Section 5: 510(k) Summary

Submitter's information: SEP 5 2012

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

Date of preparation: August 22, 2012
Device Name: MollRing® MultiTASC™ Dissection/Transection Device
Trade Name: MollRing® MultiTASC™ Dissection/Transection Device
Common/ Classification: Stripper, Artery, Intraluminal
Classification Panel: 21CFR §870.4875
Class: II
Product Code: DWX
Establishment: LeMaitre Vascular, Inc., 63 Second Avenue, Burlington, MA USA 01803
Owner/Operator: 1220948
Establishment Registration: 1220948

Proposed Intended Use:
This device is intended for remote endarterectomy of peripheral blood vessels during vascular reconstruction.

Proposed Device Description:
The MollRing MultiTASC is a single use, sterile and disposable device designed for vascular surgeons use during remote endarterectomy procedures for the facilitation of dissecting, cutting and removing atheromatous plaque core within the peripheral vascular system.

The Subject Device is a fixed, circumferential, blunt-edged, sterile, single use cutting tool. It consists of two stainless steel coaxial metal rings (proximal and distal rings) which are connected by a stainless steel rod and hypo tube system. The modular rod and hypo tube system connects to a plastic operator's handle with selective positions for ring alignment (cutting/dissecting phase).

The device is introduced over the proximal end of the atheromatous plaque core of a peripheral vascular vessel. With the two stainless steel coaxial metal rings in "alignment position", they are advanced to the distal end of the plaque core. As the device transverses the vessel it acts as a conventional circumferential dissection ring stripper, removing the plaque core to the distal endpoint. The device is then switched via the operator handle to "un-alignment position", which spreads the distal and proximal rings, thus cutting and securing the plaque core. Once secured, the device is withdrawn, facilitating the core removal.

Predicate Device:

510(k):	K950813
Device Name:	MollRing Endarterectomy Device
SE Date:	07/25/1995
Regulation:	870.4875
Device Class:	II
Common/ Classification	Stripper, Artery, Intraluminal
Product Code:	DWX

Comparison of Substantial Equivalence:
Intended Use:
The intended use of MollRing MultiTASC is identical to that of the predicate device.

Fundamental Scientific Technological Characteristics:

The MollRing MultiTASC and its predicate are both single use, sterile and disposable devices designed for vascular surgeons use during remote endarterectomy procedures for the facilitation of dissecting, cutting, stripping and removing atheromatous plaque cores within the peripheral vascular system. The difference between the MollRing MultiTASC and the predicate is that the MultiTASC is composed of two separate parts: the Shaft Ring Hub Assembly and T handle, while the predicate has the handle permanently attached to the shaft. The differences in design are not critical to the intended use of the device and do not raise any new questions regarding safety or effectiveness.

Functional/ Safety testing:
The verification activities conducted indicate that the MollRing MultiTASC device meets the product performance 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.

Performance Testing / Non- Clinical Testing:
The following tests were performed and the test results met the product design specifications.

- Dimensional Verification
- Ring Weld Strength
- Weld Flex Strength

- Inner and Outer Hypo Tube Bond Strength
- Coupler Attachment Strength
- T-Handle Pull Force
- T-Handle Torsion Strength
- Device Actuation
- Shaft Bend
- Ring Cutting Force
- Compression Fatigue
- Shelf Life Testing

Conclusion:

Based on the intended use, technological characteristics, and safety and performance testing, the MollRing MultiTASC has been shown to be appropriate for its intended use and is considered to be substantially equivalent to the currently marketed predicate device.

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

Lemaitre Vascular, Inc.
% Andrew Hodgkinson
63 2nd Avenue
Bedford, MA 01803 US

SEP 5 2012

Re: K121415
Trade/Device Name: MollRing MultiTASC Dissection/Transection Device
Regulation Number: 21 CFR 870.4875
Regulation Name: Stripper, Artery, Intraluminal
Regulatory Class: Class II
Product Code: DWX
Dated: August 23, 2012
Received: August 24, 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.

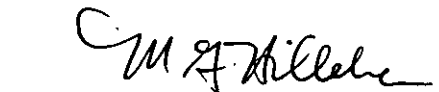
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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

510(k) Number (if known): K121415

Device Name: The Mollring® MultiTasc™ Dissection/Transection Device

Indications For Use: This device is intended for remote endarterectomy of peripheral blood vessels during vascular reconstruction.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K121415