SEP 8 1999

K992013

510(k) Premarket Notification – Additional Information
DeL2940 Dental Erbium Laser: Hard Tissue Disease
Continuum Biomedical
August 24, 1999

510(k) Summary

Submitter:	Continuum Biomedical A Medical Division of Continuum Electro-Optics, Inc. 6533 Sierra Lane Dublin, CA 94568
Contact:	Laurie A. Ridener Regulatory Affairs Officer
Date Summary Prepared:	June 15, 1999
Device Trade Name:	DeL2940 Dental Erbium Laser, DeLite Dental Erbium Laser
Common Name:	Medical laser system
Classification Name:	Instrument, surgical, powered, laser 79-GEX 21 CFR 878.48
Equivalent Device:	Centauri Er:YAG Dental Laser System, Premier Laser Systems, Inc.
Device Description:	DeL2940 Dental Erbium Laser consists of three interconnected sections: the power supply, the water cooling system and the optical bench. Delivery is via fiber optic with a quartz contact tip. At 10 pulses per second an a pulse energy of 1 Joules, the average power from the laser is 10 watts.
Intended Use:	For removal of caries and for cavity preparation in primary and secondary teeth.
Comparison:	The DeL2940 Dental Erbium Laser is substantially equivalent to the Centauri Er:YAG Dental Laser System (Premier).
Nonclinical Performance Data:	Data was provided on two bovine studies (22 teeth) and two canine studies (174 teeth). One of the canine studies compared the laser treatment to the drill. All studies supported the safety and effectiveness of the Er:YAG laser for caries removal and cavity preparation.
Clinical Performance Data:	Foreign data was provided from four clinical studies for a total of 245 human teeth (18 extracted, 23 scheduled for extraction and 204 in vivo). All studies supported the safety and effectiveness of the Er:YAG laser for caries removal and cavity preparation. Domestic data was provided from an IDE study for a total of 94 pediatric subjects and 121 adult subjects treated with the DeL2940 Dental Erbium Laser.
Conclusion:	The DeL2940 Dental Erbium Laser is substantially equivalent to other currently marketed erbium dental lasers for the removal of caries and for cavity preparation in primary and secondary teeth.
Additional Information:	None requested at this time.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 8 1999

Ms. Liza A. Burns
Regulatory Affairs Consultant
Continuum Biomedical, Inc.
6533 Sierra Lane
Dublin, California 94568

Re: K992013
Trade Name: DeL2940 Dental Erbium Laser, DeLite Dental Erbium Laser
Regulatory Class: II
Product Code: GEX
Dated: June 15, 1999
Received: June 15, 1999

Dear Ms. Burns:

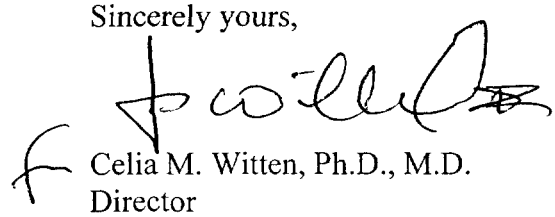
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of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



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) Premarket Notification – Additional Information
DeL2940 Dental Erbium Laser: Hard Tissue Disease
Continuum Biomedical
August 24, 1999

510(k) Number (if known):	*K992013*
Device Name:	DeL2940 Dental Erbium Laser, DeLite Dental Erbium Laser
Indications for Use:	For Removal of Caries and for Cavity Preparation in Primary and Secondary Teeth.

(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 K992013

Prescription Use X OR Over-the-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)