DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Colette Cozean, Ph.D.
President, CEO
Premier Laser Systems, Inc.
3 Morgan
Irvine, California 92618

MAY 5 1997

Re: K932683 and K933841
Trade Name: Centauri Er:YAG Laser System
Regulatory Class: II
Product Code: GEX
Dated: April 28. 1997
Received: April 30, 1997

Dear Dr. Cozean:

We have reviewed your Section 510(k) notifications 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 Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic

GMP 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 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 device as described in your 510(k) premarket notifications. 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

510(k) Number (if known) K932683 & K933841

Device Name: Centauri Er:YAG Laser System

Indications For Use:

The laser is indicated for Incision, Excision, Hemostasis, Ablation of Tissue, and Vaporization of Tissue in the oral cavity. The additional representative indications include Removal of Caries, Cavity Preparation, Modification or Etching of Enamel prior to acid etching, and Modification or Etching of Dentin prior to acid etching.

The contraindications are for children under the age of 18 years.

(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 K932683 K933841

Prescription Use X OR Over-The-Counter Use____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

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SUMMARY OF SAFETY AND EFFICACY

A. Temperature

In a benchmark publication on temperatures which cause pulpal damage, Zach and Cohen showed that 15 % of teeth in dogs where pulpal temperature was raised to 10°F (5.5°C) had irreversible damage. These findings have been substantiated by Powell, et. Al. Therefore, if the pulpal temperature rises on only 5.5°C, one may conclude that there is no permanent damage to the pulp of the tooth due to the laser treatment.

TABLE 1 - Pulp Temperatures

Energy Output	Repetition Rate	Time with H2O Cooling	Temperature in °C
20 mJ	10 Hz	2 sec	.08°
50 mJ	10 Hz	2 sec	1.07°
100 mJ	10 Hz	2 sec	.84°
150 mJ	10 Hz	2 sec	1.12°
200 mJ	10 Hz	2 sec	2.3°
Drill in Air	not applicable	10 sec	.25°
Drill in H2O	not applicable	10 sec	.05°

B. Pulp Vitality (all blinded):

1. H&E histological evidence over pulpal healing time demonstrates no deleterious effect for laser or control treatment.

2. Pulp vitality measurements over 1½ year follow-up demonstrate no compromise in pulp vitality.

3. Pulp vitality measurements on two teeth in each of 33 patients treated by laser and drill from the same patient show no difference in pulpal vitality pre-surgery, post-surgery and over three months.

4. Pulp vitality measurements on 125 randomly treated adult teeth treated by laser and drill show no significant difference between the laser and the control in pulp vitality measurements pre-surgery and after a three month period.

5. In a multi-site study of 125 randomized human adult teeth, all classes of caries (I-V) were completely removed in 100% of the teeth treated.

6. In a multi-site study of 125 randomized human adult teeth all cavity preparation and restoration was still adequate after 3 months in 100% of treated teeth.

C. Surface Morphology (all blinded):

1. Animal and human studies using SEM demonstrated no changes in surface morphology except at the treatment site.

2. Animal and human studies using SEM illustrated that the drill and laser show equivalent surface changes at the treatment site.

D. Structural Morphology

1. The ideal etched tooth presents a roughened dentin or enamel surface and no evidence of cracking, fissuring or charring. The dentin demonstrates open dentinal tubules. Organic material has been vaporized leaving the inorganic components of the tooth - leaving greater tooth surface area. In addition, a cavity preparation should show no remaining evidence of caries and a crater created by removal of tooth structure below the margin of the preparation.

2. Hibst and Keller reported on the effective removal of tooth structure with ultrastructural changes in enamel and dentin. There were no fissures or cracks. The surface was scaled and roughened without signs of thermal damage. Laser dosimetries ranged from 50 - 350 mJ.

3. Paghdiwala showed at 430 mJ, hydroxyapatite has vaporized, developing pores and surrounded by elevated fused inorganic tissue. No visible cracks radiated from the craters.

E. Adjacent Structures

1. Adjacent structures to the treated tooth surface include soft tissue, proximal teeth and underlying bone. The damage due to inadvertent lasing of adjacent structures is usually less than the drill, since the laser does not cut effectively when defocused.

F. Efficacy

1. Investigators rate caries removal more effective than the drill.

2. Investigators rate cavity preparation with the laser equal to the drill.

3. Investigators rate laser etching much more effective than acid etching.

4. Animal and human studies demonstrate that the Er:YAG laser is equivalent to standard treatment.

BIBLIOGRAPHY

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5. Zach, Leo , and Cohen, Gerson. 1965. Pulp response to externally applied heat. O.S., O.M., and O.D. 19(4):515-530.

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