ancillary devices.	Pass

Performance Data – Sterilization, Shelf-Life, and Residuals

Additionally, testing evaluating subject device and packaging for shelf-life, packaging integrity and sterilization including EO, ECH residuals, and bacterial endotoxin levels was leveraged from K223913. The subject device met all acceptance criteria.

CLINICAL PERFORMANCE DATA

The non-clinical performance data presented were determined to be sufficient to support the substantial equivalence of the Socrates™ 38 Catheter. Therefore, no clinical study was conducted.

CONCLUSION

The subject device, Socrates™ 38 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.