DEC 2 2 2011

K113140

2 510(k) Summary

Date Prepared: October 24, 2011

Submitter's Name / Contact Person

Manufacturer
Vascular Solutions, Inc.
6464 Sycamore Court
Minneapolis, MN 55369 USA
Tel: 763-656-4300; Fax: 763-656-4250
Establishment Registration # 2134812

Contact Person
Jennifer Ruether
Sr. Regulatory Product Specialist

General Information

Trade Name	Vari-Lase WireFiber
Common / Usual Name	Laser Fiber
Classification Name	878.4810; GEX; Laser instrument, surgical, powered; Class II
Predicate Devices	K072332 – Vari-Lase WireFiber (Vascular Solutions, Inc.) K091551 – Vari-Lase Platinum Bright Tip (Vascular Solutions, Inc.)

Device Description

The WireFiber is a laser fiber that is compatible with a solid state diode laser console operating at a maximum power of 14 watts and wavelengths of 810 nm, 940 nm and 980 nm. The laser fiber is comprised of a 600 µm silica core with a dual clad of silica hard clad and polymer, an outer nylon buffer, a strain relief, and an SMA connector. The distal tip of the laser fiber consists of a platinum/iridium sleeve that terminates with a stainless steel/nitinol wire. The laser fiber lengths are between 2.4 meters and 3.6 meters, as measured from the proximal end of the SMA connector to the distal tip, with a maximum diameter of 0.038". The laser fiber is provided with positioning marks.

Intended Use/Indications for Use

The Vari-Lase WireFiber is indicated for the treatment of varicose veins and varicosities associated with superficial reflux in the Great Saphenous Vein and for the treatment of incompetence and reflux of superficial veins in the lower extremity.

Technological/Performance Characteristics

The overall design features of the modified WireFiber are the same as the predicate WireFiber. These devices consist of a laser fiber with a proximal strain relief and SMA connector, and terminate in a distal platinum/iridium sleeve with a wire tip. Sleeve and wire tip design changes were made to improve device reliability. These improvements include removal of the ceramic sleeve, use of a high temperature epoxy adhesive, minor dimensional changes to the platinum/iridium sleeve, and an angled wire tip material change to stainless steel and nitinol. Minor dimensional changes were made to the modified WireFiber to align with those of the Platinum Bright Tip, as well as a buffer material change to nylon. Performance characteristics are the same as those of the predicate Vari-Lase laser fibers.

Substantial Equivalence and Summary of Studies

The Vari-Lase WireFiber is substantially equivalent to the currently marketed predicate devices, based on comparisons of the device classifications, technological and performance characteristics, and the indications for use. Technological and performance differences in design and materials have been qualified through the following tests:

- Simulated use – blood burn
- Simulated anatomy
- Ultrasound visualization
- Corrosion resistance
- Tensile strength
- Compressive force
- Biocompatibility

The results of the verification and biomaterial assessments did not raise any new safety or performance questions and confirm that the Vari-Lase WireFiber is substantially equivalent to the predicate Vari-Lase laser fibers.

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

DEC 2 2 2011

Vascular Solutions, Inc.
% Ms. Jennifer Ruether
Sr. Regulatory Product Specialist
6464 Sycamore Court
Minneapolis, Minnesota 55369

Re: K113140
Trade/Device Name: Vari-Lase WireFiber
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: Class II
Product Code: GEX
Dated: November 28, 2011
Received: November 29, 2011

Dear Ms. Ruether:

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.

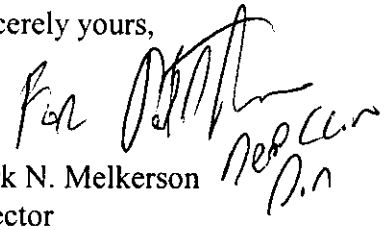
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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,



Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K113140

Device Name: Vari-Lase WireFiber

Indications for Use:

The Vari-Lase WireFiber is indicated for the treatment of varicose veins and varicosities associated with superficial reflux in the Great Saphenous Vein and for the treatment of incompetence and reflux of superficial veins in the lower extremity.

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Posted November 13, 2003)

Neil R Ogden for mkm

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K113140