K024088 1/2

JAN 02 2003

510(k) Summary
Ceralas Diode 980 nm Laser System with Endo Laser Vein System Kit

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared

biolitec, Inc.
515 Shaker Road
East Longmeadow, Massachusetts 01028
Phone: (413) 525-0600
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Contact Person: Carol J. Morello, V.M.D.
Date prepared: December 11, 2002

Name of Device and Name/Address of Sponsor

Ceralas D Diode Laser System with Endo Laser Vein System Kit
biolitec, Inc.
515 Shaker Road
East Longmeadow, Massachusetts 01028

Classification Name

Surgical laser and accessories

Predicate Devices

Ceralas D Diode Laser System (980 nm and 810 nm)

Intended Use/Indication for Use

The device is intended for endovascular coagulation of blood vessels. The device is indicated for the endovascular coagulation of the greater saphenous vein in the thigh in patients with superficial vein reflux.

Technological Characteristics

The Ceralas D 980 nm Laser with Endo Laser Vein System Kit consists of the cleared Ceralas D 980 and the ELVeS. Twelve versions of the ELVeS kit contain various combinations of the following components: (1) 19 gauge needle; (2) 21 gauge needle; (3) 5 French (F) introducer sheath; (4) 5 F introducer sheath/dilator; (5) a 0.035" J-tip guidewire; (6) a 0.018" J-tip guidewire; (7) surgical drape; (8) surgical tape; and (9) a surgical pen.

K024088 2/2

Performance Data

The device complies with the following voluntary consensus standards: 21 C.F.R. §§ 1040.10 & 1040.11; ANSI/AAMI ES1; IEC 601-1; IEC 601-2-22; EN 60825-1, and ANSI/AAMI/ISO 10993-7.

Substantial Equivalence

The Ceralas D 980 nm Laser System with ELVeS has the same intended use and indications for use as the cleared Ceralas D 980 nm Laser System and Ceralas D 810 nm Diode Laser System and the same technological characteristics as the cleared Ceralas D 810 and the cleared Ceralas D 980. The technological differences between the Ceralas D 980 with ELVeS kit and the cleared Ceralas D 980 is the addition of the ELVeS kit, which is cleared for use with the Ceralas D 810 for the same indication. Thus, the ELVeS kit is not a new technological characteristic for diode lasers for endovascular coagulation of the greater saphenous vein in the thigh in patients with superficial vein reflux. Thus, the Ceralas D 980 with ELVeS is substantially equivalent to its predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 02 2003

Biolitec, Inc.
c/o Hogan & Hartson, L.L.P.
Jonathan S. Kahan
555 Thirteenth Street, NW
Washington, DC 20004-1109

Re: K024088
Trade/Device Name: Ceralas Diode 980 nm Laser System with Endo Laser Vein System Kit
Regulation Number: 878.4810
Regulation Name: Surgical laser and accessories
Regulatory Class: Class II
Product Code: GEX
Dated: December 11, 2002
Received: December 11, 2002

Dear Mr. Kahan:

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). 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 (if known): K024088

Device Name: **Ceralas D 980 nm Diode Laser System with Endo Laser Vein System Kit**

For endovascular coagulation of the greater saphenous vein of the thigh in patients with superficial vein reflux.

(PLEASE DO NOT WRITE BELOW THIS LINE -- CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use____
(Per 21 C.F.R. 801.109) (Optional Format 1-2-96)

Miriam C. Provost
(Division Sign-Off)
Division of General, Restorative and Neurological Devices

510(k) Number K024088