K072332

Vascular SOLUTIONS

510(k) Summary

(As required by 21 CFR 807.92(c))

JAN 10 2008

510(k) Number:_____

Date Prepared

October 1, 2007

Submitter Information

Submitter's Name:	Vascular Solutions, Inc.
Address:	6464 Sycamore Court Minneapolis, MN 55369
Contact Person:	Deborah L. Neymark Vice President, Regulatory Affairs Phone 763-656-4349 Fax 763-656-4250

Device Information

Trade Name:	Vari-Lase® WireFiber
Common Name:	Optical Fiber
Class:	II
Classification Name:	Laser Surgical Instrument for use in General and Plastic Surgery and in Dermatology (21 CFR 870.4810, Product Code GEX)

Predicate Device

Vari-Lase Endovenous Bright™ Tip Fiber (K070216) manufactured by Vascular Solutions, Inc.

Device Description

The Vari-Lase Wire Fiber is a 600μm core laser fiber that is 3.5 meters in length. The distal tip of the fiber is encased in a ceramic and platinum/iridium (provides ultrasound visibility during clinical use) and includes a distal floppy spring tip.

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 treatment of incompetence and reflux of superficial veins in the lower extremity.

Summary of Testing

Bench testing was conducted on the modified laser fiber and included an assessment of physical properties and its ability to achieve its intended use. The results of the tests confirmed the suitability of the device for its intended use. Bench tests included energy transmission, integrity of the tip following simulated clinical use (tensile strength of the ceramic/metal tip, burn-back, torque response and torsional strength) and biocompatibility.

Statement of Equivalence

The Vari-Lase Wire fiber is substantially equivalent to the currently marketed Vari-Lase Bright Tip Fiber, based on comparisons of the device classification, indications for use, technological characteristics, and sterilization methods.

Conclusion

The Vari-Lase Wire Fiber is substantially equivalent to the currently marketed Vari-Lase Fibers, based on comparisons of the device classifications, indications for use, technological characteristics, and sterilization methods. Bench tests confirmed the suitability of the device for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 10 2008

Vascular Solutions, Inc.
% Ms. Deborah Neymark
VP, Regulatory Affairs, Clinical
Research and Reimbursement
6464 Sycamore Court
Minnesapolis, Minnesota 55369

Re: K072332
Trade/Device Name: Vari-Lase® Wire Fiber
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: II
Product Code: GEX
Dated: November 30, 2007
Received: December 3, 2007

Dear Ms. Neymark:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

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

Enclosure

Indications for Use Statement

510(k) Number: K072332

Device Name:

Vari-Lase® Wire Fiber

Indications for Use:

The VARI-LASE Wire Fiber is indicated for the treatment of varicose veins and varicosities associated with superficial reflux in the Great Saphenous Vein and for 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 IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division Sign-Off

Division of General, Restorative, and Neurological Devices

510(k) Number K072332