MAR 2 6 2008

510(k) Summary
(As required by 21 CFR 807.92(c))

510(k) Number: K080104

Date Prepared January 11, 2008
Ammended March 13, 2008

Submitter Information

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

Contact Person: James Chapman
Regulatory Affairs Associate
Phone 763-656-4300 x308
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Device Information

Trade Name: Vari-Lase® Endovenous Laser Console
Common Name: Laser Surgical Instrument for use in General and Plastic Surgery and Dermatology
Classification Name: Laser Surgical Instrument for use in General and Plastic Surgery and in Dermatology
Class: II
Product Code: GEX
Regulation: 21 CFR 870.4810

Predicate Devices

The Vari-Lase 90 Watt Endovenous Laser Console (Model 7542) is substantially equivalent to the Model 430(435) Diode Laser Medart Corporation (a subsidiary of Asah Medico), described in Medart 510(k) K993815 and to the current Vascular Solutions Vari-Lase console described in K062822.

Device Description

The Vari-Lase 90 Watt Endovenous Laser Console (Vari-Lase Console) is a software controlled diode laser that provides an output wavelength of 810nm. It may be used in conjunction with a cooling system in certain surface treatment applications.

Software Validation

No changes in software were required to accommodate the revised intended use; therefore, additional software validation was not required.

Intended Use/Indications for Use

The Vari-Lase® 90W laser console is indicated for use in hair removal (destruction of hair follicles) in skin types I-IV, and for soft tissue applications, such as coagulation of soft tissue, e.g., vascular lesions (visible blood vessels) and in contact mode, for the vaporization, ablation, incision, and excision of soft tissue.

The Vari-Lase® procedure is indicated for the treatment of varicose veins and varicosities associated with superficial reflux in the Great Saphenous Vein and for treatment of incompetence and reflux of superficial veins in the lower extremity.

Summary of Testing

No additional testing was completed. MedArt has previously confirmed compliance of these products to the following standards:

Standard	Description
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
ISO 13485:2003	Medical Devices - Quality management systems - Requirements for regulatory purposes

Statement of Equivalence

The Vari-Lase Endovenous Laser Console and associated cooling system are substantially equivalent to the currently marketed MedArt Model 430(435) Diode Laser (K993815) and the VSI Vari-Lase Endovenous Laser K033237, and based on comparisons of the device classification, indications for use, technological characteristics, and software.

Conclusion

The Vari-Lase Endovenous Laser Console and associated cooling system are substantially equivalent to the currently marketed predicate devices based on comparisons of the device classifications, indications for use, technological characteristics, and software.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 2 6 2008

Vascular Solutions, Inc.
% Mr. James Chapman
Regulatory Affairs Associate
6464 Sycamore Court
Minneapolis, Minnesota 55369

Re: K080104
Trade/Device Name: Vari-Lase® 90 Watt 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: March 13, 2008
Received: March 14, 2008

Dear Mr. Chapman:

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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. 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

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Indications for Use Statement

510(k) Number: K080104

Device Name:

Vari-Lase® 90 Watt Endovenous Laser Console

Indications for Use:

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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)

Mark A Milkerson

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

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