June 17, 2022

Vascular Solutions LLC
Becky Astrup
Pr. Regulatory Product Specialist
6464 Sycamore Court North
Minneapolis, Minnesota 55369

Re: K221470
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: May 19, 2022
Received: May 20, 2022

Dear Becky Astrup:

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,

Lydia Glaw
Assistant Director
DHT2C: Division of Coronary
and Peripheral Intervention Devices
OHT2: Office of Cardiovascular 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)*

K221470

Device Name
Langston dual lumen catheter

Indications for Use *(Describe)*

Each 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) SUMMARY

[As required by 21 CFR 807.92]

510(k) Number: K221470

Date Prepared: May 19, 2022

SUBMITTER

Vascular Solutions LLC

6464 Sycamore Court North

Minneapolis, MN 55369 USA

Establishment Registration # 2134812

Phone: 763-656-4300

Contact Person: Becky Astrup, Pr. Regulatory Product Specialist

DEVICE

Name of Device: Langston dual lumen catheter

Common or Usual Name: Catheter

Classification Name: Diagnostic intravascular catheter (21 CFR 870.1200)

Regulatory Class: II

Product Code: DQO

PREDICATE AND REFERENCE DEVICES

The legally marketed predicate device to which substantial equivalence is claimed is the Langston dual lumen pressure monitoring catheter, K051395, cleared June 24, 2005. The Langston dual lumen catheter, K170544, cleared November 17, 2017, is used as a reference device.

DEVICE DESCRIPTION

The Langston dual lumen catheters have two lumens, both with distal sideholes, to allow simultaneous pressure measurements from two sites. The high-pressure inner lumen, which extends the entire length of the catheter, can be used for pressure measurement and rapid delivery

of contrast medium. The outer lumen ends proximal to the distal end of the catheter and is used for pressure measurement only. A side port fitted with an extension tube and a stopcock assembly is used for fluid flow and pressure measurement within the outer lumen. The Langston dual lumen catheter will accommodate a standard ≤ 0.038" diameter guidewire and is supplied with a single use pigtail straightener. The Langston dual lumen catheter is sterilized with ethylene oxide.

INDICATIONS FOR USE

Each 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.

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The subject device is substantially equivalent to the predicate device with respect to indications for use, principle of operation, fundamental design principles, performance, sterilization, and packaging. The reason for submitting this Special 510(k) is to implement a design modification to the strain relief to hub bond.

PERFORMANCE DATA

Risk assessment was performed according to ISO 14971, “Medical Devices – Application of Risk Management to Medical Devices. The following tests were performed to evaluate the design and performance of the modified Langston dual lumen catheters and to demonstrate substantial equivalence to the predicate device:

Performance Testing- Bench

The technological differences between the subject and predicate device have been evaluated through bench tests to provide evidence that the Langston dual lumen catheter is substantially equivalent to the predicate device. The modified device was verified through the following tests:

- Aspiration
- Liquid Leak
- Flow Rate
- Hub to Shaft Tensile
- Static Burst

The results of the verification tests met the specified acceptance criteria and did not raise different questions of safety or effectiveness.

Biocompatibility Testing

Biocompatibility was leveraged from previous testing and demonstrated that the biocompatibility evaluation for the modified Langston dual lumen catheter complies with ISO 10993-1, "Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process".

CONCLUSION

The subject Langston dual lumen catheter is substantially equivalent to the predicate device based on comparisons of the device functionality, technological characteristics, and indications for use. The results of design verification tests do not raise new or different questions of safety and effectiveness; therefore, the Langston dual lumen catheter is substantially equivalent to the predicate device.