K983058

OCT 21 1998

510(k) Summary
Ceralas Diode Laser System

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

Submitted by Regulatory Counsel for:
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: September 1, 1998

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 Systems' Aurora Diode Dental Laser
American Dental Technologies Pulsemaster® 1000 ST Dental Diode Laser System
American Dental Technologies Pulsemaster® 1000 Nd:YAG Laser

Intended Use

There have been no significant changes to the Ceralas D Laser System since is was cleared by FDA (K951775, K964497). The Ceralas D Laser System has been cleared as a surgical instrument intended for incision, excision, hemostasis, coagulation, and vaporization of soft tissue in open and closed endoscopic procedures in general surgery, urology, gynecology, neurosurgery, gastroenterology,

plastic surgery, dermatology, and otolaryngology. Specific indications for the previously cleared Ceralas D Laser System include tonsillectomy, thyroidectomy, vocal cord polypectomy, hemiglossectomy, tracheal stenosis, neck dissection, and oral cavity lesions.

The company is expanding the Ceralas D Laser System's indications for use to include the following applications 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; and sulcular debridement (removal of diseased or inflamed soft tissue in the periodontal pocket).

As explained below, the Company's Ceralas D Laser System is substantially equivalent to the previously cleared Ceralas D Laser System (K951775, K964497), Premier Laser Systems' Aurora Diode Dental Laser (K954316, K974586), American Dental Technologies' Pulsemaster® 1000 ST Dental Diode Laser System (K972325), and American Dental Technologies' Pulsemaster® 1000 Nd:YAG Laser (K961269, K961136).

Technological Characteristics and Substantial Equivalence

As stated above, there have been no significant changes to the Ceralas D Laser System since it was cleared by FDA. The Ceralas D Laser System is a complete self-contained compact surgical laser that utilizes gallium aluminum arsenide (GaAlAs) semiconductor diodes to generate near-infrared laser radiation. The laser employs a modular design comprised of: (1) a laser diode; (2) a cooling module containing the laser diode, thermoelectric coolers, heat sink fins and fans; (3) an optics module containing a beamsplitter for control of optical power; (4) front control and display panel; and (5) RFI-shielded, transformer power supply and control electronics. Interchangeable fiber optic delivery systems are coupled to the laser via an SMA 905 connector to deliver laser radiation to the target tissues. The diode laser is enclosed in a rugged, factory aligned, environmentally protective module.

The wavelength for the Ceralas D Laser System is 980 ± 30nm, and its laser aiming beam wavelength is 635nm±10nm. The power output ranges from 1-15 Watts. The delivery systems for the Ceralas D Laser System consist of an optical fiber fitted with an SMA 905 connector at the proximal end. The optical fiber is composed of quartz fiber core with a coaxially mounted protective sheath.

Moreover, the optical fiber delivery system has been previously cleared for dental use (K942182).

CeramOptec has made no significant changes to the hardware or software of the Ceralas D Laser since it was cleared by FDA. Likewise, CeramOptec has made no significant changes to its software development process since its previous 510(k) submission for the Ceralas D Laser System. Additionally, the software verification and validation were conducted in accordance with FDA's Guidance Document, "Reviewer Guidance For Computer Controlled Medical Devices Undergoing 510(k) Review."

The principal technological difference between the Ceralas Diode Laser and Premier Laser System's Aurora Diode Dental Laser is that the devices operate at different wavelengths. The Ceralas D Laser's wavelength is 980 ±30nm and the Aurora Diode Dental Laser's wavelength is 805-820nm. However, it is not believed that the difference between the devices' wavelength raise new questions of safety and effectiveness.

The Ceralas D Laser is also similar to American Dental Technologies' Pulsemaster® 1000 ST Diode Dental Laser. Both devices are similar in function and intended use, and are diode lasers which operate in a continuous or pulsed mode with wavelength ranges similar to the Premier Laser System's Aurora Diode Dental Laser. In summary, although there are minor differences between the Ceralas D Laser System and its predicate devices, these differences do not raise new questions of safety and efficacy.

Performance Data

None required.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 21 1998

CeramOptec, Inc.
c/o Jonathan S. Kahan
Hogan and Hartson
Columbia Square
555 Thirteenth Street, N.W.
Washington, D.C. 20004-1109

Re: K983058
Trade Name: Ceralas Diode Laser System(Model D15)
Regulatory Class: II
Product Code: GEX
Dated: September 01, 1998
Received: September 01, 1998

Dear Mr. Kahan:

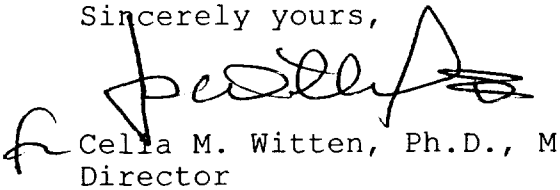
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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): K983058

Device Name: Ceralas D Laser System

Indications For Use:

The Ceralas D Laser System is indicated for the following applications 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; and sulcular debridement (removal of diseased or inflamed soft tissue in the periodontal pocket).

(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 K983058

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____

(Optional Format 1-2-96)