510(k) Summary of Safety and Effectiveness k051255

Opusmed Inc.
LumiPhase-R™

JUL 01 2005

510(k) Summary	This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 C.F.R. § 807.92.

Submission Correspondant:	Emergo Group Inc. 2454 McMullen Booth Road, Suite 427 Clearwater, FL 33759 USA
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Contact:	Mr. Ian Gordon
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Submission Sponsor:	Opusmed Inc. 3333 Graham Boulevard, Suite 306 Mount-Royal, (Quebec) H3R 3L5 Canada

Date Prepared	May 6, 2005

Name of device	LumiPhase-R™

Classification Names	Laser surgical instrument for use in general and plastic surgery and in dermatology

Device Classification	Regulatory Class: II Product Code: GEX Classification Panels: General & Plastic Surgery Regulation Number: 21 C.F.R. 878.4810

K051255

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Opusmed Inc.
LumiPhase-R™

Predicate Device(s)

510(k)#	Device	Manufacturer
K030426	Omnilux Revive	Photo Therapeutics Limited
K031425	GentleWaves LED Photomodulation Device	Light BioScience L.L.C.

Device Description

The LumiPhase-R system delivers visible light at a wavelength of 660 nanometers. This LED device consists of three interconnected sections: the base which houses the power supply, the articulated arm and the treatment head consisting of the controller, the ventilation (heat sink) system, the LED based optics and the positioning system.

Indications

The LumiPhase-R ™ is indicated for treatment of wrinkles, rhytids and fine lines in the periorbital region.

Nonclinical Performance

The LumiPhase-R was tested and complies with IEC 60825-1 Laser Safety Testing. The LumiPhase-R will comply with IEC 60601-1-2 and CAN/CSA c22.2, No. 601.1-M90.

In vitro testing and bench testing was performed and determined to be acceptable. Based upon an analysis of the overall performance characteristics for the device, Opusmed Inc. believes that no significant differences exist. Therefore, the LumiPhase-R raises no new issues of safety or effectiveness.

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Clinical Performance

Clinical studies were conducted to provide assurance that the performance of the device is equivalent to the predicate devices. Results were acceptable and did not raise any new issues of safety and effectiveness.

Conclusion

By definition, a device is substantially equivalent when the device has the same intended use and the same technological characteristics as the predicate device, or has the same intended use and different technological characteristics. But, it can be demonstrated that the device is as safe and effective as the predicate device and the new device does not raise different questions regarding safety and effectiveness as compared to the predicate device.

The differences between the Opusmed LuminPhase-R and the predicate devices cited do not raise any different questions regarding safety and effectiveness.

The LumiPhase-R device, as designed, is as safe and effective as the predicate devices, and the device is determined to be substantially equivalent to the referenced predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Opusmed Incorporated
C/o Mr. Ian Gordon
Emergo Group Incorporated
2454 McMullen Booth Road, Suite 427
Clearwater, Florida 33759

JUL 01 2005

Re: K051255
Trade/Device Name: LumiPhase-R™
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: May 9, 2005
Received: May 18, 2005

Dear Mr. Gordon:

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), 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/industry/support/index.html.

Sincerely yours,

Miriam C. Provost, Ph.D.
Acting 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): K051255

Device Name: LumiPhase-R ™

Indications for Use:

The LumiPhase-R ™ is indicated for treatment of wrinkles, rhytids and fine lines in the periorbital region.

Prescription Use X AND/OR Over-The-Counter Use_____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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

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

(510(k) Number K051255