Attachment 6
510(K) Summary
Equinox CO2 Laser System

K131903

This 510(K) Summary of safety and effectiveness for the Equinox CO2 laser System is submitted in accordance with the requirements of the SMDA 1990 and following guidance concerning the organization and content of a 510(K) summary.

Applicant:	Eclipse Aesthetics, LLC
Address:	13988 Diplomat Drive Suite 160 Dallas, TX 75234
Contact Person:	Mr. Tom O'Brien
Telephone: Email:	972-380-2911 – Phone tobrien@eclipsemed.com
Preparation Date:	June 17, 2013
Device Trade Name:	Equinox CO2 Laser System
Common Name:	CO2 Laser
Classification Name:	Instrument, Surgical, Powered, laser 79-ONG, 21 CFR 878-4810
Legally Marketed Predicate Device:	Equinox CO2 Laser K100487
Description of the Equinox CO2 laser	The Equinox CO_2 laser has a wavelength of 10,600nm. CO_2 fractional laser uses scanning optics to deliver a pattern of thermal energy to the epidermis and upper dermis. Device accessories include tip attachments. This system consists of main body, color touch screen, Arm, hand-piece and Foot switch.
Intended use of the Equinox CO2 laser	The Equinox CO 2 laser when used in traditional non-fractionated scanner mode is indicated for incision, excision, ablation, vaporization, and coagulation of body soft tissues. The Equinox CO 2 laser when used in fractionated mode is indicated for ablative skin resurfacing.
Performance Data:	Histology data was submitted to support clearance of the device in fractionated mode. The device was used on a pig with energy up to 200mJ per microbeam for both the 120um and the 800um spot sizes. The targeted area was biopsied to evaluate the effect. The data was to show the depth and width of thermal damage zones and healing response over time.

SEP 19 2013

120um Results

Energy / Day	50 mJ		100 mJ		200 mJ	
	Depth	Width	Depth	Width	Depth	Width
0	87.4µm	114.1µm	100.8µm	195.5µm	158µm	221.5µm
3	59.7µm	86.8µm	83.6µm	155.7µm	61.5µm	179.2µm
14	59.7µm	86.8µm	-	-	59.1µm	86.8µm

800um Results

Energy / Day	50 mJ		100 mJ		200 mJ	
	Depth	Width	Depth	Width	Depth	Widt
0	50.06µm	296µm	69.2µm	360.5µm	81.8µm	437µ
3	36.06 µm	256.01µm	41.03 µm	285.5 µm	66.37 µm	401µ
14	31.02 µm	170.40µm	25.30 µm	105.01 µm	20.03 µm	172.04

Results of Clinical Study: None

Conclusion: The Equinox CO2 Laser System is substantially equivalent to the previously cleared predicate devices that are currently in commercial distribution.

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

September 19, 2013

Eclipse Aesthetics, LLC
Mr. Tom O'Brien
CEO
13988 Diplomat Drive, Suite 160
Dallas, Texas 75234

Re: K131903
Trade/Device Name: Equinox CO2 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: Class II
Product Code: ONG
Dated: August 18, 2013
Received: August 23, 2013

Dear Mr. O'Brien:

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 contact 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. 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,

David Krause -S

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

Enclosure

Indications for Use

510(k) Number (if known): K131903

Device Name : Equinox CO2 Laser System

The Equinox CO 2 laser when used in traditional non-fractionated scanner mode is indicated for incision, excision, ablation, vaporization, and coagulation of body soft tissues.

The Equinox CO 2 laser when used in fractionated mode is indicated for ablative skin resurfacing.

Prescription Use ___xx___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R Ogden -A
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(Division Sign-Off) for MXM

Division of Surgical Devices

510(k) Number K131903