510(k) Summary

510(k) Number: K 062822

NOV 2 1 2006

Date Prepared September 15, 2006

Submitter Information

Submitter's Name/ Address: Vascular Solutions, Inc.
6464 Sycamore Court
Minneapolis, MN 55369

Contact Person: Patrice Stromberg
Sr. Regulatory Affairs Associate
pstromberg@vascularsolutions.com
(763) 656-4300 (phone)
(763) 656-4250 (fax)

Device Information

Trade Name: Vari-Lase™ Endovenous Laser Console and
Common Name: Laser Instrument
Classification Name: Laser Surgical Instrument for use in General and Plastic Surgery and in Dermatology
Product Code: GEX
Regulation: Class II, 21 CFR 878-4810

Predicate Devices

Vascular Solutions Vari-Lase™ Laser Console (K033237)
Diomed, Inc. Diomed 15 Plus Laser System (K023543 and K041957)

Device Description

The Vari-Lase Console is a software controlled diode laser that provides an output wavelength of 810 nm.

Intended Use/Indications for Use

The Vari-Lase™ procedure 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 Non-Clinical Testing

Additional testing was not conducted for the upgrades to this device. Testing was previously conducted to verify the laser console is in compliance with the following electrical safety standards. No circuitry was changed that would affect the electrical safety of the Vari-Lase Console.

- EN 60601-1: Medical Electrical Equipment – Part 1: General Requirements for Safety
- EN 60601-1-1: Medical Electrical Equipment – Part 1-1: General Requirements for Safety - Collateral Standard: Safety Requirements for Medical Electrical Systems
- EN 60601-2: Medical Electrical Equipment – Part 1-2: General Requirements for Safety – Collateral Standard: Electromagnetic Compatibility – Requirements and Tests
- EN 60601-1-4: Medical Electrical Equipment – Part 1-4, General Requirements for Safety – Collateral Standard: Programmable Electrical Medical Systems
- EN 60601-2-22: Medical Electrical Equipment – Part 2: Particular Requirements for Safety – Section 2.22: Specification for Diagnostic and Therapeutic Laser Equipment

Summary of Non-Clinical Testing

No clinical evaluations of this product have been conducted.

Statement of Equivalence

The Vari-Lase Endovenous Laser Console is substantially equivalent to the identified predicate devices based on a comparison of the indications for use and the technological characteristics.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Vascular Solutions
% Ms. Patrice Stromberg
Senior Regulatory Affairs Associate
6464 Sycamore Court
Minneapolis, Minnesota 55369

NOV 2 1 2006

Re: K062822
Trade/Device Name: 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 18, 2006
Received: September 20, 2006

Dear Ms. Stromberg:

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 (if known): K 062822

Device Name:

Vari-Lase™ Endovenous Laser Console

Indications for Use:

The Vari-Lase™ procedure 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 K062822