2 510(k) Summary

K091551

Date Prepared: April 15, 2009

Submitter's Name / Contact Person

Manufacturer
Vascular Solutions, Inc.
6464 Sycamore Court
Minneapolis, MN 55369 USA
Establishment Registration # 2134812

Contact Person
Loucinda Bjorklund
Senior Regulatory Affairs Associate
Tel: 763.656.4208 (direct); Fax: 763.656.4253
Email: lbjorklund@vascularsolutions.com

JUN 19 2009

General Information

Trade Name	Vari-Lase Platinum Bright Tip laser fiber
Common / Usual Name	Laser Fiber
Classification Name	878.4810, Laser Instrument, Surgical, Powered
Predicate Device	K070216, Vari-Lase Bright Tip (Vascular Solution, Inc.)

Device Description

The Platinum Bright Tip is a laser fiber that is compatible with a solid state diode laser console. The laser fiber is comprised of a platinum/iridium distal tip, a 600 μm core laser fiber and an SMA connector. The laser fiber lengths are between 2.4 meters and 3.6 meters, with a maximum diameter of 0.038". The laser fiber is available with or without positioning marks.

Intended Use / Indications

The Vari-Lase Platinum Bright Tip laser 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.

Substantial Equivalence and Summary of Studies

The Vari-Lase Platinum Bright Tip is substantially equivalent in intended use and indications to the predicate device. Technological differences in design and materials have been qualified through biomaterial assessments and other design verification testing, the results of which did not raise any new safety or performance questions.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 19 2009

Vascular Solutions, Incorporated
% Ms. Loucinda Bjorklund
Senior Regulatory Affairs Associate
6464 Sycamore Court
Minneapolis, Minnesota 55369

Re: K091551
Trade/Device Name: Vari-Lase® Platinum Bright Tip Laser Fiber
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser Surgical Instrument for use in General Surgery and Plastic Surgery and in Dermatology
Regulatory Class: II
Product Code: GEX
Dated: May 26, 2009
Received: May 27, 2009

Dear Ms. Bjorklund:

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 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/cdrh/mdr/ 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
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): K091551

Device Name: Vari-Lase® Platinum Bright Tip laser fiber

Indications for Use:

The Vari-Lase Platinum Bright Tip laser fiber is indicated for the treatment of varicose veins and varicosities associated with superficial reflux of 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)

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

510(k) Number K091551