

JUN 25 1998

K 981126

510(k) SUMMARY

**Ceralas G Frequency Doubled Nd:YAG Laser Systems
(including the Ceralas G3 Laser and Accessories)**

**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
Facsimile: 413-525-0611

Contact Person: Carol Morello, V.M.D.

Date Prepared: March 26, 1998

Name of Device and Name/Address of Sponsor

Ceralas G Frequency Doubled Nd:YAG Laser System and Accessories("Ceralas G3")

CeramOptec, Inc.
515 Shaker Road
East Longmeadow, Massachusetts 01028

Common or Usual Name

Frequency Doubled Nd:YAG Laser

Classification Name

Laser surgical instrument for use in general and plastic surgery and in dermatology.

Predicate Devices

CeramOptec's Ceralas G Frequency Doubled Nd:YAG Laser System and Accessories (K954834, K923953, K943445, and K951775), the Iris Medical DioLite 532 (K964074), and the Continuum Biomedical CB Diode/532 Laser (K954905).

Intended Use

The Ceralas G Frequency Doubled Nd:YAG Laser System, the Ceralas G3 laser and accessories, is intended as a surgical instrument for use in the photocoagulation of vascular and pigmented skin lesions.

Technological Characteristics and Substantial Equivalence

The Ceralas G3 is a complete, self-contained, compact surgical laser system that utilizes a diode pumped neodymium-doped yttrium aluminum garnet (Nd:YAG) laser whose output is frequency doubled to produce radiation in the green visible spectrum at 532 nm. Frequency doubling is achieved by the use of an intercavity Potassium Titanyl Phosphate ("KTP") crystal. KTP is a crystalline material that has nonlinear optical properties which allows the input of light of one color and output of a different light color. Specifically, it allows infrared light in and emits green light. The laser employs a modular design which includes: 1) laser crystal; 2) cooling module; 3) built in power meter with automatic calibration; 4) continuous or pulsed operating modes; and 5) front controls with a display panel. The laser system delivers up to 3 Watts of optical power. The exposure mode for the laser is selectable from 0.10 Watts to 3 Watts at 532 nm. The Ceralas G3 is identical to the Ceralas G Frequency Doubled Nd:YAG Laser Systems that has already received clearance from FDA (K954834). The Ceralas G has already been cleared for the intended use as a surgical instrument for photocoagulation and is indicated for use in ocular tissue. This submission adds an additional indication for the Ceralas G as a surgical instrument for photocoagulation of vasculare and pigmented skin lesions.

The delivery systems for the Ceralas G Frequency Doubled Nd:YAG Laser Systems consist of an optical fiber in a coaxially mounted protective sheath which is fitted with an SMA connector at the proximal end. The fiber is a bare, polished quartz fiber provided in a 200 micron to 1400 micron diameter range. The delivery systems are hand-held, designed to fit the Ceralas G3, and deliver the laser energy via the SMA connector which couples it to the laser. The Ceralas the delivery systems are supplied sterile. These systems are identical to those MegaBeam Fiber Optic Delivery Systems, which range in fiber sizes of 200 to 1200 micron diameters, and have already been cleared by the FDA. CeramOptec, the manufacturer of the MegaBeam Fiber Optic Delivery Systems, has previously obtained clearance for the use of these delivery systems as accessories to laser systems for any indication for which compatible Nd:YAG, 1.44 YAG, Ho:YAG, KTP, Argon and Diode laser systems are cleared (K923953, K943445, and K951775). This submission includes additional fiber sizes up to a 1400 micron diameter.

The Ceralas G3 has the same intended use, similar principles of operation and similar technological characteristics as previously cleared predicate laser systems. The

Ceralas G3 and its predicate devices, the CeramOptec Ceralas G Frequency Doubled Nd:YAG Laser Systems (K954834), the Iris Medical Diolite 532 (K964074), and the Continuum Biomedical, Inc. CB Diode/532 Laser System (K954905), have the identical intended use.

The Ceralas G3, like its predicate device, is a solid state laser that emits a beam in the near-infrared region of the electromagnetic spectrum. Furthermore, the Ceralas G3, the Iris Medical Diolite 532 (K964074), and the Continuum Biomedical, Inc. CB Diode/532 (K954905), all employ diode pumped frequency doubled neodymium doped yttrium aluminum garnet laser crystals to generate the treatment beam. The wavelength of all of these lasers is 532nm. Each of the lasers offers continuous and pulsed exposure modes. Thus, the laser tissue interaction and the surgical performance of the Ceralas G3, the Iris Medical Diolite 532, and the Continuum Biomedical, Inc. CB Diode/532, would be expected to be the same.

The Ceralas G3 and all of the predicate devices (K964074, K954905, and K954834) exhibit comparable power outputs of 0.1 to 3 Watts and all are air cooled. All of these devices utilize essentially the same types of fiber optic delivery accessories to transmit the laser energy to the target tissue. The Ceralas G3 delivery systems and the predicate device delivery systems likewise operate in the contact and non-contact modes. The Ceralas G3 fiber delivery systems are available with fiber core diameters of 200 to 1400 microns similar to the Diolite 532 predicate device delivery systems (K964074).

Any differences between the Ceralas G3 and the predicate devices, such as the systems' dimensions and weight, do not raise new questions of safety and effectiveness.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 25 1998

CeramOptec, Inc.
c/o Mr. Jonathan S. Kahan, Esquire
Hogan & Hartson, L.L. P.
Columbia Square
555 Thirteenth Street, NW
Washington, District of Columbia 20004-1109

Re: K981126
Trade Name: Ceralas G Frequency Doubled ND: YAG Laser Systems and
Accessories ("Cerales G3")
Regulatory Class: II
Product Code: GEX
Dated: March 27, 1998
Received: March 27, 1998

Dear Mr. Kahan:

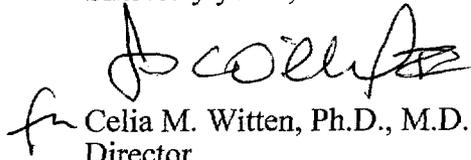
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of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


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

INDICATIONS FOR USE

510(k) Number (if known): K 981126

Device Name: Ceralas G Frequency Doubled Nd:YAG Laser System and Accessories

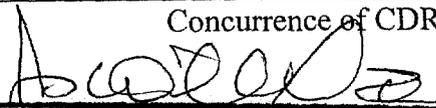
Indications For Use:

The Ceralas G Frequency Doubled Nd:YAG Laser System and Accessories is intended as a surgical instrument for use in the photocoagulation of:

- and
- 1) ocular tissue,
 - 2) vascular and pigmented skin lesions.

(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 K981126

Prescription Use _____
 OR
 Over-The-Counter Use _____

(Per 21 CFR 801.109)

(Optional Format 1-2-96)

Prescription Use X
 (Per 21 CFR 801.109)