JUN 24 1999

K991891

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 Morello, V.M.D.
Date prepared: June 1, 1999

Name of Device and Name/Address of Sponsor

Ceralas Diode Laser System (Model D15)
CeramOptec, Inc.
515 Shaker Road
East Longmeadow, MA 01028

Classification Name

Surgical laser

Predicate Device

Ceralas Diode Laser System (Model D15)
Premier Laser System'Pegasus Nd:YAG Laser

Intended Use

The Ceralas D Laser System that is the subject of this 510(k) notice is identical to the Ceralas D Laser System that has already been cleared by FDA (K983058) for use in the following dental indications: draining fistulas, coagulation and decontamination of extraction sites, frenectomy, excisional biopsy, operculectomy, implant uncovering, gingivectomy, gingivoplasty, degranulation of infrabony defects, enucleate apical lesions, gingival troughing for crown and bridge, apthus ulcers, crown lengthening, hemostasis of donor sites, removal of granulation tissue, laser assisted flap surgery, exposure of enamel for orthodontic brackets, and

surgical exposure to aid in eruption. The purpose of this submission is to expand the indications for use to include pulpotomy and pulpotomy as an adjunct to root canal therapy.

The Cerals D Diode Laser operates with a power range of 1-15W 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 previously cleared Ceralas D Laser System and the device subject to this 510(k)submission. The Ceralas D Laser System's principles of operation, function and intended use are similar to Premier Laser System's Pegasus Nd:YAG 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

JUN 24 1999

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

Re: K991891
Trade Name: Ceralas Diode Laser System (Model D15)
Regulatory Class: II
Product Code: GEX
Dated: June 1, 1999
Received: June 3, 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): K991891

Device Name: Ceralas D Diode Laser System

Indications For Use:

Pulpotomy
Pulpotomy as an adjunct to root canal therapy

NOTE: These are additional indications to the already cleared indications for market release in K983058.

(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 K991891