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JAN 2 4 2012

510(k) Summary
MegaBeam® Endo-ENT Probe

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: December 20, 2011

Name of Device and Name/Address of Sponsor

MegaBeam Endo-ENT Probe
Biolitec Medical Devices, Inc.
515 Shaker Road
East Longmeadow, Massachusetts 01028

Classification Name

Surgical laser accessory

Predicate Devices

MegaBeam Endo-ENT Probe, (K952772).

Intended Use/Indication for Use

The MegaBeam Endo-ENT Probe is a fiber optic delivery system intended as an aid for otologic procedures, for use in incision, excision, coagulation and vaporization of soft and fibrous tissue including osseous tissue. It is indicated for ENT surgery for use with compatible lasers cleared for use in the desired application.

Technological Characteristics

The MegaBeam Endo-ENT Probe for Biolitec Medical Devices, Inc. contains the identical same components and design as the device cleared under K952772 for Biolitec Inc. There are no differences in technology and as such does not raise any new questions on safety or efficacy.

Performance Data

Since the performance of the MegaBeam Endo-ENT Probe is well established and documented no performance testing is being specifically included in this submission.

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Substantial Equivalence

The MegaBeam Endo-ENT Probe is as safe and effective for these Indications for Use as the MegaBeam Endo-ENT Probe predicate device. Thus, the MegaBeam Endo-ENT Probe for Biolitec Medical Devices, Inc. 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

JAN 2 4 2012

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

Re: K113858
Trade/Device Name: MegaBeam Endo-ENT Probe
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: December 29, 2011
Received: December 30, 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): K113858

Device Name: **MegaBeam Endo-ENT Probe.**

Indications for Use: The MegaBeam Endo-ENT Probe is intended as an aid for otologic procedures, for use in incision, excision, coagulation and vaporization of soft and fibrous tissue including osseous tissue. It is indicated for ENT surgery for use with compatible lasers cleared 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)

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

OR

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

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

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