K121839

510 (k) Summary

AUG 8 2012

Submitter's information:

Name:	LeMaitre Vascular, Inc.
Address:	63 Second Avenue Burlington, MA USA 01803
Phone:	781-425-1727
Contact Person:	Bryan Cowell, MSc., RAC

Date of preparation:	3 June 2012
Device Name:	UnBalloon Non-Occlusive Modeling Catheter
Trade Name.	UnBalloon Non-Occlusive Modeling Catheter and UnBalloon Non-Occlusive Catheter
Common/ Classification Name:	Catheter, Percutaneous / Modeling Catheter
Classification Panel:	21CFR §870.1250
Class:	II (2)
Product Code:	DQY

Establishment Registration: 1220948

Establishment: LeMaitre Vascular, Inc., 63 Second Avenue, Burlington, MA USA 01803

Owner/Operator: 1220948

Proposed Device Description:

The UnBalloon Non-Occlusive Catheter is a silicone surface coated (medical grade) modeling catheter with an expandable Nitinol mesh in a 14F retractable sheath. The Nitinol mesh design allows for expansion without occluding blood flow. The Nitinol mesh and radiopaque markers are highly visible under fluoroscopy and assist in the positioning of the device. The inner lumen allows for a 0.035 or 0.038 inch guidewire for over-the-wire access. Side ports and clear handle/luer allow the device and guidewire lumen to be flushed. The blue handle allows the device to be sheathed/unsheathed while the clear handle/luer controls the expansion of the Nitinol mesh.

Proposed Intended Use:

The UnBalloon Non-Occlusive Modeling Catheter is intended to assist in the modeling of self-expanding endoprostheses in large diameter vessels.

Predicate Device:

510(k):	K110891
Device Name:	UnBalloon Non-Occlusive Modeling Catheter
SE Date:	09/13/2011
Regulation Number:	870.1250
Device Class Name:	Catheter, Percutaneous
Device Class:	2

Substantial Equivalence:

Fundamental Scientific Technological Characteristics:

The UnBalloon Non-Occlusive Modeling Catheter is a silicone surface coated percutaneous/modeling catheter designed for vascular surgeons.

Functional/ Safety testing:

The verification activities conducted indicate that UnBalloon Non-Occlusive Modeling Catheter device meets the product performance requirements of the device specifications and does not raise any additional safety issues.

Sterilization:

The device is validated for ethylene oxide (EO) sterilization according to ANSI/AAMI/ISO 11135-1:2007, "Sterilization of Medical Devices – Validation and Routine Control of Ethylene Oxide Sterilization"

Biocompatibility:

All blood contact portions of the device were subjected to Biocompatibility testing according to ISO 10993 guidelines for an externally communicating device with limited contact duration (<24 hours), in circulating blood.

Summary of Product Testing:

The following has been assessed through product characterization and validation:
Worst case simulated use *
Fatigue
Hemostasis
*Bond tensile strength**
Radial outward force
Compatibility with endoprostheses

*Lubricity testing**
*Silicone curing characterization**
*Silicone curing process characterization study**
*Silicone shelf life validation**
*Bushing & seal process qualification**

**testing specific to the silicone addition to the UnBalloon*

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

AUG 8 2012

LeMaitre Vascular, Inc.
c/o Mr. Andrew Hodgkinson
Vice President of Regulatory, Quality & Clinical Affairs
63 Second Avenue
Bedford, MA 01803

Re: K121839
Trade/Device Name: UnBalloon Non-Occlusive Modeling Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II (two)
Product Code: DQY
Dated: June 20, 2012
Received: July 9, 2012

Dear Mr. Hodgkinson:

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,

for 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) K121839

Device Name UnBalloon Non-Occlusive Modeling Catheter

Indications for Use The UnBalloon Non-Occlusive Modeling Catheter is intended to assist in the modeling of self-expanding endoprostheses in large diameter vessels.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use____X_____ OR Over-The-Counter Use_____
(Per 21 CFR 801. 109)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K121839