K101321

Syneron

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NOV - 9 2010

510(K) Summary of Safety and Effectiveness

This summary of safety and effectiveness information is being submitted in accordance with the requirements of the SMDA 1990 and 21 CFR 807.92.

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Trade Name: eMatrix CO2

Common name: CO2 laser system

Classification: **Name:** powered laser surgical instrument
Product Code: GEX
Regulation No: 878.4810
Class: II
Classification Panel: General & Plastic Surgery

Predicate Devices: Substantial equivalence to the following predicate devices is claimed:

1. Fraxel III SR Laser System (Fraxel re:pair™) and accessories K071051; Reliant Technologies.
2. Alma Lasers Family of THERMO-XEL Handpieces Pixel Models: 2940, 1060 K072182; Alma Lasers
3. Alma Lasers THERMO-XEL CO2 Laser System and Delivery Device Accessories K080463; Alma Lasers

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Device description: The eMatrix CO2 is a Fractional CO2 laser device intended for dermatological procedures requiring ablation, coagulation and resurfacing of soft tissue including skin. The device console houses the major units of the system that include the laser module, the power supply, the scanner and all other electrical components. Laser is transmitted to the tissue via a series of lens integrated into the articulated arm. The system parameters are controlled via a LCD touchscreen and proprietary SW.

Indication for Use Statement: Dermatological procedures requiring ablation, coagulation and resurfacing of soft tissue, including skin.

Performance validation: Evaluation of skin biopsies revealed morphological changes, which were created under the impact of the eMatrix CO2 of skin resurfacing, as expressed via demarcated zones of ablation and coagulation. The different treatment modes led to a different impact in depth and width of the tissue. The affected zones tended to become deeper as the level of energy employed was increased .The affected zone were of uniform fractional phenotype, leaving intact, non-affected tissue between treated spots.

Conclusion: We have demonstrated that the eMatrix *CO2* meets its labeled performance claims, and that it is substantially equivalent to the predicate devices

05/09/2010

Date

Avi Hirshnzon

VP QA & Regulatory Affairs

Syneron Medical Ltd.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
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NOV - 9 2010

Re: K101321
Trade/Device Name: eMatrix CO2
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: November 04, 2010
Received: November 05, 2010

Dear Mr. Hirshnzon:

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
Director
Division of Surgical, Orthopedic
And Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

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510(k) Number: K101321

Device Name: eMatrix CO2

Indications for Use:

Dermatological procedures requiring ablation, coagulation and resurfacing of soft tissue, including skin.

Prescription Use ____x_____ (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 OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K101321