K030700 1/2

JUN - 4 2003

510(k) Summary
Ceralas Diode Laser System

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: March 4, 2003

Name of Device and Name/Address of Sponsor

Ceralas Diode Laser System (Model D10-60) 810nm
Biolitec, Inc.
515 Shaker Road
East Longmeadow, MA 01028

Classification Name

Surgical laser

Predicate Device

Diomed 810nm Surgical Laser
Biolitec Ceralas D10-60 810nm Diode Laser
Biolitec Ceralas D 980 nm Diode Laser

Intended Use / Indications For Use

In addition to the already cleared indications:
For use in treatment of varicose veins and varicosities associated with superficial reflux of the greater saphenous vein.

Technological Characteristics

The Ceralas D810 Diode Laser and the predicate devices operate with a power range of 1-60W in the CW or pulsed mode. The Ceralas D180 contains an ELVeS kit for gaining access to the vasculature to treat varicose veins and varicosities associated with superficial reflux of the greater saphenous vein.

Substantial Equivalence

The Ceralas D810 with ELVeS has the exact same intended use and indications for use as its predicate devices, the cleared Diomed 810 laser, the Ceralas D810, and the Ceralas D980. The Ceralas D810's proposed varicose vein indication, which is a modification to its cleared superficial vein reflux indication, is exactly the same as the Diomed 810's varicose vein indication. The laser component of the Ceralas D810 with ELVeS kit is identical to the cleared Ceralas D810 laser, and its ELVeS kit is identical to the Ceralas D 980's cleared ELVeS kit. Moreover, each component of the Ceralas D810's and Ceralas D980's ELVeS kit is a cleared device, a preamendment device, or a 510(k) exempt device for the same general intended use. Any minor technical differences between the Ceralas D980 and the Ceralas D810 do not raise the question of safety or effectiveness. Thus, the Ceralas D810's cleared with ELVeS kit is substantially equivalent to a combination of its predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN - 4 2003

Biolitec, Inc.
c/o Mr. Jonathan S. Kahan
Hogan & Hartson, L.L.P.
555 Thirteenth Street, NW
Washington, D.C. 20004

Re: K030700
Trade/Device Name: Ceralas D10-60 810 nm Diode Laser System with Endo Laser Vein System Kit
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 4, 2003
Received: March 6, 2003

Dear Dr. Morello:

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.

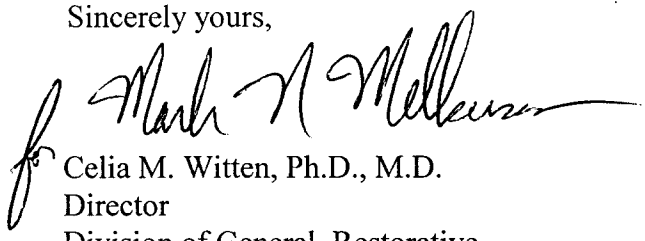
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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) you may obtain. 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,



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): K030700

Device Name: Ceralas D10-60 810 nm Diode Laser System with Endo Laser Vein System Kit

Indicated for use in treatment of varicose veins and varicosities associated with superficial reflux of the greater saphenous vein.

(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)

for Mark N Melkerson
(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K030700