April 28, 2021

Scientia Vascular, LLC
% Prithul Bom
Responsible Third Party Official
Regulatory Technology Services, LLC
1000 Westgate Drive, Suite #510k
Saint Paul, Minnesota 55114

Re: K210601
Trade/Device Name: Plato 17 Microcatheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: DQY, QJP
Dated: April 20, 2021
Received: April 21, 2021

Dear Prithul Bom:

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, 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)*
K210601

Device Name
Plato® 17 Microcatheter

Indications for Use *(Describe)*

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.

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
(Per 21 CFR 807.92)

SCIENTIA VASCULAR, LLC
Plato® 17 Microcatheter

Submitter Name and Address:

Scientia Vascular, LLC

3487 West 2100 South Suite 100

West Valley City, UT 84119

Contact Person: **Amy McManus**

Regulatory Affairs Manager

Phone: 1 (888) 385-9016

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Date Prepared: March 2021

Trade Name:	Plato® 17 Microcatheter
Common Name:	Microcatheter
Classification Name:	Catheter, Percutaneous
Primary Product Code:	DQY
Secondary Product Code:	QJP
Review Panel:	Cardiovascular
Device Class:	Class II device per 21 CFR 870.1250
Predicate Device:	Excelsior™ SL-10 Pre-Shaped Microcatheter (K042568, cleared 10/15/2004)
Reference Device	Excelsior XT-17 Microcatheter (K142565, cleared 11/14/2014)

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 distal vasculature. The Plato 17 Microcatheter is supplied sterile and is for single use only. The Plato 17 Microcatheter is packaged with 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 intraluminal delivered embolic coils and contrast media; the distal exterior section of the catheter shaft is hydrophilic coated to reduce friction during manipulation in vessels. The working length of the catheter is 160 cm. The microcatheter includes two radiopaque tip markers to facilitate fluoroscopic visualization and a clear hub with luer lock and a strain relief. The Plato 17 Microcatheter is compatible with 0.014 inch guidewires or embolic coils.

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 technological characteristics, design, and materials to the currently marketed Excelsior™ SL-10 Pre-Shaped Microcatheter cleared under K042568, by Boston Scientific.

INDICATIONS FOR USE / INTENDED USE

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.

TECHNOLOGICAL CHARACTERISTICS

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

- Functionality
- Intended use
- Indication for use
- 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 Excelsior SL-10 Pre-Shaped Microcatheter (K042568) and reference device Excelsior XT-17 Microcatheter (K142565).

Table 1: Comparison between Subject, Predicate & Reference Device Technological Characteristics:				
Characteristic	Subject Device Plato® 17 Microcatheter	Predicate Device Excelsior™ SL-10 Pre-Shaped Microcatheter (K042568)	Reference Device Excelsior XT-17 Microcatheter (K142565)	Comparison Analysis
Anatomical Location	Neuro and peripheral vasculature	Neuro, coronary, and peripheral vasculature	Neuro, coronary, and peripheral vasculature	Similar
Indications for Use	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.	"Boston Scientific's Excelsior™ SL-10 Pre-Shaped Microcatheter and Excelsior™ 1018™ Pre-Shaped Microcatheter are intended to assist in the delivery of diagnostic agents, such as contrast media, and therapeutic agents, such as occlusion coils to the peripheral, coronary, and neuro vasculature."	"Stryker Neurovascular's Excelsior XT-17 Microcatheters are intended to assist in the delivery of diagnostic agents, such as contrast media, and therapeutic agents, such as occlusion coils, into the peripheral, coronary and neuro vasculature."	Similar
Materials	Hub: Clear polymer	Hub: Clear polymer	Hub: Clear polymer	Same
	Strain Relief: Thermoplastic Elastomer	Strain Relief: Thermoplastic Elastomer	Strain Relief: Thermoplastic Elastomer	Same
	Catheter Shaft: Polyamide over **Nitinol**, Stainless Steel, and **PTFE**	Catheter Shaft: Polyamide, Stainless Steel and rubber	Catheter Shaft: Polyamide, Stainless Steel and rubber	Different
	Radiopaque Marker Bands: Platinum Iridium	Radiopaque Marker Bands: Platinum Iridium	Radiopaque Marker Bands: Platinum Iridium	Same
Proximal ID	0.17" (0.43mm)	0.165" (0.42mm)	0.17" (0.43mm)	Same

Table 1: Comparison between Subject, Predicate & Reference Device Technological Characteristics:				
Characteristic	Subject Device Plato® 17 Microcatheter	Predicate Device Excelsior™ SL-10 Pre-Shaped Microcatheter (K042568)	Reference Device Excelsior XT-17 Microcatheter (K142565)	Comparison Analysis
Proximal OD	**2.1F (0.70mm)**	2.4F (0.80mm)	2.4F (0.80mm)	Different
Distal ID	0.17" (0.43mm)	0.165" (0.42mm)	0.17" (0.43mm)	Similar
Distal OD	1.7F (0.60mm)	1.7F (0.60mm)	1.7F (0.60mm)	Same
Effective Length	**160cm**	150cm	150cm	Different
Tip Design	Straight and pre-shaped tips	Straight and pre-shaped tips	Straight and pre-shaped tips	Same
Steam-Shapeable tip	Yes	Yes	Yes	Same
Distal Coating	Hydrophilic coating	Hydrophilic coating	Hydrophilic coating	Same
Coating Length	**90cm**	100cm	100cm	Different
Radiopaque Markers	2 radiopaque markers located at distal tip of the microcatheter	1 or 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)	100% Ethylene Oxide (EO)	Same
Guidewire Compatibility	0.014"	0.014"	0.014"	Same
Accessories: Introducer	Included	Included	Included	Same
Accessories: Tip Shaping Mandrel	**0.015**" diameter stainless steel tip shaping mandrel included	0.013" diameter stainless steel tip shaping mandrel included	0.016" diameter stainless steel tip shaping mandrel included	Different
Accessories: Ruler	Included	Included	Included	Same

The subject device and predicate device indications for use statements are similar but not the same. The differences in the indications for use statements are device name, anatomical location for use and the example of therapeutic device. These differences do not raise new questions of safety and effectiveness or alter the intended use of the subject device. The subject device is not indicated for use in the coronary vasculature, but only in the peripheral and neuro vasculature systems; this is a subset of the predicate

device and this subset does not raise any additional safety and effectiveness concerns for the subject device. The predicate device indicates an occlusion coil as an example of a therapeutic device and the subject device lists only embolic coils. The subject device was tested for compatibility with embolic coils only; this does not represent additional risk or impact to safety and effectiveness of the device when compared to the predicate.

The subject device, Plato® 17 Microcatheter, has two technological characteristic differences compared to the predicate device: catheter shaft materials and dimensions (effective length, proximal OD and coating length); these differences do not raise new questions of safety and effectiveness for the subject device. The subject device design completed and passed functional testing. The differences in materials were evaluated through functional and biological testing. The evaluation of the risks for the subject device in the form of failure modes and effects analysis (FMEA) was conducted along with testing of the subject device to demonstrate the substantial equivalence of the device.

NON-CLINICAL PERFORMANCE TESTS

Results of bench tests performed on the new Plato® 17 Microcatheter demonstrates it met the testing acceptance criteria, performs as well as the predicate device, and/or meets requirements of relevant standards. Further, any differences in technological characteristics of the Plato 17 Microcatheters when compared with predicate device characteristics do not raise new questions of safety and effectiveness.

Biocompatibility

The biocompatibility evaluation for the subject device, Plato 17 Microcatheter was performed in accordance with ISO 10993-1: 2018. The testing is summarized in Table 2.

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.
Sensitization	Study animals with subject device were observed for dermal sensitization.	No sensitization reaction.
Intracutaneous Reactivity– by extract	Study animals with subject device were observed for dermal reaction.	No significant dermal reactions at the injected site.
Acute Systemic Toxicity – by extract	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	Study animals were observed for individual temperature rise.	Non-pyrogenic.

Table 2: Summary of Subject Device Biocompatibility Testing Performed.		
Name of Test	Test Summary	Conclusion of Testing
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.	The difference in average clot time between the subject device and predicate was 7 seconds. 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 subject device had similar or lower potential to activate the complement system when compared to the predicate.
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.	The lab testing concluded that the subject device showed minimal thrombus formation and is considered thromboresistant.

Functional Testing

Functional testing was performed in accordance with the following standards:

- 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,
- 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).

Table 3 Summarizes the functional verification testing performed.

Table 3: Summary of Subject Device Functional Testing.		
Test	Attribute and Acceptance Criteria	Results
Visual and Dimensional Inspection	Visual inspection of the catheter effective length to be free from surface defects, surface extraneous matter, and coating droplets. Catheter to meet the dimensional specifications per the design specifications.	PASS
Tensile Strength	The minimum tensile force for all microcatheters must meet the tensile requirements of ISO 10555-1.	PASS
Tip Flexibility	Comparable to the tip flexibility of the predicate catheter.	PASS
Flexural Fatigue	Catheter shall withstand cyclic fatigue without catheter damage.	PASS

Table 3: Summary of Subject Device Functional Testing.		
Test	Attribute and Acceptance Criteria	Results
Flow Characterization and Power Injection	Characterize fluid (saline and contrast media) flow rate through the catheter. No leak or break in the catheter when subject to power injection.	PASS
Catheter Liquid Leak Under Pressure	No liquid leakage on the hub or catheter body.	PASS
Catheter Static Burst	Maximum catheter burst pressure > 300psi.	PASS
Torque Turns to Failure	Maintain catheter integrity after applied hub rotations with the distal end held stationary.	PASS
Particulate Generation During Simulated Use	The amount of particulate matter that comes off the hydrophilic coated shaft during simulated use testing shall be determined and compared to the competitive products.	PASS
Coating Lubricity, Durability and Integrity	After 15 cycles the coating must maintain a minimum lubricity and maintain a minimum surface coating coverage.	PASS
Negative Collapse Pressure and Air Ingress	No air ingress while under vacuum with a syringe held for 10 seconds. No catheter lumen collapse after applied vacuum with a syringe.	PASS
Kink Radius	The catheter must maintain lumen integrity while wrapped around an anatomically relevant bend radius.	PASS
Tip Shape and Shape Retention	Catheter tip meets defined tip dimensional tolerances and must maintain tip shape.	PASS
Catheter Elongation	Catheter shaft elongation at breakage should be comparable to the predicate.	PASS
Catheter Hub Luer Validation	Plato 17 Microcatheter hub will be compliant to requirements found in ISO 80369-7.	PASS
Simulated Use Model and Product Compatibility Evaluation	Simulated use testing of the microcatheter was performed with accessory devices in a neurovascular model. The microcatheter and interfacing devices were delivered through the model and evaluated for effectiveness of delivery and functionality.	PASS
Accessory Verification	The Peel-Away Introducer must facilitate introduction of catheter into a guide catheter. The tip shaping mandrel must facilitate steam shaping of the catheter tip and show no signs of corrosion. The ruler on the accessories card must meet design specifications.	PASS
Radiopacity	Catheter tip markers to be visible under X-Ray fluoroscopy within the neuro vasculature.	PASS
Catheter Usability Study	Physician evaluation of the microcatheter in a cadaver study demonstrates acceptable use when compared to current marketed devices. The microcatheter and interfacing devices were delivered through a representative procedure and evaluated for effectiveness of delivery and functionality.	PASS
Corrosion Resistance	No corrosion is visible on the catheter samples in compliance with ISO 10555-1.	PASS

Additionally, the Plato 17 Microcatheter and packaging were evaluated for Shelf-life testing(subject device), packaging integrity, and sterilization including EO, ECH residuals and bacterial endotoxin levels.

CONCLUSION:

The Plato® 17 Microcatheter has a similar intended use and indications for use statement as the predicate device. The identified technological differences do not raise new questions of safety or effectiveness regarding the use of the subject device. 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 share the same intended use, basic technological characteristics, and similar functional performance, as demonstrated through testing.