DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

April 18, 2017

Scientia Vascular LLC
% Mr. Mark Job
Regulatory Technology Services LLC
1394 25th Street, NW
Buffalo, Minnesota 55313

Re: K170406
Trade/Device Name: Plato MICROCATH® 27B Microcatheter
Regulation Number: 21 CFR 870.1200
Regulation Name: Diagnostic Intravascular Catheter
Regulatory Class: Class II
Product Code: DQO, KRA, DQY
Dated: April 13, 2017
Received: April 14, 2017

Dear Mr. Job:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Carlos L. Pena -S

Carlos L. Peña, PhD, MS
Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K170406

Device Name
Plato MICROCATH® 27B Microcatheter

Indications for Use *(Describe)*
The Plato MICROCATH 27B Microcatheter is intended for the introduction of interventional devices and infusion of diagnostic agents to the peripheral and neurovascular systems. The catheter is also intended for the introduction of therapeutic agents to the peripheral system. The 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.

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510(K) SUMMARY
(Per 21 CFR 807.92)

SCIENTIA VASCULAR LLC
PLATO MICROCATH® 27B MICROCATHETER

510(k) Sponsor: Scientia Vascular LLC
3487 West 2100 South Suite 100
West Valley City, UT 84119
Tel: (775) 657-6330
Fax: (888) 503-6529

Contact Person: David Sabodski, Director of Quality Assurance
Tel: 801.573.5897
Fax: 888.503.6529
E-mail: dsabodski@scientiavascular.com

Date Prepared: April 10, 2017

Prepared by: Phil Triolo PhD, RAC
President, Phil Triolo and Associates LC
Tel: 801.699.9846
Fax: 801.328.2399
E-mail: philt@philt.com

Trade Name: Plato MICROCATH® 27B Microcatheter

Common Name: Microcatheter for neurovascular use

Classification Name and Product Code: Diagnostic Intravascular Catheter per 21 CFR 870.1200, DQO
Continuous Flush Catheter per 21 CFR 870.1210, KRA
Percutaneous Catheter per 21 CFR 870.1250, DQY

Predicate Device: ev3 Marksman™ Catheter (K111490, K091559)

Reference Device: Scientia Vascular, LLC Plato MICROCATH 27 Microcatheter (K143398)

Device Description:
The Plato MICROCATH® 27B Microcatheter is a single lumen microcatheter with a flexible polymer shaft of varying stiffness to aid in navigation of the neurovasculature. The catheter is designed to be used with a guide catheter and a steerable guidewire. The proximal end of the catheter has a diameter of 3.4F tapering to a distal OD of 3.2F. The catheter can be inserted into a 5F guide catheter. The inner diameter is constant over the entire length of the catheter shaft and accommodates guidewires up to 0.025" in diameter. The catheter is 150 cm in length with a straight tip configuration which can be shaped, using steam heat and the provided mandrels, to the users' preferred shapes. A steam shaping mandrel is included in the packaging. The microcatheter has a hydrophilic coating on the outer distal shaft to reduce friction during catheter manipulation in the vasculature and has one radiopaque tip marker at its distal tip to facilitate fluoroscopic visualization.

The subject microcatheter is identical with respect to its technological characteristics, design and materials to Scientia's currently marketed Plato MICROCATH 27B Microcatheters cleared under K143398. This 510k was prepared to expand the indications for use of the device to include its use in the neurovasculature.

Indications for Use:
The Plato MICROCATH 27B Microcatheter is intended for the introduction of interventional devices and infusion of diagnostic agents to the peripheral and neurovascular systems. The catheter is also intended for the introduction of therapeutic agents to the peripheral system. The catheter is not intended for use in the coronary vasculature.

> NOTE: The indications for use are the same as those of the predicate ev3 Marksman Catheter, with the exception that the Marksman Catheter is also indicated for coronary use. The identical reference MICROCATH 27B is currently cleared for the intended use of the introduction of interventional devices and infusion of diagnostic or therapeutic agents to the peripheral system; not the neurovascular system.

Technological Characteristics:
The Plato MICROCATH 27B Microcatheter is a single lumen, variable stiffness microcatheter designed to provide increased flexibility for navigating the peripheral and neurovasculature. The proximal end of the catheter incorporates a polycarbonate female Luer adapter to facilitate the attachment of accessories and devices terminating in a male Luer. The distal end has a polymeric skeletal support for improved distal navigation. The device is compatible with 5 F or larger guiding catheters and can be advanced over guidewires up to 0.025" in diameter. The steam-shapeable distal shaft has a hydrophilic coating applied to impart lubricity.

The technological characteristics of the new microcatheter are comparable to those of the predicate device, the ev3 Marksman Catheter. Both the Marksman Catheter and the Plato 27B have a single PTFE lumen within a polymeric laminate. Both catheters have variable stiffness along the length designed for a flexible distal end and a stable proximal end enabling the catheter to be introduced over a steerable guidewire into the peripheral

and neurovasculature systems. The proximal end of both catheters incorporates a standard female luer adapter to facilitate the attachment of devices and accessories that terminate in male luer adapters. The proximal ends of both catheters also have a reinforcing braid embedded in the polymeric coatings to impart strength and stiffness. Both catheters are compatible with 5F or larger guiding catheters and can accommodate guidewires up to 0.021" in diameter. The distal ends of both catheters have a steam shapeable tip. Further, the outer surface of the distal ends of both catheters has a hydrophilic coating to aid catheter movement in the vasculature.

The Plato MICROCATH 27B differs from the predicate Marksman Catheter in that the predicate has a coiled support structure embedded in the polymeric laminate at its distal end while the Plato 27B has a polymeric skeletal support embedded in the polymeric laminate at its distal end. Both designs provide mechanical support and minimize the potential for catheter collapse in tortuous vessels. Additionally, the predicate and MICROCATH 27B differ in material composition.

Results of tests performed on the new Plato MICROCATH 27B Microcatheter demonstrate that the new catheters perform as well as the predicate devices and/or meet requirements of relevant standards. Further, the differences in technological characteristics, including differences in materials used in the manufacture of the predicate and new catheters, do not raise different questions of safety and effectiveness.

Non-Clinical Performance Data:

Biocompatibility

The materials used in the manufacture of the subject Microcatheters are identical to those used in the manufacture of Plato MICROCATHETER 27B Microcatheters also manufactured by Scientia Vascular LLC, cleared 26 June, 2015 after review of K143398; in formulation, processing, sterilization, and geometry, and no other chemicals have been added (e.g., plasticizers, fillers, color additives, cleaning agents, mold release agents).

There are no additional biologic interactions that need to be considered in order to use the cleared Microcatheters in the neurovasculature. Consequently, no additional evaluations are needed to determine that the subject Microcatheters present a low and acceptable biological and toxicological risk when used in accordance with their intended and indicated uses, and no additional biological safety information is provided in this 510(k).

Functional Testing

The results of functional testing completed to comply with ISO 10555-1:2013 requirements, the relevant portions of the FDA document, Class II Special Controls Guidance Document for Certain Percutaneous Transluminal Coronary Angioplasty (PTCA) Catheters (Part VIII, section 13), issued September 8, 2010, and the relevant portions of the FDA document, Guidance on Premarket Notification [510(k)] Submission for Short-Term and Long-Term Intravascular Catheters, issued March 16, 1995 are reported herein. The following tables summarize the functional tests performed and test results obtained to demonstrate substantial equivalence.

Table 1. Summaries of Tests Conducted to Support this Premarket Notification

Test	Test Method Summary	Results
Tensile Strength	Tensile testing performed per ISO 10555-1 on distal, medial and proximal catheter sections after simulated use	All catheters meet minimum force breakage requirements specified in ISO 10555-1.
Coating Lubricity and Durability	Frictional force of uncoated and coated catheters was determined	All catheters met specified frictional force requirements.
Coating Integrity	Coating uniformity and integrity visually examined on dyed samples after simulated use in a tortuous path	All samples showed acceptable coating coverage and no defects were identified post simulated use.
Particulates	Particulates of various size ranges counted after inserting a guidewire and advancing the Microcatheter through a guide catheter multiple times.	The test and predicate catheters had comparable numbers of particles in each size range.
Torque to Failure	Torque turns to failure in an anatomical model to provide a 4 fold safety factor	All catheters showed no signs of breakage, twists or collapsed lumens after specified number of torque turns.
Plato 27B Neurovascular Model Evaluation	Evaluate ability to deliver and withdraw interventional devices through catheter in a model designed to simulate the tortuous anatomy of the neurovasculature.	Interventional devices were successfully delivered into and withdrawn from the 27B Microcatheter while it was located in the model simulating the tortuous anatomy of the neurovasculature.

Table 2. Summaries of Tests that were Repeated to Evaluate the Performance of 13-month Real Time or Accelerated Aged Microcatheters to Establish a Shelf Life Claim
NOTE: Summaries of tests conducted on unaged catheters were previously reported in k143398.

Test	Test Method Summary	Results
Liquid Leakage under Pressure/Leakage at Hub	Test for leakage at 300- 320 kPa per ISO 10555-1	No leakage from hub or catheter body
Static Burst Pressure	Burst pressure tested per ISO 10555-1	Maximum peak pressures all exceeded 300 psi.
Air Ingress/Negative Collapse	Tests per ISO 10555	Hub fittings do not allow air ingress and no evidence of lumen collapse
Kink Resistance	Tests for kinks after distal tip of catheter is wrapped around cylindrical forms	Device was resistant to kinking around small diameter turns per specification
Tip Stiffness	Test for stiffness per ASTM D747-10	Tip stiffness was comparable that of the predicate devices.
Flexural Fatigue and Profile	Worst case bend of 90° with an 8-fold safety factor for repetitions per ASTM D747-10	All catheters showed no signs of cracks or breakage after worst case simulated use.
Tip Shape Retention	Catheters must retain angle shaped by steam and meet tensile strength specifications after conditioning and simulated use.	All tips formed by steam met shape and tensile requirements after conditioning and simulated use.
Simulated Use	Anatomical model designed to simulate the tortuous anatomy of the neurovasculature used for simulated use testing.	Catheters and predicate devices were found to perform acceptably in evaluations of guidewire tracking and guide catheter movement. Interventional devices were successfully deployed and withdrawn.

Table 2. Summaries of Tests that were Repeated to Evaluate the Performance of 13-month Real Time or Accelerated Aged Microcatheters to Establish a Shelf Life Claim
NOTE: Summaries of tests conducted on unaged catheters were previously reported in k143398.

Test	Test Method Summary	Results
Visual/Dimensional Inspection	Tests per ISO 10555-1 Visual inspection for extraneous matter, process and surface defects or defects that may cause trauma to vessels. Dimensional inspection per drawings	No surface defects or visible droplets of coating on catheters. All catheters met dimensional specifications. Plato MICROCATH 27B Microcatheters do not exhibit clinically significant hydration as defined in ISO 10555-1:2013.
Pressure vs. Flow Characterization	Flow rates measured at two typical injection pressures per ISO 10555-1	Flow rates reported in Instructions for Use at 100 and 300 psi
Dynamic Flow	Product used with power injector at pressure-limited setting to 700 psi	No leaks, breaks or occluded lumens at 700 psi
Packaging Testing	Pouch evaluated for seal strength per ASTM F 88-00 and leak tests (bubble test) per ASTM F 2096-04	All sterile barrier pouches met minimum seal strength and released no bubbles under leak test conditions.

Table 3. Summaries of Tests Whose Results Were Already Reported in K143398 that and are Being Leveraged for this Premarket Notification		
Test	**Test Method Summary**	**Results**
Cadaver Testing	Human Cadaver used to evaluate catheter and predicate devices by physicians for performance, access time, and ability to deploy and retrieve	Test and predicate devices both exhibited comparable performance with similar access time to the designated target.
Radiopacity	Catheters and predicate devices evaluated by physicians in human cadaver model	Both test and predicate catheters exhibited acceptable radiopacity.
MRI Compatibility	Catheters contain metallic materials and should not be exposed to MRI procedures.	Catheters are labeled MRI Unsafe in IFU.
Chemical compatibility	Catheters were exposed to saline and contrast agent/saline solutions and examined for degradation.	All catheters showed no signs of degradation, corrosion or physical decomposition.
Latex Content	Tested for trace latex proteins per ASTM D6499-07	No detectable traces of latex were found.
Corrosion Resistance	Test for corrosion resistance per ISO 10555- 1	No signs of corrosion on metallic components of catheters

Conclusion:

Scientia Vascular, LLC has presented information in this premarket notification supporting its contention that the Plato MICROCATH 27B Microcatheter is substantially equivalent with respect to technological characteristics and indications for use to the ev3 predicate device.