

DEC 16 2004

**A. 510(k) Summary**                      **K040270**

**I. General Information**

Submitter:                                      Lumenis, Inc.  
2400 Condensa Street  
Santa Clara, CA 950511

Contact Person:                              Karen L Baker/ Martha Murari, PhD

Summary Preparation Date:              December 2004

**II. Names**

Device Names:                                OpusDent Family of Dental Laser Systems

Primary Classification Names:          Surgical Powered Laser Instrument

**III. Predicate Devices**

- OpusDent Duo, OpusDent 20, and OpusDent Spectra (K021508)
- Stryker Total Performance System (TPS) (K032117 and K991696)
- Hoya Conbio VersaWave Dental Er:YAG Laser System (K041710)

**IV. Product Description**

The OpusDent Family of Dental Laser Systems is comprised of the following main components:

- A light/ laser system console (including software and control electronics) with a control and display panel;
- Delivery devices; and
- One or more attached hand-piece(s).

**V. Intended Use and Indications for Use**

Intended Use: The OpusDent Family of Er:YAG and CO<sub>2</sub>/Er:YAG Combination Laser Products (and the delivery accessories that are used with them to deliver laser energy) are intended for use in dental procedures performed in oral and maxillofacial surgery and dentistry.

**VI. Rationale for Substantial Equivalence**

The OpusDent Family of Er:YAG and CO<sub>2</sub>/Er:YAG Combination Laser Products (and the delivery accessories that are used with them to deliver laser energy) share the same or similar indications for use, device operation, overall technical and functional capabilities, and therefore are substantially equivalent for use in general and plastic surgery, and dentistry for surgical applications to the predicate OpusDent Duo, OpusDent 20, and OpusDent Spectra (K021508), the Stryker Total Performance System (TPS) (K032117 and K991696), and the Hoya Conbio VersaWave Dental Er:YAG Laser System (K041710).

**VII. Safety and Effectiveness Information**

Review of indications for use and technical characteristics and data provided were used to support the safety and effectiveness and substantial equivalence of the OpusDent Family of Er:YAG and CO<sub>2</sub>/Er:YAG Combination Laser Products for use in specific applications in the medical specialties of general and plastic surgery, and dentistry.

**VIII. Conclusion**

The OpusDent Family of Er:YAG and CO<sub>2</sub>/Er:YAG Combination Laser Products (and the delivery accessories that are used with them to deliver laser energy) was found to be substantially equivalent to the predicate OpusDent Duo, OpusDent 20, and OpusDent Spectra (K021508), the Stryker Total Performance System (TPS) (K032117 and K991696), and the Hoya Conbio VersaWave Dental Er:YAG Laser System (K041710).

The OpusDent Family of Er:YAG and CO<sub>2</sub>/Er:YAG Combination Laser Products (and the delivery accessories that are used with them to deliver laser energy) shares the same indications for use, and similar design features, and functional features, and thus are substantially equivalent to the predicate devices.



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

DEC 16 2004

Lumenis, Inc.  
c/o Ms. Ann Worden  
Consultant  
3637 Bernal Avenue  
Pleasanton, California 94566

Re: K040270  
Trade/Device Name: Opus Dent Family of Dental Lasers  
Regulation Number: 21 CFR 878.4810  
Regulation Name: Laser surgical instrument for use in general and  
plastic surgery and in dermatology  
Regulatory Class: II  
Product Code: GEX  
Dated: November 16, 2004  
Received: November 17, 2004

Dear Ms. Worden:

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.

Page 2 - Ms. Ann Worden

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), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act 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

510(k) Number (if known): K040270

Device Name: OpusDent Family of Dental Laser Systems

Indications for Use:

The OpusDent Dental Laser System is intended to aid during dental procedures performed in oral and maxillofacial surgery and dentistry.

The Er:YAG laser component is indicated for a variety of hard tissue (tooth and bone) applications, and for the incision, excision, cutting, ablation, vaporization, and coagulation of soft tissue in oral and maxillofacial surgery and dentistry.

This includes the following:

Hard Tissue Indications of Er:YAG Laser Energy

- Caries removal
- Cavity preparation
- Enamel etching
- Enameloplasty, excavation of pits and fissures for placement of sealant

Bone Indications of Er:YAG Laser Energy

- Contact and non-contact cutting, shaving, contouring, and resection of oral osseous tissue (bone)
- Apicoectomy – amputation of the root end
- Osseous crown lengthening
- Cutting bone to prepare a window access to the apex (apices) of the root(s)
- Osseoplasty
- Osteotomy

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Prescription Use    
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use \_\_\_\_\_   
(21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

*Miriam C. Provost*  
**(Division Sign-Off)**  
**Division of General, Restorative,  
and Neurological Devices**

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LUMENIS, INC.  
MODIFICATION TO ER: 510(k) Number K040270 COMBINATION PRODUCT FAMILIES

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510(k) Number (if known): K040270

Device Name: OpusDent Family of Dental Laser Systems

Indications for Use: \*\*\* Continued from Previous Page \*\*\*

Soft Tissue and Periodontal Indications of Er:YAG Laser Energy

- Excisional and incisional biopsies
- Exposure of unerrupted teeth
- Incision and drainage of abscesses
- Gingival incision and excision
- Gingivoplasties
- Gingivectomies, Gingivectomy in case of hyperplasias of the gingival or excision of hyperplasias
- Gingival troughing for crown impressions
- Hemostasis
- Implant recovery
- Frenectomies and frenotomies
- Fibromatosis (fibroma removal)
- Benign and malignant lesion removal
- Operculectomy
- Oral papillectomies
- Reduction of gingival hypertrophy
- Soft tissue crown lengthening
- Preprosthetic surgery; flabby alveolar ridge, vestibuloplasty, exposure of implants, hyperplasia, epulides, papilomas, fibromatoses, benign growths
- Vestibuloplasty
- Sicular 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)

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Prescription Use ✓  
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 801 Subpart C)

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510(k) Number (if known): K040270

Device Name: OpusDent Family of Dental Laser Systems

Indications for Use: **\*\*\* Continued from Previous Page \*\*\***

Endodontal Applications of Er:YAG Laser Energy:

- Tooth preparation to obtain access to root canal
- Pulpotomy, Pulpotomy as an adjunct to root canal therapy
- Pulp extirpation
- Root canal debridement and cleaning
- Root canal preparation including enlargement

The CO<sub>2</sub> laser component is indicated for the incision, excision, cutting, ablation, vaporization, and coagulation of soft tissue in a variety of soft tissue applications, and in oral and maxillofacial surgery and dentistry.

Periodontal Applications of CO<sub>2</sub> Laser Energy:

- Removal of diseased or inflamed soft tissue in the periodontal pocket (sulcular debridement)
- Biopsies
- Frenectomy, Frenum release
- Gingivectomy
- Gingivoplasty
- Papillectomy
- Vestibuloplasty
- Hyperplasia
- Operculectomy
- Drainage (abscess)
- Flap surgery
- Fibroma (nonmalignant tumor; mucosa, tongue)
- Epulis (tumor of the gum)
- Aphthous ulcers
- Removal of soft tissue, cysts, and tumors

Prescription Use   ✓    
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 801 Subpart C)

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