510(k) SUMMARY

Biolitec, Inc.'s
Ceralas E 980nm Diode Laser (Models E15/980,30)

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

OCT 24 2008

Hogan & Hartson
555 13th Street NW
Washington DC 20004

Phone: 202 637-5794
Facsimile: (202) 637-5910

Contact Person: Jonathan S. Kahan

Date Prepared: July 24, 2008

Name of Device and Name/Address of Sponsor

Ceralas E 980nm Diode Laser (Models E15/980,E30/980)

Biolitec, Inc.
515 Shaker Road
East Longmeadow, MA 01028

Common or Usual Name

Diode Laser

Classification Name

Laser, Surgical Diode Laser System

CFR Provision and Product Code

21 C.F.R. 878.4810, GEX

Predicate Devices

Biolitec Ceralas D 980 Diode Laser (Models D15, D25) (K032863, K072779, K081015)

Purpose of the Special 510(k) notice.

The Ceralas E15/980, E30/980 is a modification to Ceralas D 980.

Intended Use

The Ceralas E15/980, E30/980 is intended for delivery of laser light to soft tissue in the contact or non-contact mode during surgical procedures, including via endoscopes, introducers, or catheters. The Ceralas E15/980, E30/980 is generally indicated for incision, excision, vaporization, ablation, hemostasis, or coagulation of soft tissue in ear, nose and throat and oral surgery (otolaryngology), dental procedures, arthroscopy, gastroenterology, general surgery, dermatology, plastic surgery, podiatry, urology, gynecology, neurosurgery (peripheral nervous system), pulmonary surgery, cardiothoracic surgery, and ophthalmology. This Ceralas E15/980, E30/980 is specifically indicated for hemostasis and coagulation of soft tissue (including cardiac tissue) and laser assisted lipolysis.

Specific Indications for Use

Ear, Nose and Throat and Oral Surgery:

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
- Tonsillectomy
- Thyroidectomy
- Vocal cord polypectomy
- Hemiglossectomy
- Tracheal stenosis
- Oral cavity lesions

Dental Applications:

Intraoral and extraoral soft tissue (including marginal and interdental gingiva and epithelial lining of free gingiva). Examples include:

- Frenectomy
- Frenotomy
- Biopsy
- Operculectomy
- Implant recovery
- gingivectomy
- gingivoplasty
- gingival troughing
- crown lengthening

K082263 P3 3=4 6

- 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
- vestibuloplasty
- excision of lesions
- exposure of unerupted/partially erupted teeth
- leukoplakia
- removal of hyperplastic tissues
- treatment of aphthous ulcers
- Sulcular debridement (removal of diseased or inflamed soft tissue in the periodontal pocket)
- pulpotomy
- pulpotomy as an adjunct to root canal therapy
- light activation of bleaching materials for teeth whitening

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
- 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
- Phototcoagulation of teleangectasia of the legs and face
- Photocoagulation of vascular lesions of the face and extremities
- Endovascular coagulation of the greater saphenous vein of the thigh in patients with superficial vein reflux

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

Gynecology:

Ablation, excision, incision, coagulation, hemostasis and vaporization of gynecological tissue. Examples include:

- Endometrial ablation
- Excision or vaporization of condylomata acuminata
- Vaporization of cervical intraepithelial neoplasia
- Cervical conization
- Menorrhagia

Neurosurgery:

Vaporization, coagulation, excision, incision, ablation and hemostasis of soft tissue. Example includes:

Hemostasis in conjunction with menigiomas

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

Cardiothoracic Surgery:

Incision, excision, vaporization, ablation, hemostasis, or coagulation of soft tissue, including cardiac tissues.

Laser Assisted Lipolysis

Ophthalmology:

The ablation, vaporization, excision, incision, and coagulation of soft tissue in ophthalmology. Examples include:

- Open Dacryocystorhinostomy
- Endonasal Dacryocystorhinostomy
- Blepharoplasty
- Oculoplastics
- Tumor excision and biopsy
- Eyelid reconstruction

Technological Characteristics

The Ceralas E15/980, E30/980 has the same technological characteristics as the cleared Ceralas D. The laser has an additionally incorporated RFID sensor/antenna in the fiber port so as to recognize fibers with an RFID chip in their connectors. The fibers used with the Ceralas E have been previously cleared by FDA (K951775, K964497, K060050) for use with its other laser products and have an RFID chip incorporated into the proximal connector end.

Substantial Equivalence

The Ceralas E15/980, E30/980 has the same intended use and similar indications, principles of operation, and technological characteristics as the cleared Ceralas D 980 (Models D15, D25). The minor differences in the Ceralas E15/980, E30/980 technological characteristics do not raise

any new questions of safety or effectiveness. Thus, the Ceralas E15/980, E30/980 is substantially equivalent to its predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Biolitec, Inc.
% Hogan & Hartson, LLP
Mr. Jonathan S. Kahan
Columbia Square
555 Thirteenth Street, Northwest
Washington, District of Columbia 20004

OCT 24 2008

Re: K082263
Trade/Device Name: Ceralas E 980nm Diode Laser (Models E15/980,E30/980)
Regulation Number: 21 CFR 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 30, 2008
Received: September 30, 2008

Dear Mr. Kahan:

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), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

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

Enclosure

K082203 Pg 1 of 5

Indications for Use Statement

510(k) Number (if known):_____

Device Name: Ceralas E 980nm Diode Laser (Models E15/980,E30/980)

Indications for Use:
The Ceralas E15/980, E30/980 is intended for delivery of laser light to soft tissue in the contact or non-contact mode during surgical procedures, including via endoscopes, introducers, or catheters. The Ceralas E15/980, E30/980 is generally indicated for incision, excision, vaporization, ablation, hemostasis, or coagulation of soft tissue in ear, nose and throat and oral surgery (otolaryngology), dental procedures, arthroscopy, gastroenterology, general surgery, dermatology, plastic surgery, podiatry, urology, gynecology, neurosurgery (peripheral nervous system), pulmonary surgery, cardiothoracic surgery, and ophthalmology. This Ceralas E15/980, E30/980 is specifically indicated for hemostasis and coagulation of soft tissue (including cardiac tissue) and laser assisted lipolysis.

Specific Indications for Use
Ear, Nose and Throat and Oral Surgery:
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
- Tonsillectomy
- Thyroidectomy
- Vocal cord polypectomy
- Hemiglossectomy
- Tracheal stenosis
- Oral cavity lesions

Dental Applications:

Intraoral and extraoral soft tissue (including marginal and interdental gingiva and epithelial lining of free gingiva). Examples include:

- 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
- Vestibuloplasty
- Excision of lesions
- Exposure of unerupted/partially erupted teeth
- Leukoplakia
- Removal of hyperplastic tissues
- Treatment of aphthous ulcers
- Sulcular debridement (removal of diseased or inflamed soft tissue in the periodontal pocket)
- Pulpotomy
- Pulpotomy as an adjunct to root canal therapy
- Light activation of bleaching materials for teeth whitening

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
- 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
- Phototcoagulation of teleangectasia of the legs and face
- Photocoagulation of vascular lesions of the face and extremities
- Endovascular coagulation of the greater saphenous vein of the thigh in patients with superficial vein reflux

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

Gynecology:

Ablation, excision, incision, coagulation, hemostasis and vaporization of gynecological tissue. Examples include:

- Endometrial ablation
- Excision or vaporization of condylomata acuminata
- Vaporization of cervical intraepithelial neoplasia
- Cervical conization
- Menorrhagia

Neurosurgery:

Vaporization, coagulation, excision, incision, ablation and hemostasis of soft tissue. Example includes:

Hemostasis in conjunction with menigiomas

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

Cardiothoracic Surgery:

Incision, excision, vaporization, ablation, hemostasis, or coagulation of soft tissue, including cardiac tissues.

Laser Assisted Lipolysis

Ophthalmology:

The ablation, vaporization, excision, incision, and coagulation of soft tissue in ophthalmology. Examples include:

- Open Dacryocystorhinostomy
- Endonasal Dacryocystorhinostomy
- Blepharoplasty
- Oculoplastics
- Tumor excision and biopsy
- Eyelid reconstruction

K082263 Pg 5 of 5

Prescription Use __X___ AND/OR Over-The-Counter Use____
(Per 21 C.F.R. 801.109) (Per 21 C.F.R. 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE -- CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for max

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K082263