K 080496

510(k) Summary for the
Lutronic Corporation MOSAIC eCO2 Laser System

JUL - 7 2008

This 510(k) Summary is being submitted in accordance with the requirements of the SMDA 1990 and 21 CFR 807.92.

1. General Information

Submitter: Lutronic Corporation
#403-2,3,4, Ilsan Technotown
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Republic of Korea

Contact Person: Maureen O'Connell
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Summary Preparation Date: July 1, 2008

2. Names

Device Name: MOSAIC eCO2 Laser System (Trade Name: MOSAIC eCO2)

Classification Name: Laser Instrument, Surgical, Powered
Product Code: GEX
Panel: General & Plastic Surgery

3. Predicate Devices

The MOSAIC eCO2 is substantially equivalent to the predicate devices, including the Lumenis, Inc. (Lumenis UltraPulse Encore Carbon Dioxide Surgical Laser and Delivery Device Accessories) (K022060); the Sharplan Lasers, Inc. Model 1080 CO2 Surgical Laser System (K933918); the Lumenis, Inc. Modified Lumenis Family of UltraPulse SurgiTouch CO2 Laser Systems (K030147); the Reliant Technologies, Inc. Fraxel III SR Laser System (Fraxel re:pair) and Accessories (K071051); and the Cynosure, Inc. Smart CO2 (K031224).

4. Device Description

The MOSAIC eCO2 Laser System consists of a self-contained console, an articulated arm delivery system with scanner handpiece and a footswitch. The MOSAIC eCO2 produces a beam of coherent infrared light (10.6um) and has two operation modes (Static mode and Dynamic Mode). The laser works in medical applications because 10.6um is near the peak of tissue water absorption. When the water in the tissue absorbs the laser energy, it heats up. This heating causes instantaneous vaporization of the target tissue.

The MOSAIC eCO2 Laser System utilizes a CO_2 tube to generate a laser beam with a wavelength of 10.6 um and uses a scanner handpiece. The physician can optimize the effect for different applications by controlling the power of the laser pulse and using a different scan pattern.

5. Indications for Use

The MOSAIC eCO2 is indicated for use in dermatological procedures requiring ablation (removal), resurfacing and coagulation of soft tissue. Treatment of wrinkles; rhytides, furrows, fine lines, textural irregularities, pigmented lesions and vascular dyschromia.

6. Performance Data

None presented.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL - 7 2008

Lutronic Corporation
% O'Connell Regulatory Consultants
Ms. Maureen O'Connell
5 Timber Lane
North Reading, Massachusetts 01864

Re: K080496
Trade/Device Name: MOSAIC eCO2 Laser System
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: June 16, 2008
Received: June 17, 2008

Dear Ms. O'Connell:

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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
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): K080496

Device Name: MOSAIC eCO2 Laser System

Indications for Use:

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Barbara Ouellette

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

510(k) Number K080496