

1/2  
AUG 13 2002

**510(k) Summary  
Ceralas Diode Laser System  
(K013691)**

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

biolitec, Inc.  
515 Shaker Road  
East Longmeadow, Massachusetts 01028  
Phone: (413) 525-0600  
Facsimile: (413) 525-0611

Contact Person: Carol J. Morello, V.M.D.  
Date prepared: May 29, 2001

**Name of Device and Name/Address of Sponsor**

Ceralas D 980 nm Diode Laser System (Model D50)  
biolitec, Inc.  
515 Shaker Road  
East Longmeadow, Massachusetts 01028

**Classification Name**

Surgical laser

**Predicate Devices**

Ceralas D Diode Laser System  
VNUS Medical Technologies' VNUS Closure System  
DioMed, Inc.'s 810 nm Surgical Laser and EVLT Procedure Kit Laser

**Intended Use/Indication for Use**

The Ceralas D 980 nm Diode Lasers are intended for endovascular coagulation of blood vessels. The Ceralas D 980 nm Diode Lasers are indicated for use in endovascular coagulation of the greater saphenous vein of the thigh in patients with superficial vein reflux.

**Performance Data**

The device complies with the following voluntary consensus standards: 21 C.F.R. §§ 1040.10 & 1040.11; ANSI/AAMI ES1; IEC 60601-1; IEC 601-2-22; and EN 60825-1.

In addition, biolitec performed a single arm, open study at a single site with two clinical investigators to determine the ability of the Ceralas D Laser System to treat

K013691 2/2

superficial vein reflux of the greater saphenous vein. Ninety-six percent of the patients enrolled in the study achieved complete closure of the vein. All adverse events were of limited duration and resolved completely.

**Substantial Equivalence**

The Varicose Vein Ceralas D has the same intended use and indications for use as VNUS Medical Technologies' VNUS Closure System and Diomed, Inc.'s 810 nm Surgical Laser and EVLT Procedure Kit laser. In addition, the superficial vein reflux Ceralas D is the exact same device as the cleared Ceralas D. Furthermore, clinical data demonstrate that the superficial vein reflux Ceralas D is substantially equivalent for endovascular coagulation of blood vessels in patients with superficial vein reflux.



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

**AUG 13 2002**

Biolitec, Inc.  
c/o Jonathan S. Kahan  
Hogan & Hartson, L.L.P.  
555 Thirteenth Street, N.W.  
Washington, D.C. 20004-5910

Re: K013691

Trade/Device Name: Ceralas D 980nm Diode Laser Systems

Regulation Number: 878.4810

Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology

Regulatory Class: Class II

Product Code: GEX

Dated: May 29, 2002

Received: May 29, 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.

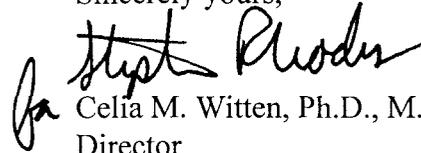
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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.

Page 2 – Mr. Jonathan Kahan

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 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), 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” (21 CFR 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,

A handwritten signature in black ink, appearing to read "Celia M. Witten". The signature is written in a cursive style with a large initial "C" and "W".

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): K013691

Device Name: Ceralas D Diode Laser System

In addition to the already cleared indications:

**The Ceralas D 980 nm Diode Lasers are indicated for use in 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 ✓  
(Per 21 C.F.R. 801.109)

OR

Over-The-Counter Use \_\_\_\_\_  
(Optional Format 1-2-96)

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

510(k) Number K013691