K 112324

SEP - 6 2011

510(k) Summary
Ceralas 980nm Diode Laser Family

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

Biolitec Medical Devices, Inc.
515 Shaker Road
East Longmeadow, Massachusetts 01028
Phone: (413) 525-0600
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Contact Person: Harry Hayes, Ph.D. – Regulatory Consultant
Date prepared: August 10, 2011

Name of Device and Name/Address of Sponsor

Ceralas 980nm Diode Laser Family
Biolitec Medical Devices, Inc.
515 Shaker Road
East Longmeadow, Massachusetts 01028

Classification Name

Surgical laser & accessories

Predicate Devices

Ceralas 980nm Diode Laser Family (covering models: D15, D25, D50, E15, & E30; D100, D120, D150 & D180)

Intended Use/Indication for Use

The Ceralas Fiber-Coupled 980nm Diode Laser family (and their delivery accessories used to deliver optical energy) are indicated for use in general surgical applications for incision, excision, ablation, cutting, vaporization, hemostasis, and coagulation of soft tissue contact or non-contact, open or closed endoscopic applications where incision, tissue dissection, excision of external tumors and lesions, complete or partial resection of internal organs, tumors and lesions, tissue vaporization, hemostasis and/or coagulation may be indicated.

Technological Characteristics

The Ceralas 980nm family for Biolitec Medical Devices, Inc. is identical (contains the same components, technology and principles of operation and assembled by the same manufacturer) as the cleared Ceralas 980nm family for Biolitec, Inc..

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 Biolitec Medical Devices Inc Ceralas 980nm family is as safe and effective as the Biolitec Inc. Ceralas 980nm family as the products are identical in all aspects except labeling relating to the manufacturer/ distributor.

The Ceralas 980nm family has the same intended uses, indications, technological characteristics, and principles of operation as its predicate devices. Thus, the Ceralas 980nm family from Biolitec Medical Devices, Inc. is substantially equivalent to its predicate devices from Biolitec, Inc.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Biolitec Medical Devices, Inc.
% Harry Hayes, Ph.D.
515 Shaker Road
East Longmeadow, Massachusetts 01028

SEP - 6 2011

Re: K112324
Trade/Device Name: Ceralas Fiber Coupled Diode Laser Family 980nm
(covering 980nm Models: D15, D25, D50, E15 & E30;
D100, D120, D150 & D180)
Regulation Number: 21 CFR 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: August 10, 2011
Received: August 12, 2011

Dear Dr. Hayes:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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 (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K112324

Device Name: Ceralas Fiber-Coupled Diode Laser Family 980nm (covering 980nm Models: D15, D25, D50, E15, & E30; D100, D120, D150 & D180)

Indications for Use: The Ceralas Fiber-Coupled 980nm Diode Laser family (and their delivery accessories used to deliver optical energy) are indicated for use in general surgical applications for incision, excision, ablation, cutting, vaporization, hemostasis, and coagulation of soft tissue contact or non-contact, open or closed endoscopic applications where incision, tissue dissection, excision of external tumors and lesions, complete or partial resection of internal organs, tumors and lesions, tissue vaporization, hemostasis and/or coagulation may be indicated.
Indications include: General Surgery, Urology, Gynecology, Gastroenterology, Otolaryngology, Plastic Surgery, Dermatology, Podiatry, Neurosurgery/ Peripheral, Pulmonary Surgery, Arthroscopy, Cardiothoracic Surgery, Laser Assisted Lipolysis, Ophthalmology, Dental Applications, Endovenous Occlusion 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)

(Division Sign-Off)
Division of Surgical, Orthopedic, and Restorative Devices

510(k) Number K112324

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