FEB 1 2000

K993927

510(k) Summary
Ceralas Diode Laser System

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

CeramOptec, Inc.
515 Shaker Road
East Longmeadow, Massachusetts 01028
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Contact Person: Carol J. Morello, V.M.D.
Date prepared: August 17, 1999

Name of Device and Name/Address of Sponsor

Ceralas Diode Laser System (Model D10)
CeramOptec, Inc.
515 Shaker Road
East Longmeadow, MA 01028

Classification Name

Surgical laser

Predicate Device

Premier Laser System' *Aurora* Diode Laser
Biolase *Twilight* Diode Laser

Intended Use

See the attached pages 1-3 for a list of indications for use.

The Cerals D10 Diode Laser operates with a power range of 1-10W in the CW or pulsed mode. The delivery systems for the Ceralas D Laser System consist of optical fiber fitted with an SMA 905 connector at the proximal end.

There are no technological differences between the Ceralas D10 Laser System and the Premier Laser Systems *Aurora* Diode Laser. or the Biolase *Twilight* Diode Laser. The

Ceralas D10 Laser System's principles of operation, function and intended use are similar to Premier Laser System's *Aurora* Diode Laser System and Biolase *Twilight* Diode Laser and no new questions of safety or effectiveness are raised.

Performance Data

None required.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 1 2000

Carol J. Morello, V.M.D.
Regulatory Affairs
CeramOptec, Inc.
515 Shaker Road
East Longmeadow, Massachusetts 01028

Re: K993828
Trade Name: Ceralas D10 810nm Diode Laser System
Regulatory Class: II
Product Code: GEX
Dated: November 10, 1999
Received: November 12, 1999

Dear Dr. Morello:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

for James E. Dillard III
Acting Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K993822

Device Name: Ceralas D10 810nm Diode Laser System

Indications For Use:

The attached list of indications are in addition to the already cleared indications.

(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 General Restorative Devices
510(k) Number K993828

(Optional Format 3-10-98)

Prescription Use X
(Per 21 CFR 801.109)

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

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

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Division of General Restorative Devices

Prescription Use ___ (Per 21 CFR 801.109)

510(k) Number K953826

- 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

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

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510(k) Number K993[illegible]

Prescription Use X
(Per 21 CFR 801.109)

- 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

Ophthalmology

Retinal photocogulation
Diabetic retinopathy

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

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Division of General Restorative Devices
510(k) Number K993124

Prescription Use Y
(Per 21 CFR 801.109)