K030654

JUN 1 8 2003

510(K) SUMMARY

Common/Usual Name:	Laser Instrument Fiber and Procedure Kit
Product Trade Name:	Vari-Lase Endovenous Laser Procedure Kit
Classification Name:	Laser Surgical Instrument for use in General and Plastic Surgery and in Dermatology 21 CFR 878-4810 (Product Code GEX)
Manufacturer:	Vascular Solutions, Inc. 2495 Xenium Lane North Minneapolis, Minnesota 55441
Establishment Registration:	2134812
Contact:	Deborah Jensen V. P., Regulatory Affairs, Clinical Affairs, and Quality Systems (763) 656-4349 phone (763) 656-4252 fax
Performance Standards:	No performance standards have been developed under section 514 for this device.
Device Description:	The VARI-LASE procedure kit contains a 600µm fiber and the following accessories used to gain endovascular access: 0.035"/150cm stainless steel guide wire 5Fr/45cm introducer sheath 19 Gauge/7cm Percutaneous Entry Needle
Intended Use:	The VARI-LASE procedure kit is indicated for the treatment of varicose veins and varicosities associated with superficial reflux of the Greater Saphenous Vein.
Summary of Non-Clinical Testing:	Testing has been conducted to verify the integrity and biocompatility of the marker bands that are placed on the fiber and introducer sheath.
Predicate Devices:	EVLT Kit (Diomed, Inc. K023543) SLT Venous Fiber Delivery Systems (Surgical Laser Technologies, Inc. K023624) Angiodynamics ELVS Kit (Angiodynamics, Inc.)
Conclusions:	The VARI-LASE Procedure Kit is substantially equivalent to the identified predicate devices based on a comparison of the indications for use and the components supplied and the technological characteristics of the supplied components.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 1 8 2003

Ms. Deborah L. Jensen
Vice President, Regulatory Affairs,
Clinical Research, and Quality Systems
Vascular Solutions, Inc.
2495 Xenium Lane North
Minneapolis, Minnesota 55441

Re: K030654
Trade/Device Name: Vari-Lase Endovenous Laser Procedure Kit
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: May 30, 2003
Received: June 2, 2003

Dear Ms. Jensen:

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 (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. 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 may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
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: K036654

Device Name: Vascular Solutions Vari-Lase™ Endovenous Laser Procedure Kit

Indications for Use:

The VARI-LASE procedure kit is indicated for the treatment of varicose veins and varicosities associated with superficial reflux of the Greater Saphenous Vein.

Miriam C. Provost

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K036654