

K 983950

FEB 3 1998

**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: February 4, 1998

Name of Device and Name/Address of Sponsor

Ceralas H 808nm Diode Laser System
CeramOptec, Inc.
515 Shaker Road
East Longmeadow, Massachusetts 01028

Classification Name

Laser, Surgical Diode Laser System

Predicate Device

Star Medical Technologies, Inc.'s StarLight™ Pulsed Diode Array Laser System
(K974346 and K973324).

Intended Use

The Ceralas H Laser System is a surgical instrument indicated to treat leg veins in dermatology and plastic surgery procedures. Specific indications for the Ceralas H Laser System include the treatment of leg veins. As explained below, the Ceralas H Laser System is substantially equivalent to Star Medical Technologies, Inc.'s StarLight™ Pulsed Diode Array Laser System (K974346 and K973324).

Technological Characteristics and Substantial Equivalence

The Ceralas H 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 system consists of a console, footswitch, and handpiece which are connected to the device's console. The diode laser is enclosed in a rugged, factory aligned, environmentally protective module. The handpiece is placed against the patient's skin and a pulse of light is delivered to the skin surface when the footswitch and handpiece trigger are depressed.

The wavelength for the Ceralas H Laser System is $808 \pm 20\text{nm}$. The laser delivers pulsed light with a selectable pulse duration of 5-30 milliseconds and a fluence of 10-40J/cm². The corresponding pulse energy delivered through the 9x9mm handpiece is 8-32 Joules. The laser pulses are generated at a maximum pulse repetition frequency of up to 1 Hz. Additionally, the software and software development activities are in accordance with FDA's guidance document, "Reviewer Guidance For Computer Controlled Medical Devices Undergoing 510(k) Review."

The Ceralas H Laser System and the StarLight Diode Laser System have equivalent technological characteristics. For instance, both devices are diode lasers which operate at a similar beam mode, fluence, repetition rate, pulse width, and pulse energy. The principle technological distinction between the two devices is that the StarLight Diode Laser System's wavelength is 800nm and the Ceralas H Laser System's wavelength is $808 \pm 20\text{nm}$. However, it is not believed that the difference between the devices' wavelength raises any new questions of safety and effectiveness. In summary, although there are minimal differences between the Ceralas H Laser System and its predicate device, these differences are minor and raise no new questions of safety and efficacy.

Performance Data

None required.



FEB 3 1999

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Jonathan S. Kahan
c/o Hogan & Hartson, L.L.P.
555 13th Street, NW
Washington, D.C. 20004-1109

Re: K983950
Trade Name: Ceralas Diode Laser System (Model H)
Regulatory Class: II
Product Code: GEX
Dated: November 4, 1998
Received: November 5, 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.

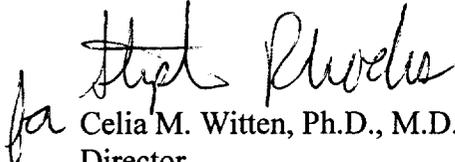
If your device is classified (see above) into either class II (Special Controls) or class III (Pre-market Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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.

Page 2 – Mr. Jonathan Kahan

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

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510(k) Number (if known): K983950

Device Name: Ceralas H 808nm Diode Laser System

Indications For Use:

The Ceralas H 808nm Diode Laser System is indicated to treat leg veins in dermatology and plastic surgery procedures.



 (Division Sign-Off)
 Division of General Restorative Devices
 510(k) Number K983950

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

_____ Concurrence of CDRH, Office of Device Evaluation (ODE)

(Optional Format 3-10-88)

Prescription Use X
(Per 21 CFR 801.109)