FEB 2 4 2011

510(k) Summary
K110080 - Radial-Emitting Shaped Fiber Optic Delivery System

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

Biolitec, Inc.
515 Shaker Road
East Longmeadow, Massachusetts 01028
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Contact Person: Harry Hayes, Ph.D. – Regulatory Consultant
Date prepared: January 10, 2011

Name of Device and Name/Address of Sponsor

Radial-Emitting Shaped Fiber Optic Delivery System
Biolitec, Inc.
515 Shaker Road.
East Longmeadow, Massachusetts 01028

Classification Name

Surgical laser accessory

Predicate Devices

Megabeam Radial Fiber (K924258) for Nd: YAG lasers.
Ceralas F 1060 nm & 1320nm (K953851).
Ceralas 980nm & 1470nm diode laser family, (K100726, K101712, K102755).

Intended Use/Indication for Use

The Radial-Emitting Shaped Fiber Optic Delivery System, is intended for use as a fiber delivery system in conjunction with any surgical laser with an SMA 905 compatible connector. It is 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. The fiber is indicated for use in general surgery, urology, gastroenterology, gynecology, dermatology, neurosurgery, plastic surgery, ENT/ otolaryngology, endovenous occlusion of the greater saphenous vein in patients with superficial vein reflux and laser assisted lipolysis with a compatible laser marketed for use in the desired application.

Technological Characteristics

The Radial-Emitting Shaped Fiber Optic Delivery System contains the same basic components and design as the cleared Megabeam Radial fiber and theCeralas diode laser family is substantially similar in performance and technology to the cleared Nd:YAG laser. Any minor differences in technology do not raise any new questions on safety or efficacy.

Performance Data
Since the performance of the Radial-Emitting Shaped Fiber Optic Delivery System is well established and documented on soft tissue no performance testing is being specifically included in this submission.

Substantial Equivalence
The Radial-Emitting Shaped Fiber Optic Delivery System is as safe and effective for these Indication for Use as the Megabeam Radial-Emitting Shaped Fiber Optic Delivery System. The Ceralas diode laser family has the same intended uses, indications, technological characteristics, and principles of operation as its predicate Nd:YAG devices. Thus, the Ceralas diode laser family is substantially equivalent to its predicate device.

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, Inc.
% Ms. Nancy Foley
515 Shaker Road
East Longmeadow, Massachusetts 01028

FEB 24 2011

Re: K110080
Trade/Device Name: Radial-Emitting Shaped Fiber Optic Delivery System
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: January 10, 2011
Received: January 11, 2011

Dear Ms. Foley:

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,

for

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): K110080

Device Name: **Radial-Emitting Shaped Fiber Optic Delivery System**

Indications for Use: The Radial-Emitting Shaped Fiber Optic Delivery System, is intended for use as a fiber delivery system in conjunction with any surgical laser with an SMA 905 compatible connector. It is 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. The fiber is indicated for use in general surgery, urology, gastroenterology, gynecology, dermatology, neurosurgery, plastic surgery, ENT/ otolaryngology, endovenous occlusion of the greater saphenous vein in patients with superficial vein reflux and laser assisted lipolysis with a compatible laser marketed for use in the desired application.

(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 K110080

Orthopedic,

510(k) Number

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

OR

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