DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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August 27, 2015

LeMaitre Vascular, Inc
Xiang Zhang
Director of Regulatory Affairs
63 Second Avenue
Burlington, Massachusetts 01803

Re: K143454
Trade/Device Name: Pruitt F3-S Carotid Shunt
Regulation Number: 21 CFR 870.4450
Regulation Name: Vascular Clamp
Regulatory Class: Class II
Product Code: MJN
Dated: July 20, 2015
Received: July 27, 2015

Dear Xiang Zhang,

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 yours,

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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K143454

Device Name
Pruitt F3-S Carotid Shunt

Indications for Use *(Describe)*
The Pruitt F3-S 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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510k Summary

Submitter's Information

Name:	LeMaitre Vascular, Inc.
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Contact Person:	Xiang (Vic) Zhang Global Director of Regulatory Affairs LeMaitre Vascular, Inc. Email: xzhang@lemaitre.com
Date Prepared:	August 26, 2015
Device Name:	Pruitt F3-S Carotid Shunt
Trade Name:	Pruitt F3-S Carotid Shunt
Common Name:	Catheter, intravascular occluding, temporary
Regulation Number:	21CFR §870.4450
Classification Panel:	Cardiovascular
Class:	II (2)
Product Code:	MJN
Establishment Registration:	1220948
Establishment:	63 Second Avenue Burlington, MA 01803
Predicate Device:	Pruitt F3 Carotid Shunt K051067
Reference Device:	Vascushunt Carotid Shunt K861790
Device Description:	The Pruitt F3-S 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-S 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-S 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.
Intended Use:	The Pruitt F3-S 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.
Summary of Technological Characteristics:	Comparisons of the Pruitt F3-S Shunt with the predicate Pruitt F3 Shunt show that technological characteristics such as materials, biocompatibility, performance, sterilization, and packaging of the proposed device are substantially equivalent to the predicate device. The design modification of the proposed device compared to that of the predicate device are: • Removal of the pressure relief balloon on the internal inflation arm; • Provide balloon diameter vs. inflation volume data in the IFU to guide the users
Functional/Safety Testing:	The verification activities conducted indicate that Pruitt F3-S Carotid Shunt meets the product performance requirements of the device specifications and does not raise any additional safety issues.
Sterilization:	The device is ethylene oxide (EO) sterilized according to ANSI/AAMI/ISO 11135-1:2007, "Sterilization of Medical Devices – Validation and Routine Control of Ethylene Oxide Sterilization"
Biocompatibility:	The materials used in Pruitt F3-S Carotid Shunt are identical to those in the predicate device which has established biocompatibility.
Summary of Product Testing:	The following tests have been completed to evaluate the safety and performance of the Pruitt F3-S Carotid Shunt: • Shunt lumen diameter • Balloon diameter • Balloon deflation time • Balloon radial force • Kink test • Balloon inflation curve

Summary of Pre-clinical Study:	N/A
Conclusion:	LeMaitre Vascular has demonstrated that the Pruitt F3-S Carotid Shunt is substantially equivalent to the predicate devices based on its intended use and fundamental scientific technology.