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510(K) SUMMARY

OPUS 10™ DENTAL DIODE LASER SYSTEM

510(k) Number K 011769

Applicant's Name:

OpusDent Ltd.
Atid Science Based industrial Park, Hagavish 4 St., Natania south
P.O.Box 8737 Natania 42505, Israel
Tel.: 972-9-892 3333
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Contact Person:

Shoshana Friedman, RAC
Push-med Ltd.
117 Ahuzah St.
Ra'anana 43373, Israel
Tel: 972-9- 7718130
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or:

Jonathan S. Kahan
Hogan & Hartson L.L.P.
555 Thirteenth St, NW
Washington, DC 20004
Tel: (202) 637-5794
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Date Prepared:

June 2001

Trade Name:

Opus 10™ Dental Diode Laser System

Classification Name:

Laser Instrument, Surgical, Powered

Classification:

FDA has classified laser device as a class II device (product code GEX) and it is reviewed by the General & Plastic Surgery Panel.

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Predicate Devices:

The Opus 10™ Dental Diode Laser System with the tooth whitening application is substantially equivalent to the Opus 10™ Dental Diode Laser System (OpusDent Ltd.) in terms of, technological characteristics, performance, intended use (generally), indications for use and user interface.

In addition, the Opus 10™ is substantially equivalent to a combination of the Twilite™ Dental Diode Laser system (Biolase Technology, Inc.), to the Aurora™ Diode Laser System (Premier Laser Systems, Inc.) and to the Dentek™ LD 15 Diode laser (Dentek™ Austria GMBH) in terms of intended use, indication for use, technological characteristics and performance.

Performance Standards:

The Opus 10™ Diode Laser complies with:
U.S. Federal Performance Standards 21 CFR 1040.10 and 21 CFR 1040.11 for class IV Laser Products.

In addition, the device complies with the European Medical Directive 93/42/EEC concerning medical devices (Annex II) and with the voluntary standards, EN 60601-1, EN-60825-1, EN-601-2-22, CISPR 11, IEC 61000-4-2/3/4/5, EN55011 and IEC 801-2

Intended Use / Indication for Use:

The Opus 10™ Dental Diode Laser System is intended for incision, excision, ablation, vaporization and/or coagulation (hemostasis) of oral soft tissue (including marginal and interdental gingiva and epithelial lining of free gingiva). In addition, the system is intended for teeth whitening.

The Indications for Use of the Opus 10™ Dental Diode Laser System include:

Cosmetic Dentistry
- Light activation for bleaching materials for teeth whitening
- Laser-assisted bleaching/whitening of the teeth

Endodontology
- Pulpotomy
- Pulpotomy as an adjunct to root canal therapy

Periodontology
- Sulcular debridement (removal of diseased or inflamed soft tissue in the periodental pocket)

Oral Soft Tissue Surgery
- Biopsy
- Operculectomy
- Gingivectomy
- Gingivoplasty
- Papillectomy
- Lesion (tumor) removal
- Leukoplakia
- Treatment of aphthous ulcers
- Fibroma removal
- Frenectomies and frenotomies
- Tissue retraction for impressions
- Incising and draining of abscesses
- Exposure of unerupted teeth

Device Description:

The Opus 10™ Dental Diode Laser is designed to perform several medical procedures in the oral soft tissue and to perform laser assisted aesthetic tooth whitening procedures.
A Gallium Aluminum Arsenide (GaAlAs) solid state laser diode provides optical energy to oral soft tissues.

A fiber optic held by an handpiece delivers the Opus 10™ laser energy. A visible light emitted from the handpiece's distal end targets the area of treatment. The optical power output and pulse may be adjusted to specific use requirements.

Substantial Equivalence:

There are no unique applications, indications, material or specifications presented herein. Evidence of equivalence has been demonstrated through:

- The Opus 10™ intended use and indications for use were previously cleared by FDA for the predicate devices.
- The technical characteristics of the Opus 10™ with the tooth whitening application are similar to those of the cleared Opus 10™, Twilite™, Aurora™ and Dentek™.
- Laser output values of the Opus 10™ are well within previous cleared values of the predicate dental diode laser systems as described.
- The predicate devices and other previous cleared lasers with similar energy output has a proven safety and effectiveness in the treatment of the claimed indications.
- Safety and performance testing.

Therefore, the Opus 10™ Dental Diode Laser System with the tooth whitening application is substantially equivalent to its predicate devices cited above and raises no new safety and/or effectiveness issues.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 3 0 2001

OpusDent Ltd.
c/o Ms. Shoshana Friedman, RAC
Push-Med, Ltd.
117 Ahuzah Street
Ra'ananna 43373 Israel

Re: K011769
Trade/Device Name: Opus 10™ Dental Diode Laser System
Regulation Number: 878.4810
Regulatory Class: II
Product Code: GEX
Dated: June 2, 2001
Received: June 7, 2001

Dear Ms. Friedman:

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 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). 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 requirements, 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) 594-4659. 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 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,

Susan Walker, M.D.
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

510(k) Number (if known): K011769

Device Name: Opus 10™ Dental Diode Laser System

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

510(k) Number K011769

Prescription Use ✓
(Per 21 CFR 801.109)

OR

Over the Counter Use _____

(Division Sign-Off)
Division of General, Restorative and Neurological Devices

510(k) Number _____