November 17, 2017

Vascular Solutions, Inc.
Jake Schultz
Regulatory Product Specialist
6464 Sycamore Court North
Minneapolis, Minnesota 55369

Re: K170544
Trade/Device Name: Langston Dual Lumen Catheter
Regulation Number: 21 CFR 870.1200
Regulation Name: Diagnostic Intravascular Catheter
Regulatory Class: Class II
Product Code: DQO
Dated: October 10, 2017
Received: October 11, 2017

Dear Jake Schultz:

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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Kenneth J. Cavanaugh -S

for

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K170544

Device Name
Langston Dual Lumen Catheter

Indications for Use *(Describe)*
The Langston dual lumen catheter is indicated for delivery of contrast medium in angiographic studies and for simultaneous pressure measurement from two sites. This type of pressure measurement is useful in determining transvalvular, intravascular, and intraventricular pressure gradients.

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

[As required by 21 CFR 807.92]

Date Prepared: 11/15/2017

510(k) Number: K170544

Submitter's Name / Contact Person

Manufacturer
Vascular Solutions, Inc.
6464 Sycamore Court North
Minneapolis, MN 55369 USA
Establishment Registration # 2134812

Contact Person
Jake Schultz
Regulatory Product Specialist
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General Information

Trade Name	Langston dual lumen catheter
Common / Usual Name	Diagnostic intravascular catheter
Classification Product Code	DQO
Classification Name	21 CFR 870.1200 Diagnostic intravascular catheter
Predicate Devices	K061565, Langston dual lumen catheter, Vascular Solutions, Inc. K051395, Langston dual lumen catheter, Vascular Solutions, Inc.

K170544 Device Models					
Model	**Description**	**Length**	**Outer Lumen Diameter**	**Inner Lumen Diameter**	**Max Pressure Rating**
5515	145° Pigtail	125 cm	7 F	5 F	1200 psi
5540	145° Pigtail	110 cm	6 F	5 F	1000 psi
5550	Multipurpose A2	100 cm	6 F	4 F	1000 psi

Device Description

The Langston dual lumen catheter consists of a coaxial tube (outer lumen) mounted over a braided catheter shaft (inner lumen) and an extension line with a 3-way stopcock. The extension line with stopcock connects to the outer lumen. The outer lumen, inner lumen, and extension line are joined by an over molded manifold. The manifold also includes a luer that connects to the inner lumen. The manifold is printed with the Langston catheter length, French size, maximum guidewire diameter, and product logo ("Langston"). The Langston dual lumen catheter tip terminates in either a pigtail or multipurpose tip configuration.

Intended Use

The Langston dual lumen catheter is indicated for delivery of contrast medium in angiographic studies and for simultaneous pressure measurement from two sites. This type of pressure measurement is useful in determining transvalvular, intravascular, and intraventricular pressure gradients.

Technological Characteristics Comparison

The Langston dual lumen catheter has identical indications for use and principle of operation as the predicate devices and they are all diagnostic intravascular catheters. The subject and predicate devices are intended for delivery of contrast medium in angiographic studies and for simultaneous pressure measurement from two sites. The Langston dual lumen catheter is equivalent in design and technological characteristics to the predicate devices. The subject and predicate devices are dual lumen catheters sterilized via ethylene oxide and intended for single use. The proximal manifold of the Langston dual lumen catheter will be modified to remove the adhesive bonds and replace it with an over molded proximal manifold component. The manifold component introduces Nylon 12 Grilamid as a new material to the Langston dual lumen catheter. The extension line tubing material of the Langston dual lumen catheter will also be modified to increase stiffness and to remove the adhesive bond by including an additional strain relief.

Substantial Equivalence and Summary of Studies

The technological differences between the subject and predicate devices have been evaluated through biocompatibility and bench tests to provide evidence of Langston dual lumen catheter substantial equivalence. Clinical testing was not performed to validate the performance of the subject device. The Langston dual lumen catheter is substantially equivalent to the specified predicate devices based on comparisons of the device functionality, technological characteristics, and indications for use. The device design has been verified through the following tests:

- Package Integrity
- Tortuosity in Simulated Anatomy
- Pressure Monitoring
- Flow Rate vs. Injection Pressure
- Tensile Force
- Torque to Failure
- Air Leakage During Aspiration
- Liquid Leakage Under Pressure
- Torque Strength
- Dimensional Analysis
- Hub Luer Taper

Device samples passed the following biocompatibility tests performed in accordance with ISO 10993-1:

- Cytotoxicity
- Sensitization
- Irritation
- Acute Systemic Toxicity
- Pyrogenicity
- Hemocompatibility

The results of the verification tests met the specified acceptance criteria and did not raise new safety or performance issues. Therefore, the Langston dual lumen catheter is substantially equivalent to the predicate devices.