November 16, 2018

LeMaitre Vascular
John Bradsher
Senior Regulatory Affairs Specialist
63 Second Avenue
Burlington, Massachusetts 01803

Re: K182916
Trade/Device Name: Pruitt F3 Carotid Shunt
Regulation Number: 21 CFR 870.4450
Regulation Name: Vascular clamp
Regulatory Class: Class II
Product Code: MJN
Dated: October 15, 2018
Received: October 18, 2018

Dear John Bradsher:

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 and Part 809); 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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

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,

Brian D. Pullin -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)*
K182916

Device Name
Pruitt F3 Carotid Shunt

Indications for Use *(Describe)*
The Pruitt F3 Carotid Shunt is indicated for use in carotid endarterectomy as a temporary conduit to allow for blood flow between the common and internal carotid arteries.

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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SECTION 8: 510k Summary K182916

I. SUBMITTTER	LeMaitre Vascular, Inc. 63 Second Avenue Burlington, MA 01803
Establishment Registration	1220948
Phone:	781-425-1685
Fax:	781-425-5049
Contact Person:	John N. Bradsher Senior Regulatory Affairs Specialist Email: jbradsher@lemaitre.com
Date Prepared	October 15, 2018
I. DEVICE	
Device Name:	Pruitt F3 Carotid Shunt
Trade Name:	Pruitt F3 Carotid Shunt
Common Name:	Catheter, intravascular occluding, temporary
Classification Panel:	Cardiovascular
Regulation Number:	21CFR §870.4450
Class:	II (2)
Product Code:	MJN
Prior Submissions:	No prior submissions have been made for the changes detailed in this special 510(k).
II. PREDICATE DEVICE	Pruitt F3 Carotid Shunt (K051067) This predicate device has not been subject to a design-related recall. No reference devices were used in this submission.
III. DEVICE DESCRIPTION:	The Pruitt F3 Carotid Shunt is used in patients with carotid artery disease in instances where removal of vascular occlusions is the therapeutic objective. The Pruitt F3 Carotid Shunt is employed in Carotid Endarterectomy (CEA), where the shunt is used as a short-term conduit for blood flow between the common

carotid and the internal carotid arteries. The Pruitt F3 Shunt is provided sterile for single use, and is provided with two 3 ml syringes used to inflate the balloons (accessory syringes have been previously cleared in K051067).

The Pruitt F3 Carotid Shunt is designed to serve as an artificial passage connecting two blood vessels, allowing blood flow from one vessel to another. This is accomplished by using a clear, plastic, sterile conduit that is held in place by a stabilization technique (balloons) on both ends of the conduit.

The Pruitt F3 Shunts are multi-lumen devices with balloons on both the distal (internal carotid) and proximal (common carotid) ends of the shunt. The balloons, when inflated independently, act as a stabilization mechanism to maintain the position of the shunt when it is placed within the common and internal carotid arteries.

The Pruitt F3 Carotid Shunt has features to aid the user during shunt insertion and balloon inflation. The inflation path of the proximal (common carotid) balloon is color-coded. Sterile saline is injected from the blue stopcock, through the blue lumen and into the blue common carotid balloon.

IV. INDICATIONS FOR USE:

The Pruitt F3 Carotid Shunt is indicated for use in carotid endarterectomy as a temporary conduit to allow for blood flow between the common and internal carotid arteries.
The indications for use and intended use of the modified device, as described in the labeling, have not changed as a result of the modifications described in this special 510(k).

V. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The Pruitt F3 Carotid Shunt maintains the same technological characteristics as the predicate device. Skive holes in the shunt have increased on both arms and the angle of the cutting of the common inflation arm and the internal inflation arm, which connect to the shunt body, have changed from 45 to 70 degrees. In all other respects of design, chemical composition and material, the subject device and the predicate device are identical.

Device Modifications and Rationales:
There are 2 modifications to the design of the Pruitt F3 Carotid Shunt that are different between the predicate and the subject device:

1. The previous design of the F3 Carotid Shunt featured 2 skive holes on each of the Common Carotid Artery Arm and the Internal Carotid Artery Arm. These skive holes are positioned under the occlusion balloon and are designed to facilitate inflation and deflation of the balloon as desired for completion of the CEA procedure. In the subject device, the number of skive holes in the Internal Arm of the device has been increased to 3, and the skive holes on the Common Arm of the device has been increased to 4. This change is being made to improve the characteristics of deflation of the arms of the shunt when the shunt is to be removed at completion of the endarterectomy procedure.
2. The previous design of the F3 Carotid Shunt features inflation conduits that are cut at a 45-degree angle. In the subject device, this angle has been increased to 70-degrees. Engineering studies showed that in some cases, the inflation conduit tubing cut at 45-degrees was actually partially occluding the lumen and resulting in increased back-pressure during deflation. This change has been made to improve the airflow characteristics of the balloon in the interest to avoid turbulent flow.

Table: List and description of each device for which clearance is requested

Model	Description	Usable Length	Diameter
2011-10	Pruitt F3 Carotid Shunt with T-port (Outlying)	31 cm	10 Fr
2011-12	Pruitt F3 Carotid Shunt with T-port (Inlying)	15 cm	10 Fr
2012-10	Pruitt F3 Carotid Shunt with T-port (Outlying)	31 cm	9 Fr
2012-11	Pruitt F3 Carotid Shunt (Outlying)	31 cm	9 Fr
2012-12	Pruitt F3 Carotid Shunt with T-port (Inlying)	15 cm	9 Fr
2012-13	Pruitt F3 Carotid Shunt (Outlying)	15 cm	9 Fr
2013-10	Pruitt F3 Carotid Shunt with T-port (Outlying)	31 cm	8 Fr

VI. PERFORMANCE DATA

BENCH TEST DATA

The following performance data are provided in support of the substantial equivalence determination.

- Main Lumen Flow Test
- Inflated Common Balloon Diameter
- Inflated Internal Balloon Diameter:
- Deflation Time, Common Balloon:
- Deflation Time, Internal Balloon
- Deflation Integrity
- Balloon Location
- Pressure Inspection for Backflow
- Inflation Lumen to Shunt Body Adhesion:

Summary of non-clinical and clinical Studies:	N/A
VII. CONCLUSION:	LeMaitre Vascular has demonstrated that the Pruitt F3 Carotid Shunt is substantially equivalent to the predicate device based on its intended use and fundamental scientific technology, and that the subject device is as safe, as effective, and performs as well as the predicate device.