510(k) Summary

OCT 16 2002

K022351

Submitted by:	Continuum Electro-Optics, Inc. 3150 Central Expressway Santa Clara, CA 95051 (408) 727-3340 - Phone (408) 727-3550 - FAX
Contact:	Thomas J. Haney Manager, Dental Products
Date Summary Prepared:	July 17, 2002
Device Trade Name:	DioDent Dental Laser System
Common Name:	Medical Laser System
Classification Name:	Instrument, Surgical, Powered, Laser
Equivalent Device(s):	**TwiLite/TwiLiteWhite** by Biolase Technology, Inc. **Ceralas Model D15** by Ceramoptec, Inc. **Opus 10** by OpusDent, Inc.
Intended Use:	Teeth Whitening
Comparison:	Principles of operation, function and intended use for the DioDent, TwiLite/TwiLiteWhite, Ceralas Model D15 and Opus 10 laser systems are identical.
Non-Clinical 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

OCT 16 2002

Continuum Electro-Optics, Inc.
Thomas J. Haney
Manager, Dental Products
3150 Central Expressway
Santa Clara, California 95051

Re: K022351
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: Class II
Product Code: GEX
Dated: July 17, 2002
Received: July19, 2002

Dear Mr. Haney:

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 setforth 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" (21 CFR 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): K022351

Indications for Use:

1. Light activation for bleaching materials for teeth whitening.
2. Laser-assisted bleaching/whitening for teeth.

(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
and Neurological Devices

510(k) Number K022351

Perscription Use: ✓ OR Over-The-Counter Use: _____
(Per 21 CFR 801.109) (Optional Format 1-2-96)

000083