

K 12 1734



SCIENTIA

JUL 30 2012

510(K) SUMMARY (21 CFR 807.92)

**SCIENTIA VASCULAR LLC
PLATO MICROCATH[®] 27 MICROCATHETER**

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Date Prepared: May, 2012

Trade Name: Plato MICROCATH[®] 27 Microcatheter

Common Name: Microcatheter

Classification Name: Percutaneous catheter per 21 CFR 870.1200, DQO

Predicate Device: ev3 Rebar-027, K993672

Device Description: The Plato MICROCATH[®] 27 Microcatheters are single lumen catheters designed to be used with a guiding catheter and a steerable guidewire for accessing the vasculature. The microcatheter contains a metal hypotube reinforced shaft with a maximum diameter of 3.7F, tapering to a distal end of 3.3F, which can be inserted into a 6F guide catheter. The inner diameter is constant throughout the shaft length and accommodates up to a 0.025" guidewire. The catheter is 150 cm in length with two tip configurations; straight and 45°. All have steam shapeable tips, hydrophilic coating and a radiopaque marker at the distal tip. The devices are marketed with an accessory mandrel which allows the catheter tips to be steam-shaped to the doctor's preferred shape when desired.

Indications for Use: The Scientia Vascular LLC Plato MICROCATH 27 Microcatheters are intended to assist in the delivery of diagnostic and/or therapeutic agents to the peripheral and neurovascular systems.

The indications are substantively identical to those of the ev3 Rebar-027 microcatheter.

Technological
Characteristics:

The Plato MICROCATH 27 Microcatheter is designed with a low profile distal shaft with enhanced skeletal support, and a proximal hypotube to increase the ability to advance the catheter in peripheral and neuro vasculature. The proximal end of the catheter incorporates a standard luer adapter to facilitate the attachment of accessories. The device is compatible with 6 Fr or larger guiding catheters and can be advanced over guidewires up to 0.025". The distal shaft has a hydrophilic coating for lubricity.

The technological characteristics are comparable to the predicate device, the ev3 Rebar-027 Microcatheter. The Rebar-027 is a single lumen catheter designed to be introduced over a steerable guidewire into the vasculature. The proximal end of the catheter incorporates a standard luer adapter to facilitate the attachment of accessories. The catheter has a semi-rigid proximal shaft which transitions into the flexible distal shaft. The outer surface of the catheter is coated to increase lubricity.

The technological differences between the Plato MICROCATH 27 Microcatheter and the predicate device reside in the design of the catheter reinforcement. The predicate catheter has embedded wires which are shaped to impart additional strength and stiffness to the proximal and distal ends. The Plato MICROCATH 27 Microcatheter uses a proximal stainless steel hypotube to improve the control the physician has over the distal end and then uses a polymeric skeletal support in the distal end to support the lumen and prevent collapse in tortuous vessels. The technological differences do not raise new questions of safety or efficacy.

Non-Clinical
Performance Data:

Non-clinical testing included biocompatibility testing of the assembled device as defined in ISO 10993, functional testing as defined in ISO 10555-1 with Amendments 1 and 2, and in the FDA guidance for Short-Term and Long-Term Intravascular Catheters, dated March 16, 1995. Testing performed on the proposed device included:

- Visual/Dimensional Inspection

- Air Ingress/Negative Collapse
- Kink Resistance
- Tensile Strength/Elongation
- Liquid Leakage under Pressure/Leakage at Hub
- Tip Stiffness
- Pressure vs. Flow Characterization
- Static and Dynamic Burst Pressure
- Flex Fatigue
- Shape Retention
- Coating Lubricity and Durability
- Coating Integrity
- Particulates
- Chemical compatibility
- Latex
- Corrosion Resistance

Additionally, simulated use testing included navigating the device through an anatomical model to test the guidewire tracking and movement within the catheter. In a human cadaver model, the device was comparable to the predicate for advancement to the intended vascular site.

Conclusions:

The non-clinical bench testing, simulated-use testing and human cadaver test results demonstrate that the Plato MICROCATH 27 Microcatheter functions as intended, meets the requirements of ISO 10555-1, and performs equivalent or better than the predicate devices in small tortuous vessels. The testing supports a determination of substantial equivalence to products previously cleared by FDA.



Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room - WO66-G609
Silver Spring, MD 20993-0002

JUL 30 2012

Scientia Vascular LLC
c/o Mark Job
Responsible Third Party Official
Regulatory Technical Services LLC
1394 25th Street NW
Buffalo, MN 55313

Re: K121734

Trade/Device Name: Plato MICROCATH 27 Microcatheter
Regulation Number: 21 CFR 870.1200
Regulation Name: Diagnostic intravascular catheter
Regulatory Class: Class II (Two)
Product Code: DQO
Dated: June 12, 2012
Received: June 13, 2012

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 go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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 yours,



f Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K121734

Device Name: Plato MICROCATH[®] 27 Microcatheter

Indications for Use: The Plato MICROCATH[®] 27 Microcatheter is intended to assist in the delivery of diagnostic and/or therapeutic agents to the peripheral and neurovascular systems.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE
IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

M. A. Hillebr

(Division Sign-Off)
Division of Cardiovascular Devices

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