

JUL 29 1998

K 980389

510(k) SUMMARY

CeramOptec's MegaBeam Reusable Fiber Optic Handpiece and Needles

**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: February 2, 1998

Name of Device and Name/Address of Sponsor

MegaBeam Reusable Fiber Optic Handpiece and Needles

Common or Usual Name

Nd:YAG Laser Fiber Optic Delivery System Handpiece; 1.44 YAG Laser Fiber Optic Delivery System Handpiece; Ho:YAG Laser Fiber Optic Delivery System Handpiece; KTP Laser Fiber Optic Delivery System Handpiece; and Diode Laser Fiber Optic Delivery System Handpiece;

Classification Name

Accessory to Laser Surgical Instruments

Predicate Devices

CeramOptec's original disposable handpieces (K923953), CeramOptec's disposable arthroscopy handpiece (K946336); CeramOptec's disposable general surgery straight handpiece and adjustable handpiece (K943445); TTI Medical's Optic Handpiece; and Coherent Medical's VersaLink reusable handpiece (K960032).

Intended Use

The MegaBeam Reusable Fiber Optic Handpiece and Needles are intended to be used with the company's disposable MegaBeam Fiber Optic Delivery Systems, which have already been cleared by FDA (K923953, K943445 and K946336). The MegaBeam Fiber Optic Delivery Systems, which contain disposable contact and non-contact fibers, are intended to vaporize, coagulate, incise and excise tissue and are cleared for any indication for which compatible Nd:YAG, 1.44 YAG, Ho:YAG, KTP and diode laser systems have been cleared by FDA.

Technological Characteristics and Substantial Equivalence

The company's MegaBeam Reusable Fiber Optic Handpiece and Needles have the same general intended use as the previously cleared predicate devices. The MegaBeam Reusable Fiber Optic Handpiece and Needles are designed to be used with the company's cleared disposable MegaBeam Fiber Optic Delivery Systems which are intended to vaporize, coagulate, incise and excise tissue and which are designed for any indication for which compatible laser systems have been cleared by FDA. Similarly, the predicate devices also are components of delivery systems designed to deliver laser radiation to a specified point.

The MegaBeam Reusable Fiber Optic Handpiece and Needles have similar technological characteristics as their predicate devices. The needle is available with 0°, 15°, 30° and 70° angles. They are designed to fit 400 micron, 600 micron, 800 micron and 1000 micron disposable optical fibers. The labeling includes instructions for sterilizing the devices using EtO or steam. The needle is attached to the handpiece by a threaded connector. The fiber optic is then threaded through the handpiece and needle. At the end of the procedure, the fiber optic is discarded and the handpiece and needle are reusable.

CeramOptec's original, disposable handpieces that were cleared for use with the MegaBeam Delivery System (K923953) are compatible with Nd:YAG lasers and with 400, 600, 800 and 1000 micron fibers. In addition, the company's cleared disposable arthroscopy handpiece (K946336) is compatible with 1:44 YAG, Ho:YAG and Nd:YAG lasers and with 400 and 600 micron fibers. CeramOptec's cleared, disposable general surgery straight handpiece and adjustable handpiece (K943445) are compatible with Nd:YAG, KTP and diode lasers and with fibers ranging in size from 200-1200 microns.

Coherent's VersaLink Laser Delivery System consists of a reusable VersaLink handpiece assembly and VersaTip™ laser probe. The delivery system is compatible for use with Ho:YAG lasers (2.1 μm wavelength). The reusable handpiece assembly, consisting of a handpiece, a fiber optic cable, a laser connector, and a protective cap, is shipped non-sterile. The handpiece assembly may be sterilized using either steam or EtO gas. The reusable VersaTip laser probe, which is

provided sterile, is available in the following configurations: 0° straight probe; 15° angled probe; 30° angled probe; and a 70° side fire probe. It must be sterilized using steam or EtO prior to reuse. The system is designed to be used with 600µm fibers.

TTI Medical's Fiber Optic Handpiece is compatible with Nd:YAG and Ho:YAG lasers and is designed to be used with 600µm, 800µm and 1000µm fibers. The reusable, malleable handpiece is supplied non-sterile and may be sterilized using EtO or steam in accordance with the manufacturer's instructions.

In sum, although there are some differences between the MegaBeam Reusable Fiber Optic Handpiece and Needles and their predicate devices, these differences are minor and raise no new questions of safety and effectiveness.

Performance Data

None provided.



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Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

CeramOptec, Inc.
c/o Mr. Jonathan S. Kahan
Hogan & Hartson, L.L.P.
555 Thirteenth Street, N.W.
Washington, D.C. 20004

Re: K980389
Trade Name: MegaBeam Reusable Fiber Optic Handpiece and Needles
Regulatory Class: II
Product Code: GEX
Dated: May 1, 1998
Received: May 1, 1998

Dear Mr. Kahan:

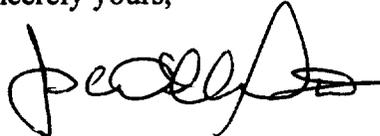
We have reviewed your Section 510(k) notification of intent to market the devices referenced above and we have determined the devices are substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date 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 devices, 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 devices are classified (see above) into either class II (Special Controls) or class III (Premarket Approval), they may be subject to such additional controls. Existing major regulations affecting your devices 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 requirements, 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. In addition, FDA may publish further announcements concerning your devices in the Federal Register. Please note: this response to your premarket notification submissions 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 devices as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your devices to a legally marketed predicate device results in a classification for your devices and thus, permits your devices to proceed to the market.

If you desire specific advice for your devices 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) 594-4648. Additionally, for questions on the promotion and advertising of your devices, 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,



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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): K 980389

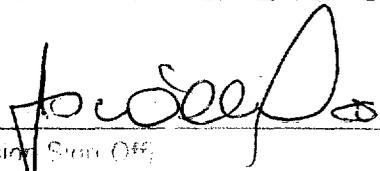
Device Name: MegaBeam Reusable Handpiece

Indications For Use:

Intended to be used as a fiber optic delivery system handpiece with the capability to be reused with a disposable optical fiber.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Staff Off)
Director, Division of Restorative Devices
510(k) Number K980389

Prescription Use
(Per 21 CFR 801.109)

OR

Over-The-Counter Use