k013216

510(k) Summary

FEB 2 7 2002

Submitter:	Continuum Electro-Optics, Inc. 3150 Central expressway Santa Clara, CA 95051
Contact:	Ronald Kohlhardt
Date Summary Prepared:	September 24, 2001
Device Trade Name:	DioDent Dental Laser System
Common Name:	Medical Laser System
Classification Name:	Instrument, surgical, powered, laser 79-GEX
Equivalent Device(s):	Aurora by Premier Laser System, TwiLight or Dentek LD-15 Diode Laser System by BioLase Technologies, DioLase ST by American Medical Technology (formerly ADT)
Intended Use:	The DioDent Dental Laser System is intended for incision, excision, ablation, vaporization and/or coagulation of oral soft tissue (including marginal and interdental gingiva and epithelial lining of free gingiva).
Comparison:	The DioDent Dental Laser System, Aurora Diode Laser System, TwiLight/Dentek LD-15 Dental Diode Laser, and DioLase ST are equivalent in operating parameters, physical characteristics and intended uses.
Nonclinical Performance Data:	None
Clinical Performance Data:	None
Additional Information:	None

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 2 7 2002

Mr. Ronald Kohlhardt
Director, Regulatory Compliance
and Quality Assurance
Continuum Electro-Optics, Inc.
3150 Central Expressway
Santa Clara, California 95051

Re: K013216
Trade/Device Name: DioDent Dental Laser System
Regulation Number: 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: II
Product Code: GEX
Dated: January 22, 2002
Received: January 23, 2002

Dear Mr. Kohlhardt:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate 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) that do not require approval of a premarket approval application (PMA). 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 (PMA), 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 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 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 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. 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" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): *pending* K013216

Device Name: DioDent Dental Laser System

Indications for Use:

For the incision, excision, ablation, vaporization and hemostasis of oral soft tissue.
Examples:
Excisional and incisional biopsies
Exposure of unerupted teeth
Fibroma removal
Frenectomy and frenotomy
Gingival troughing for crown impressions
Gingivectomy
Gingivoplasty
Gingival incision and excision
Hemostasis
Implant recovery
Incision and drainage of abscess
Leukoplakia
Operculectomy
Oral papillectomies
Pulpotomy
Pulpotomy as an adjunt to root canal therapy
Reduction of gingival hypertrophy
Soft tissue crown lengthening
Sucular debridement (removal of diseased or inflamed soft tissue in the periodontal pocket to improve clinical indices including gingival index, gingival bleeding index, probe depth, attachment loss and tooth mobility)
Treatment of aphthous ulcers
Vestibuloplasty
Biopsy incision and excision
Lesion (tumor) removal

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

Optional Format 1-2-96)

for Mark N Milhern
(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K013216