August 21, 2023

Scientia Vascular, Inc.
Max Alfonso
Regulatory Affairs Specialist
3487 West 2100 South Suite 100
West Valley City, Utah 84119

Re: K223560
Trade/Device Name: Plato 17 Microcatheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: QJP, DQY
Dated: July 20, 2023
Received: July 21, 2023

Dear Max Alfonso:

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
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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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K223560

Device Name
Plato® 17 Microcatheter

Indications for Use *(Describe)*
The Plato 17 Microcatheter is intended for the introduction of therapeutic devices, infusion of diagnostic agents, such as contrast media, and delivery of embolization materials to the peripheral and neuro vasculature systems. The Plato 17 Microcatheter 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.

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510(K) SUMMARY K223560
(Per 21 CFR 807.92)

SCIENTIA VASCULAR, INC.
Plato® 17 Microcatheter

Submitter Name and Address:

Scientia Vascular, Inc.

3487 West 2100 South Suite 100

West Valley City, UT 84119

Contact Person: **Max Alfonso**

Regulatory Affairs Specialist

Phone: 1 (888) 385-9016

Email: regulatory@scientiavascular.com

Date Prepared: 18 August 2023

Trade Name:	Plato® 17 Microcatheter
Common Name:	Microcatheter
Classification Name:	Catheter, Percutaneous
Primary Product Code:	QJP
Secondary Product Code:	DQY
Review Panel:	Neurology
Device Class:	Class II device per 21 CFR 870.1250
Predicate Device:	Plato® 17 Microcatheter (K210601, cleared 04/28/2021)

DEVICE DESCRIPTION

Scientia Vascular's Plato® 17 Microcatheter is a single lumen, open-ended catheter designed to be flexible and axially stable, to aid the physician in the accessing of the distal neuro and peripheral vasculature. The Plato® 17 Microcatheter is supplied sterile and is for single use only. The Plato® 17 Microcatheter is supplied in various tip configurations, including straight and pre-shaped (45° and 90°). The microcatheter shaft design includes nitinol, polymers of varying durometer, and an internal liner providing lubricity for therapeutic device, diagnostic agent, and embolization material delivery. The distal exterior section of the catheter shaft is hydrophilic coated to reduce friction during manipulation in vessels. The microcatheter includes two radiopaque tip markers to facilitate fluoroscopic visualization and a clear hub with luer lock and a strain relief.

The microcatheter is provided with a steam shaping mandrel, peel-away introducer, and a ruler. The shaping mandrel, peel-away introducer, and ruler are accessories included to facilitate use of the microcatheter and are not intended to contact the patient's body.

The Plato® 17 Microcatheter is substantially equivalent with respect to intended use, technological characteristics, design, and materials to Scientia Vascular's currently marketed Plato® 17 Microcatheter cleared under K210601.

INTENDED USE

To assist in delivery of therapeutic devices and embolization materials and infusion of diagnostic agents to the neuro and peripheral vasculature during interventional or diagnostic procedures.

INDICATIONS FOR USE

The Plato 17 Microcatheter is intended for the introduction of therapeutic devices, infusion of diagnostic agents, such as contrast media, and delivery of embolization materials to the peripheral and neuro vasculature systems. The Plato 17 Microcatheter is not intended for use in the coronary vasculature.

TECHNOLOGICAL CHARACTERISTICS

The Plato® 17 Microcatheter is equivalent or similar to the predicate device in the following ways:

- Functionality
- Intended use
- Materials
- Design
- Biological safety

Shown in the table below is the comparison of technological characteristics for the Plato® 17 Microcatheter to those of the predicate device, the Plato® 17 Microcatheter (K210601).

Table 1: Comparison between Subject & Predicate Device Technological Characteristics: Note: Differences are **bolded**.			
Characteristic	Subject Device Plato® 17 Microcatheter (K223560)	Predicate Device Plato® 17 Microcatheter (K210601)	Comparison Analysis
Anatomical Location	Neuro and peripheral vasculature	Neuro and peripheral vasculature	Same
Indications for Use	The Plato 17 Microcatheter is intended for the introduction of **therapeutic devices**, infusion of diagnostic agents, such as contrast media, and **delivery of embolization materials** to the peripheral and neuro vasculature systems. The Plato 17 Microcatheter is not intended for use in the coronary vasculature.	The Plato 17 Microcatheter is intended for the introduction of embolic coils and infusion of diagnostic agents, such as contrast media, to the peripheral and neuro vasculature systems. The Plato 17 Microcatheter is not intended for use in the coronary vasculature.	Similar
Materials	Hub: Clear polymer	Hub: Clear polymer	Same
	Strain Relief: Thermoplastic Elastomer	Strain Relief: Thermoplastic Elastomer	Same
	Catheter Shaft: Polyamide, Nitinol, Stainless Steel, and PTFE	Catheter Shaft: Polyamide, Nitinol, Stainless Steel, and PTFE	Same
	Radiopaque Marker Bands: Platinum Iridium	Radiopaque Marker Bands: Platinum Iridium	Same
Proximal ID	0.017” (0.43mm)	0.017” (0.43mm)	Same
Proximal OD	2.1F (0.70mm)	2.1F (0.70mm)	Same
Distal ID	0.017” (0.43mm)	0.017” (0.43mm)	Same
Distal OD	1.7F (0.60mm)	1.7F (0.60mm)	Same
Effective Length	160cm	160cm	Same
Tip Design	Straight and pre-shaped tips	Straight and pre-shaped tips	Same
Steam-Shapeable tip	Yes	Yes	Same

Table 1: Comparison between Subject & Predicate Device Technological Characteristics: Note: Differences are **bolded**.			
Characteristic	Subject Device Plato® 17 Microcatheter (K223560)	Predicate Device Plato® 17 Microcatheter (K210601)	Comparison Analysis
Distal Coating	Hydrophilic coating	Hydrophilic coating	Same
Coated Length	90cm	90cm	Same
Radiopaque Markers	2 radiopaque markers located at distal tip of the microcatheter	2 radiopaque markers located at distal tip of the microcatheter	Same
Sterilization Method	100% Ethylene Oxide (EO)	100% Ethylene Oxide (EO)	Same
Guidewire Compatibility	0.014”	0.014”	Same
Accessories: Introducer	Included (**ID: 0.060”**)	Included (ID: 0.045”)	Different
Accessories: Tip Shaping Mandrel	0.015” diameter stainless steel tip shaping mandrel included	0.015” diameter stainless steel tip shaping mandrel included	Same
Accessories: Ruler	Included	Included	Same

The subject device, Plato® 17 Microcatheter, has similar intended use and the same fundamental technological characteristics (design, materials, and device features) when compared to the predicate device. The subject device completed and passed required nonclinical testing to support the expanded indications for use. The difference in technological characteristics and intended use do not raise new or different questions of safety and effectiveness for the subject device.

NON-CLINICAL PERFORMANCE TESTS

Results of tests performed on the subject Plato® 17 Microcatheter demonstrates it met the testing acceptance criteria, performs as well as the predicate device, and/or meets requirements of relevant standards and FDA guidance documents.

Biocompatibility

The biocompatibility evaluation for the subject device, Plato® 17 Microcatheter, was performed in accordance with ISO 10993-1: 2018. The previously conducted testing from the predicate device submission, K210601, was used to support the biocompatibility of the subject device and the following

additional testing was also conducted:

Table 2: Summary of Subject Device Biocompatibility Testing Performed.		
Name of Test	Test Summary	Conclusion of Testing
Cytotoxicity: MEM Elution	Cell culture was observed for cytotoxic reactivity.	Non-cytotoxic.
Direct Contact and Extract method Hemolysis Test	The difference between the hemolytic indexes of the subject device and the negative control was evaluated.	Non-hemolytic.
Partial Thromboplastin Time (PTT) Test	The clotting time was observed for both the subject device and the predicate.	Non-activator.
Platelet Leukocyte Counts	The concentration of platelets and leukocytes were determined on an automated hematology analyzer.	Non-activator.

Functional Testing

Functional testing was performed in accordance with the following standards:

- ISO 80369-7:2021 - 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,
- ISO 10555-1:2013 (corrected 2014) - Intravascular catheters - Sterile and single-use catheters - Part 1: General requirements,

as well as the FDA Guidance Documents:

- Premarket Notifications [510(k)] Submissions for Short-Term and Long-Term Intravascular Catheters (March 1995),
- Non-Clinical Engineering Tests and Recommended Labeling for Intravascular Stents and Associated Delivery Systems (April 2010),
- Coronary, Peripheral, and Neurovascular Guidewires - Performance Tests and Recommended Labeling (October 2019),
- Intravascular Catheters, Wires, and Delivery Systems with Lubricious Coatings - Labeling Considerations (October 2019).

The design of the subject device is unchanged when compared to the predicate device, K210601. Therefore, the functional testing from K210601 for the predicate device is utilized and adopted for the subject device. Table 3 Summarizes the additional functional verification testing performed as part of this submission.

Table 3: Summary of Subject Device Functional Testing.		
Test	Attribute and Acceptance Criteria	Results
Accessory Verification	The Peel-Away Introducer must facilitate introduction of catheter into a guide catheter.	PASS
Therapeutic Device Compatibility and Simulated Use	The Plato® 17 Microcatheter can successfully deliver representative therapeutic devices, including stent, in a tortuous neurovascular model. The Plato® 17 Microcatheter was evaluated for delivery to target location and functionality post therapeutic device delivery.	PASS
Embolization Material Compatibility	Visual inspection, lumen check, liquid leakage, static burst, tensile and force to withdraw testing was conducted for the Plato® 17 Microcatheter using representative embolization materials in a tortuous neurovascular model.	PASS

Additionally, the sterilization process of the subject device is identical to the predicate device K210601. The shelf-life testing, packaging integrity, and sterilization including EO, ECH residuals and bacterial endotoxin levels for the subject device are supported by the testing conducted for the predicate device.

CONCLUSION

The Plato® 17 Microcatheter has similar intended use and technological characteristics when compared to the predicate device. The identified differences in the indications for use statement and accessory introducer diameter do not raise new questions of safety or effectiveness. Risk evaluation along with testing, functional and biological, was completed for the subject device. The testing and risk evaluation demonstrate that the subject device is substantially equivalent to the predicate. The subject device and the predicate device have similar intended use, the same fundamental technological characteristics, and similar functional performance, as demonstrated through testing.