DEC 1 4 2012

510(k) Summary

K123257

Summary Preparation Date:	August 23, 2011
Company:	Emvera Technologies, LLC. 641 10th Street Cedartown, GA 30125
Contact Information:	
Phone:	770-749-1530
Fax:	888-361-7636
Contact Person:	Lyle Fuller
Device Name:	Emvera Diolux
Common/Usual Name:	Surgical Laser
Classification Name:	Powered Laser Surgical Instrument
Regulation Number:	21 CFR 878.4810
Product Code:	GEX
Device Class:	Class II
Review Panel:	Division of General, Restorative and Neurological Devices

Predicate Device:

Manufacturer	Trade Name	510(k) Number
Alma Lasers, Inc.	Soprano XL	K102716

Device Description

This laser operation equipment is a diode laser of 808nm of pulsed diode laser.

This equipment is composed of a main body to operate each function of equipment and a hand piece for irradiation of laser, and is designed to be use in various treatments by effecting the skin by laser beam of 808nm.

Diode laser of 808nm is able to transfer stable and uniform pulses to skin, therefore operator can treat patient safely and effectively using this equipment. This equipment provides direct visual color LCD screen configured with prompts for ease of use for the operator.

Indications for Use

The Emvera Diolux is indicated for hair removal, permanent hair reduction and for the treatment of benign vascular and pigmented lesions.

Permanent hair reduction is defined as the long-term, stable reduction in the number of hairs re-growing when measured at 6, 9, and 12 months after the completion of a treatment regimen.

Hair removal by laser or IPL sources can cause increase hair growth in some individuals. Based upon currently available data, the highest risk groups for this response are females of Mediterranean, Middle Eastern, and South Asian heritage treated on the face and neck.

Caution: Federal (USA) law restricts this device for use by or on the order of a physician.

Safety Testing

Electrical Safety Testing and Biocompatibility requirements have been met.

Predicate Product Comparison

Parameters	Emvera Diolux	Alma Lasers, Inc. Soprano XL
510(k) Number		K102716
Indications for Use	The Emvera Diolux is indicated for hair removal, permanent hair reduction and for the treatment of benign vascular and pigmented lesions.	The Diode Laser Module: The HR Mode is intended for hair removal, permanent hair reduction. The LaserBlanche Mode is intended for the treatment of benign vascular and pigmented lesions.
Laser Type	Laser Diode	AlGaAs Diode / CW
Wave Length	808nm	800nm
Fleunce	Up to 120 J/cm^2	Up to 120 J/cm^2
Mode	Pulsed	Pulsed
Duration	5-625 ms	10-1,350 ms
Repetition	1-2 Hz DP 2 1-3 Hz DP 1 5-10 Hz FDP Mode	1-3 Hz Pulse Mode 1-10 Hz SHR Mode
Spot Size	12.0 mm (Square)	12 x 10 mm (Square)
Cooling	Water Cooling	Dual Chill
Weight	26 Kg	27 Kg
Power Input	120/230V 20/10 A 50/60 Hz	120/230V 20/10 A 50/60 Hz

Based on the comparisons found in the predicate product comparison table no new issues of safety and effectiveness are raised in this original new 510(k).

This conclusion is based on the fact that the Emvera Diolux and the Alma Lasers Soprano XL have the same as or similar product characteristics, such as laser type, wave length, flounce, mode, duration, repetition, spot size, cooling and power input.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

Letter dated: December 14, 2012

Emvera Technologies, Incorporated
% Smith Associates
Mr. Ned Devine
Senior Staff Engineer
333 Pfingsten Road
Northbrook, Illinois 60062

Re: K123257
Trade/Device Name: Emvera Diolux
Regulation Number: 21 CFR 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: October 16, 2012
Received: October 18, 2012

Dear Mr. Devine:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson

Mark N. Melkerson
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Form

Indications for Use

510(k) Number K123257

Emvera Diolux

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Prescription Use _____√_____ AND/OR (Part 21 CFR 801 Subpart D)

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

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

Neil R Ogden
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(Division Sign-off) for MXM
Division of Surgical Devices
510(k) Number_____