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JAN 13 2012

510(k) Summary
Evolve® HPD 980/ 1470nm Multiwavelength Diode Laser

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: July 5, 2011

Name of Device and Name/Address of Sponsor

Evolve® HPD 980/ 1470nm Multiwavelength Diode Laser; Evolve® HPD Dual
Biolitec, Inc.
515 Shaker Road
East Longmeadow, Massachusetts 01028

Classification Name

Surgical laser (21 CFR 878.4810, Product Code GEX)

Predicate Devices

Ceralas 150W 980/ 1470nm Multiwavelength Diode Laser, (K090164)
Ceralas 180W 980nm Diode Laser, (K083682)
Ceralas 980nm Diode Laser Family, (K100726 & K112324)

Intended Use/Indication for Use

The device is intended for delivery of laser light to soft tissue in the contact and non contact mode during surgical procedures including via endoscopes. The Evolve HPD Multiwavelength 980/ 1470 Diode Laser (up to 150W) is generally indicated for use in incision, excision, vaporization, ablation, hemostasis or coagulation of soft tissue in ear, nose and throat and oral surgery (otolaryngology), arthroscopy, gastroenterology, general surgery, dermatology, plastic surgery, podiatry, urology, gynecology, neurosurgery (peripheral nervous system), pulmonary surgery, cardiothoracic surgery, dental applications, and endovenous occlusion of the saphenous veins in patients with superficial vein reflux. The Multiwavelength laser is further indicated for laser assisted lipolysis. Power from 151W to 200W is indicated in the vaporization of the prostate to treat Benign Prostatic Hyperplasia (BPH).

The device is specifically indicated for use as follows:

Ear, Nose and Throat and Oral Surgery (Otolaryngology)
Hemostasis, incision, excision, ablation, coagulation, and vaporization of tissue from the ear, nose, throat and adjacent areas including soft tissue in the oral cavity.
Examples include:
Removal of benign lesions from the ear, nose and throat
Excision and vaporization of vocal cord nodules and polyps
Incision and excision of carcinoma in situ
Ablation and vaporization of hyperkeratosis
Excision of carcinoma of the larynx
Laryngeal papillomectomy
Excision and vaporization of herpes simplex I and II
Neck dissection

Arthroscopy
Hemostasis, incision, excision, coagulation, vaporization and ablation of joint tissues during arthroscopic surgery. Examples include:
Menisectomy
Synovectomy
Chondromalacia

Gastroenterology
Hemostasis, incision, excision, ablation, coagulation and vaporization of tissue in the upper and lower gastrointestinal tracts and also with endoscopic procedures.
Examples include:
Hemostasis of upper and lower GI bleeding
Excision and vaporization of colorectal carcinoma
Excision of polyps

General Surgery, Dermatology, Plastic Surgery and Podiatry
Excision, ablation, vaporization and photocoagulation of skin lesions, hemostasis, incision, excision, vaporization, ablation and debulking of soft tissue, abdominal, rectal, skin, fat or muscle tissue and dermabrasion.
Examples include:
Matrixectomy
Excision of neuromas
Excision of periungual and subungual warts
Excision of plantar warts
Excision of keloids
Liver resection

Excision of cutaneous lesions
Hemorrhoidectomy
Appendectomy
Debridement of decubitus ulcers
Hepatobiliary tumors
Mastectomy
Dermabrasion
Laser Assisted Lipolysis
Vaporization and hemostasis of capillary hemangioma
Excision, vaporization and hemostasis of abdominal tumors
Excision, vaporization and hemostasis of rectal pathology
Pilonidal cystectomy
Herniorapphy
Adhesiolysis
Parathyroidectomy
Laparoscopic cholecystectomy
Thyroidectomy
Resection of organs
Debridement of wounds
Photocoagulation of teleangectasia of the legs and face
Photocoagulation of vascular lesions of the face and extremities
Endovenous Occlusion of the Saphenous Veins in Patients with Superficial Vein Reflux Associated with Varicose Veins and Varicosities
Treatment of reticular veins and branch varicosities

Urology
Excision, vaporization, incision, coagulation, ablation and hemostasis of urological tissues.
Examples include:
Vaporization of urethral tumors
Release of urethral stricture
Removal of bladder neck obstruction
Excision and vaporization of condyloma
Lesions of external genitalia
Vaporization of the prostate to treat benign prostatic hyperplasia (BPH). Note: powers from 151W to 200W should only be applied in the vaporization of the prostate to treat Benign Prostatic Hyperplasia (BPH).

Gynecology
Ablation, excision, incision, coagulation, hemostasis and vaporization of gynecological tissue.
Examples include:
Endometrial ablation
Excision or vaporization of condylomata acurninate
Vaporization of cervical intraepithelial neoplasia

Cervical conization
Menorrhagia

Neurosurgery
Vaporization, coagulation, excision, incision, ablation and hemostasis of soft tissue.
Examples include:
hemostasis in conjunction with menigiomas

Cardiac Surgery
Hemostasis and coagulation of soft tissue, including cardiac tissue.

Pulmonary Surgery
Hemostasis, vaporization, coagulation, incision, excision and ablation of soft tissue in the pulmonary system.
Examples include:
Tracheobronchial malignancy or stricture
Benign and malignant pulmonary obstruction
Endoscopic pulmonary applications

Dental Applications
Indicated for the following applications on intraoral and extraoral soft tissue (including marginal and interdental gingival and epithelial lining of free gingival): frenectomy, frenotomy, biopsy, operculectomy, implant recovery, gingivectomy, gingivoplasty, gingival troughing, crown lengthening, hemostasis of donor site, removal of granulation tissue, laser assisted flap surgery,

debridement of diseased epithelial lining, incisions and draining of abscesses, tissue retraction for impressions, papillectomy, vestibuloplasy, excision of lesions, exposure of unerupted/ partially erupted teeth, leukoplakia, removal of hyperplastic tissues, treatment of aphthous ulcers and sulcular debridement (removal of diseased or inflamed soft tissue in the periodontal pocket), pulpotomy, pulpotomy as an adjunct to root canal therapy and light activation of bleaching materials for teeth whitening.

Powers from 151W to 200W
Powers from 151W to 200W should only be applied in the vaporization of the prostate to treat Benign Prostatic Hyperplasia (BPH).

Technological Characteristics

The Evolve HPD 980/ 1470nm Multiwavelength Diode Laser contains the same basic components as the cleared Ceralas 150W 980/ 1470nm Diode Laser (K090164). The purpose of this submission is to increase the energy from 150W to 200W for application in the vaporization of the prostate to treat Benign Prostatic Hyperplasia, (BPH)

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. Published clinical data supplied quantifies ablation rates on a per Watt basis for a 980nm laser versus a 1470nm laser, which together with studies using 200W 980nm lasers on human cadaver prostates and 50W 1470nm lasers on prostates of patients with bladder outlet obstruction along with its predicate devices support the conclusion that the device is safe and effective and substantially equivalent to its predicate devices.

Substantial Equivalence

The Evolve HPD 980/ 1470nm Multiwavelength Diode Laser is as safe and effective for these Indication for Use as the cleared Ceralas 150W 980/ 1470nm Diode Laser. The Evolve HPD 980/ 1470nm Multiwavelength Diode Laser has the same intended uses, indications, technological characteristics, and principles of operation as its predicate device. Thus, the Evolve HPD 980/ 1470nm Multiwavelength Diode Laser is substantially equivalent to its predicate devices.

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, Incorporated
% Genmarhay BDA
Harry Hayes, Ph.D.
515 Shaker Road
East Longmeadow, Massachusetts 01028

JAN 13 2012

Re: K112013
Trade/Device Name: Evolve HPD 980/1470nm Multiwavelength Diode Laser
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 5, 2012
Received: January 10, 2010

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 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 Dep Cen Dir

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): K112013

Device Name: **Evolve® HPD 980/ 1470nm Multiwavelength Diode Laser**

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

510(k) Number K112013

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Neil R P Ogden for mxn
(Division Sign-Off)
Division of Surgical, Orthopedic, and Restorative Devices

510(k) Number K112013

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Neil R Ogden for mxm
(Division Sign-Off)
Division of Surgical, Orthopedic, and Restorative Devices

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(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)

Neil R P Ogden for mxm
(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K112013