JAN 8 2002

510(k) Summary

OpusDent Ltd.

Opus Spectrum 1/3

510(k) Number K014100

Submitter's Name:

OpusDent Ltd.
Atid Science Based industrial Park, Hagavish 4 St., Natania south
P.O.Box 8737 Natania 42505, Israel
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Contact Person:

Arava Hacohen
Push-Med Ltd.
117, Ahuza St., Ra'ananna 43373, Israel
Tel: 972-9-7718130
Fax: 972-9-7718131
e-mail: arava@push-med.com

Trade Name:

Opus Spectrum (a model of Opus 20)

Classification Name:

Laser Instrument, Surgical, Powered

Classification:

Laser Instrument, Surgical, Powered are class II devices (Product Code GEX).

Predicate Device:

The Opus Spectrum dental laser system is substantially equivalent to Opus 20 dental laser system (OpusDent Ltd, Israel) cleared under K002899.

Indication for use:

The OpuDuo Dental Laser System is intended to aid during dental procedures performed either in hard or soft oral tissue.
The Er:YAG laser component is indicated for caries removal, cavity preparation, and enamel etching.

K014160 4/3

The CO_2 laser component is indicated for vaporization, incision, excision and coagulation of oral soft tissue in procedures such as gingivectomy; frenum release; removal of soft tissue, cysts and tumors.

Device Description:

The Opus Spectrum c is a model of the Opus 20 Dental Laser System which is intended to aid during dental procedure performed either in hard or soft oral tissue. This is a dual laser system incorporating an Er:YAG laser and a CO_2 laser. The system is operating at a wavelength of 2.94 microns and 10.6 microns respectively. The Er:YAG laser delivers to the tissue pulses with energies up to 1 joule per pulse and power up to 12 Watts. . The CO_2 laser delivers to the tissue power in continuous mode (CW) up to 10 Watts and pulses (SP) up to 6 Watts.

Substantial Equivalence:

The Opus Spectrum dental laser system is substantially equivalent to the Opus 20 dental laser system (OpusDent Ltd.). In fact, it is an improved model of Opus 20 that is similar to its predicate device except the following features:

- Opus Spectrum software runs on Window NT® Operating System while Opus 20 incorporates a stand-alone software.
- Opus Spectrum is controlled by a PC Computer (PCM-5820) while Opus 20 is controlled by an embedded CPU.
- Opus Spectrum has a Touch-Screen technology instead of soft keys.
- Opus Spectrum incorportes an On Line Monitor that monitors the Er:YAG lasing power in addition to the two power meters in Opus 20.
- Opus Spectrum has two masts - one for Er:YAG and one for CO_2. Opus 20 has one mast for both lasers.
- Additional safety feature was added to Opus Spectrum. A microswitch is located in each handpiece carrier to indicate the handpiece in use and to identify miscorrelation between handpiece and desired laser mode.
- Opus Spectrum has external cooling system that cools the coolant of the internal cooling systems while Opus 20 has internal water/air cooling system.
- Opus Spectrum incorporates a new power supply.
- Opus Spectrum is smaller in size and it is half weight than Opus 20.
- The external design of the Opus Spectrum differs from Opus 20.

K014100 3/3

Design Control Activities Summary:

The risk analysis methods used to assess the impact of the modification on the device and its components, and the result of the analysis are presented in **Section 4** of the submission.

Based on the risk analysis, an identification of the verification and/or validation activities required, including methods or tests used and acceptance criteria to be applied are presented in **Sections 6 and 8** of this submission.

A declaration of conformity with design control is attached to **Section 6** of this submission.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 8 2002

OpusDent Ltd.
c/o Mr. Arava Hacohen
Project Manager
Push-med Ltd.
117 Ahuza Street
Ra'ananna 43373
Israel

Re: K014100
Trade/Device Name: Opus Spectrum
Regulation Number: 878.4810
Regulation Name: Laser surgical instrument for use in general surgery and plastic surgery and in dermatology
Regulatory Class: II
Product Code: GEX
Dated: November 19, 2001
Received: December 13, 2001

Dear Mr. Hacohen:

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: K014100

Device Name: Opus Spectrum

Indications for Use:

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(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
and Neurological Devices

510(k) Number K014100

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