

NOV 20 2003

K033237

1 of 1

510(K) SUMMARY

Common/Usual Name: Laser Instrument

Product Trade Name: Vari-Lase Laser Console

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) 656-4250 fax

Performance Standards: No performance standards have been developed under section 514 for this device. The laser console is in compliance with the standards established in 21 CFR 1040.

Device Description: The VARI-LASE Laser is a semiconductor diode laser operating at 810 ± 20 nanometers.

Intended Use: The VARI-LASE laser 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 laser console is in compliance with the following standards:

EN60601-1	Medical Electrical Equipment - Part 1: General Requirements For Safety"
EN60601-1-1	Medical Electrical Equipment - Part 1: General Requirements For Safety 1: Collateral Standard: Safety Requirements For Medical Electrical Systems
EN60601-2	Medical Electrical Equipment - Part 1-2: General Requirements For Safety - Collateral Standard: Electromagnetic Compatibility - Requirements And Tests
EN60601-1-4	Medical Electrical Equipment - Part 1-4: General Requirements For Safety - Collateral Standard: Programmable Electrical Medical Systems
EN60601-2-22	Medical Electrical Equipment - Part 2: Particular Requirements For safety - Section 2.22: Specification For Diagnostic And Therapeutic Laser Equipment

Predicate Devices: Diomed 15/30 Plus Diomed, Inc. (K023543)
Medart 425P/426 Laser Consoles (K991659)

Conclusions: The VARI-LASE Laser is substantially equivalent to the identified predicate devices based on a comparison of the indications for use and the technological characteristics.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 20 2003

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

Re: K033237

Trade/Device Name: Vascular Solutions Vari-Lase™ Endovenous Laser Console

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: September 30, 2003

Received: October 7, 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.

Page 2 - Ms. Deborah Jensen

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. 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 (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:

K033237

Device Name:

Vascular Solutions Vari-Lase™ Endovenous Laser Console

Indications for Use:

VARI-LASE 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 K033237