

JUN - 8 1998

K974641

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| Summary of Safety and Effectiveness Information Section 510(k) Premarket Notification | <i>FutureLase 3000/3002 Erbium Laser System</i> Pharos Optics, Inc. |
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Regulatory Authority: Safe Medical Devices Act of 1990, 21 CFR 807.92

1. Device Name:

Trade Name: *FutureLase 3000/3002 Erbium Laser System*
Common Name: Dental Laser System
Classification Name: Laser Instrument, Surgical, Powered

2. Establishment Name & Registration Number:

Name: Pharos Optics, Inc.
Number: Pending

3. Classification:

§ 878.4810 Laser surgical instrument for use in general and plastic surgery and in dermatology. (a) Identification. (1) A carbon dioxide laser for use in general surgery and in dermatology is a laser device intended to cut, destroy, or remove tissue by light energy emitted by carbon dioxide. (2) An argon laser for use in dermatology is a laser device intended to destroy or coagulate tissue by light energy emitted by argon.

Device Class: Class II for the cleared indications
Classification Panel: General & Plastic Surgery Devices Panel
Product Code: 79GEX

4. Company Contact:

Ms. Marion Fay, C.E.O.
Pharos Optics, Inc.
3002 Dow Avenue, Suite 126
Tustin, CA 92780
714.505.2782 - 714.505.2782 - fax

5. Special Controls:

Pharos Optics, Inc. is in compliance with special controls as outlined in 21 CFR Part 1040 - Performance Standards for Light-Emitting Products. See 21 CFR §1040.10, Laser products.

6. Substantially Equivalent Device(s):

1. TriLase 2940 Erbium Laser System, Schwartz Electro-Optics, Inc. (SEO Medical, K954013)
2. MedLite Erbium Laser System, Continuum Biomedical, Inc., K961748, & K970934.
3. PulseMaster™ Dental Laser System, K922901

7. Device Description:

Pharos Optics, Inc. offers a dental laser system known as the *FutureLase 3000/3002 Erbium Laser System*. The device utilizes laser radiation energy produced at a frequency of 2.94μ . This laser system is intended for intraoral or dental soft tissue surgery including the marginal and interdental gingiva. The *FutureLase 3000/3002 Erbium Laser System* is used to assist the dentist or oral surgeon with the following general intended use and/or specific indications for use:

Intended Use. For use in oral/dental procedures for the incision, excision, ablation, vaporization and hemostasis of soft tissue.

Specific Indications for Use:

1. Gingivoplasties
2. Gingivectomies
3. Frenectomies
4. Benign and malignant lesion removal
5. Biopsies
6. Leukoplakia
7. Fibrotomy

Laser Head. The laser is a pulsed solid-state erbium YAG laser. Application of a current pulse to the flash lamp produces an intense pulse of light from the laser head. The light produced by the erbium atoms being returned to their ground state provides a laser beam which is highly coherent.

The laser output produced is at a wavelength of 2.94μ which is in the infrared portion of the spectrum and is not visible.

A beam attenuator or shutter in the laser head blocks all laser emission for safety when laser output is not desired. The shutter has position sensors to confirm whether it is open or closed.

Power Supply. The current pulse needed to produce lasing is generated by a discharge capacitor, an inductor, and a switch. The capacitor is charged by the charging power supply. The capacitor is discharged through the inductor and flash lamp. The inductor helps to shape the pulse to give the desired laser pulse width.

Cooling System. Most of the energy produced by the laser flash lamp is converted into waste heat. In order to remove the heat, water is circulated through it. The cooling system contains a pump for water circulation, a reservoir for the coolant, and an air-to-water heat exchanger to remove the heat. Also included is a flow switch to assure the integrity of the laser if there is a failure in the cooling system.

Control System. All of the laser functions are under the control of a microprocessor. The controller sets the energy level, the repetition rate of the laser, calibrates the output pulses to assure correct energy, monitors the interlock sensors and checks for proper operation of the switches, power supply, shutter and control panel. The system self checks at start-up each time the laser system is turned on.

Control Panel. The laser control panel allows the user to set the laser output pulse energy and repetition rate. Values are read out on the panel. A button must be pushed which enables the foot switch control to fire the laser. A Standby button deactivates the foot switch and leaves the system in standby mode.

Beam Delivery. The output of the laser is delivered via fiber-optic cable. The laser hand piece has a non-contact style treatment tip. The fiber tip does not make contact with the tissue to be treated. Fiber diameter is 400 microns and tip diameters currently offered range from 600 microns to 1.0 millimeters. A sensor determines the presence of the cable so that the laser cannot be fired if the fiber is not in place. A laser calibration port is also present on the housing.

Contraindications and Cautions. Only dentists and oral surgeons fully experienced in laser treatment of the indicated dental conditions should utilize the device. Specialized training and instruction in the specific use of the *FutureLase 3000/3002 Erbium Laser System* is available from the manufacturer.

8. Cleaning/Sterilization/Re-sterilization:

The laser handpiece tips may be sterilized and/or re-sterilized up to ten times. After cleaning and inspection, standard autoclave flash processing at 270 degrees for 15 minutes will produce a sterility assurance level (SAL) of 10^{-6} . Several tips may be sterilized at once, however, the tips should not be sterilized as part of larger heavily wrapped autoclave loads. The handpiece housing and transmission fiber may be cleaned, washed and surface disinfected only. Hospital grade soap/detergent & water followed by surface disinfection may be employed using commercially available liquid germicidal agents such as gluteraldehyde or quaternary amonium based agents. The device is reusable for a limited period of time.

9. Equivalence:

Based on the materials, intended use, design and clinical indications, the *FutureLase 3000/3002 Erbium Laser System* is substantially equivalent to one or more of the referenced legally marketed Erbium laser systems shown in the feature comparison chart below.

10. Feature Comparison Table:

| Parameter | <i>FutureLase</i> | MedLite Erbium | TriLase 2940 |
|--|--|--|---|
| Laser Type | Erbium YAG laser | Erbium YAG laser | Erbium YAG laser |
| Wavelength (nm) | 2.94 microns (2940 nm) | 2.94 microns (2940 nm) | 2.94 microns (2940 nm) |
| Pulse Rate (Hz) | 10Hz to 20Hz | 5Hz and 10Hz | 5Hz to 20Hz |
| Pulse Duration (µsec) | 120 | 250 | 300 |
| Maximum Pulse Energy (Joules) | 2 | 2 | 1 |
| Power (watts) Laser Head Fiber Tip | 10.5 -11 5.5-6 | 10 | 5 |
| Beam Delivery | Hand piece from laser via optical fiber | Hand piece from laser via optical fiber | Hand piece from laser via articulated arm |
| Fiber Material Transmission Loss | 400 microns dia. Saphire 45%+ 2% | Saphire Unknown | Saphire Unknown |
| Electrical Requirements | 120/220 VAC ± 10%, 20 Amps max, 50/60 Hz | 120/220 VAC ± 10%, 12 Amps max, 50/60 Hz | 220 VAC, 20 Amps 50/60 Hz, single phase |
| Indication | Dental/Oral soft tissue | Dental | Dental |
| K Number | K974641 | K961748 - K970934 | K954013 |



JUN - 8 1998

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Pharos Optics, Incorporated
c/o Mr. David Schlerf
Buckman Company, Incorporated
1000 Burnett Avenue, Suite 450
Concord, California 94520

Re: K974641
Trade Name: FutureLase 3000/3002 Erbium Laser System
Regulatory Class: II
Product Code: GEX
Dated: March 25, 1998
Received: April 3, 1998

Dear Mr. Schlerf:

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.

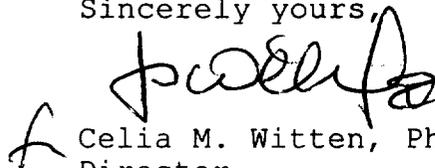
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially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

Page 2 - Mr. David Schlerf

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

Statement of Intended Use:

Page 1 of 1

510(k) Number: **K974641**

Device Name: *FutureLase 3000/3002 Erbium Laser System*

Intended Use:

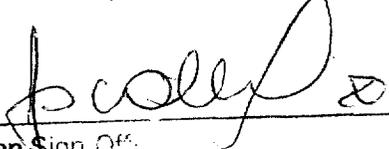
1. For use in oral/dental procedures for the incision, excision, ablation, vaporization and hemostasis of soft tissue.

Indications for Use:

1. Gingivoplasties
2. Gingivectomies
3. Frenectomies
4. Benign and malignant lesion removal
5. Biopsies
6. Leukoplakia
7. Fibrotomy

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NECESSARY

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign Off)
Division of General Restorative Devices
510(k) Number K974641

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____
(Optional format 1-2-96)