K 013193

DEC 21 2001

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
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Contact Person: Carol Morello, V.M.D.
Date prepared: September 24, 2001

Name of Device and Name/Address of Sponsor

MegaBeam/Ceralas Non Sterile Collimating Handpiece
Biolitec, Inc.
515 Shaker Road
East Longmeadow, MA 01028

Classification Name

Accessory to Surgical Laser Instrument

Predicate Device

Biolitec Inc MegaBeam Sterile Fiber optic Delivery System's Bare Fibers
Coherent VersaSpot & Collimated Handpiece
Coherent Ultrafine TrueSpot Collimating Handpiece

Intended Use

The company's MegaBeam/Ceralas Non Sterile Collimating Handpiece is intended to be used as a fiber optic delivery accessory to a laser device. Please refer to the Laser User Manual for complete list of indications.

Technological Characteristics and Substantial Equivalence

The Mega Beam/Ceralas Collimating Handpiece consists of a 3 meter quartz optical fiber encased in an anodized aluminum handpiece. The aluminum handpiece has lenses that collimate the beam to create a 7mm beam and resulting 7mm spot size. The MegaBeam/Ceralas Collimating Handpiece maximum power output was less than the predicate devices and its divergence angle is less than the predicate. However, these technological differences do not raise any new questions of safety and effectiveness, as demonstrated by the performance data.

Performance Data

Biolitec conducted testing comparing the MegaBeam/Ceralas Collimating Handpiece's and the MegaBeam Bare Fiber's handpiece efficiency, energy density and divergent half angle. These

performance tests demonstrate that the MegaBeam /Ceralas Collimating Handpiece is as safe and effective as the Fiber Optic Delivery System's Bare Fiber.

Substantial Equivalencies

The MegaBeam/Ceralas Collimating Handpiece has the same intended use as all three of its predicate devices, the same indications as one of the predicate devices, except that it cannot be used in endoscopic applications, and very similar principles of operation as the predicate collimating handpieces and similar technical characteristics as a combination of the predicate devices. The minor technical differences between the MegaBeam/Ceralas Collimating Handpiece and its predicate devices do not raise new questions of safety or effectiveness. Performance data Demonstrates that the MegaBeam/Ceralas Collimating Handpiece is as safe and effective as its predicate device. Thus, the MegaBeam/Ceralas Collimating Handpiece is substantially equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 21 2001

Carol J. Morello, V.M.D.
Manager of Regulatory Affairs
Biolitec, Inc.
515 Shaker Road
East Longmeadow, Massachusetts 01028

Re: K013193
Trade/Device Name: MegaBeam/Ceralas Non-Sterile Collimating Handpiece
Regulation Number: 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 24, 2001
Received: September 24, 2001

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.

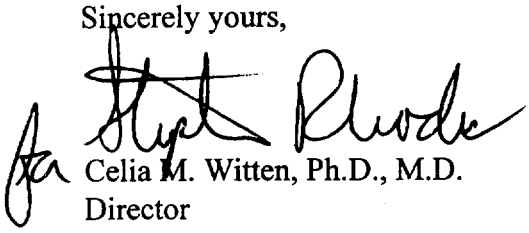
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish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



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 Form

510(k) Number (if known): K 013193

Device Name: Mega Beam/Ceralas Nonsterile Collimating Handpiece

Indications for Use:

The company's MegaBeam/Ceralas NonSterile Collimating Handpiece is intended to be used as a fiber optic delivery accessory to a laser device. Please refer to the Laser User Manual for a complete list of indications.

(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 K013193

Prescription Use X
(Per 21 C.F.R. 801.109)

OR

Over-The-Counter Use____

(Optional Format 1-2-96)