K992773

SEP -1 1999

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
Phone: (413) 525-0600
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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

Intended Use

The Ceralas D10 Laser System that is the subject of this 510(k) notice is intended for the following dental indications on intraoral and extraoral soft tissue (including marginal and interdental gingiva and epithelial lining of free gingiva): 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 and pulpotomy as an adjunct to root canal therapy.

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.. 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 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

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Carol J. Morello, VMD
Manager, Regulatory Affairs
CeramOptec, Inc.
515 Shaker Road
East Longmeadow, Massachusetts 01028

Re: K992773
Trade Name: Ceralas D10 810nm Diode Laser System
Regulatory Class: II
Product Code: GEX
Dated: August 17, 1999
Received: August 18, 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,

Celia M. Witten, Ph.D., M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K992773

Device Name: Ceralas D10 810nm Diode Laser System

Indications For Use:

The Ceralas D10 Diode laser is indicated for the following dental indications on intraoral and extraoral soft tissue (including marginal and interdental gingiva and epithelial lining of free gingiva); frenectomy, frenotomy, biopsy, operculectomy, implant recovery, gingivectomy, gingivoplasty, gingival troughing, crown lengthening, hemostasis of donor sites, 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, and pulpotomy as an adjunct to root canal therapy.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X
(Per 21 CFR 801.109)

(Optional Format 3-10-98)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K992773