OCT 14 1999

K993002

510(k) Summary
Ceralas Diode Laser System

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

Submitted by:
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 2, 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

American Dental Technologies Plasma Arc Curing System

Intended Use

The Ceralas D Laser System that is subject to this 510(k) notice is an instrument intended for light activation of bleaching materials for tooth whitening. This indication is added to the already cleared indications for use.

Technological Characteristics and Substantial Equivalence

The Ceralas D Laser System that is the subject of this 510(k) notice is identical to the Ceralas D Laser System, which has already been cleared by FDA. The cleared 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 delivery systems for the Ceralas D Laser System consist of 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.

Although the Ceralas D 980nm Diode laser is different technologically from the predicate device the effect of the laser used as a light source is equivalent to that of the PAC System as demonstrated by the attached study. In summary although there are differences the intended use and effect on the tissue is similar and no new questions of safety or efficacy are raised.

Performance Data

Bench studies demonstrated that the Ceralas D 980nm Laser System performed similarly to the PAC light for light activation of bleaching materials for teeth whitening.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 14 1999

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

Re: K993002
Trade Name: Ceralas Diode Laser System (Model D15)
Regulatory Class: II
Product Code: GEX
Dated: September 2, 1999
Received: September 7, 1999

Dear Dr. Morello:

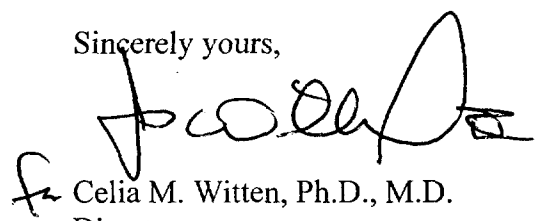
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosures) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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 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): K993002

Device Name: Ceralas Diode Laser System (Model D15)

Indications For Use:

Intended for light activation of bleaching materials for teeth whitening.

Note: This is an additional indication to the already cleared indications for use.

(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 K993002

(Optional Format 3-10-98)

Prescription Use X
(Per 21 CFR 801.109)