MAR 16 2007

510(k) Summary

(As required by 21 CFR 807.92(c))

510(k) Number: K070216

Date Prepared

January 17, 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® Bright Tip™
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 Devices

Vari-Lase Endovenous Laser Procedure Kits (K050021) manufactured by Vascular Solutions, Inc.

Device Description

The Vari-Lase Bright Tip Fiber is a 600μm core laser fiber that is 3.5 meters in length. The distal tip of the fiber is encased in ceramic which provides ultrasound visibility during clinical use.

Intended Use/Indications for Use

The Vari-Lase® Bright Tip fiber is indicated for the treatment of varicose veins and varicosities associated with superficial reflux of 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 visibility under ultrasound, energy transmission, and integrity of the tip following simulated clinical use (tensile strength of the ceramic tip and burn-back)

Statement of Equivalence

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

Conclusion

The Vari-Lase Bright Tip 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

Vascular Solutions, Inc.
% Ms. Deborah L. Neymark
Vice President, Regulatory Affairs
6464 Sycamore Court
Minneapolis, Minnesota 55369

MAR 16 2007

Re: K070216
Trade/Device Name: Vari-Lase® Bright Tip™
Regulation Number: 21 CFR 870.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: II
Product Code: GEX
Dated: January 17, 2007
Received: January 23, 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 Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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: K070216

Device Name:
Vari-Lase® Bright Tip™ Fiber

Indications for Use:
The Vari-Lase® Bright Tip fiber is indicated for the treatment of varicose veins and varicosities associated with superficial reflux of 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 070216