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: 972-380-2911 – Phone
Email: 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 CO2 laser has a wavelength of 10.600nm. CO2 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 CO2 laser when used in traditional non-fractionated scanner mode is indicated for incision, excision, ablation, vaporization, and coagulation of body soft tissues.

The Equinox CO2 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.
### 120μm Results

<table>
<thead>
<tr>
<th>Day</th>
<th>Energy</th>
<th>50 mJ</th>
<th>100 mJ</th>
<th>200 mJ</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Depth</td>
<td>Width</td>
<td>Depth</td>
<td>Width</td>
</tr>
<tr>
<td>0</td>
<td>87.4μm</td>
<td>114.1μm</td>
<td>100.8μm</td>
<td>195.5μm</td>
</tr>
<tr>
<td>3</td>
<td>59.7μm</td>
<td>86.8μm</td>
<td>83.6μm</td>
<td>155.7μm</td>
</tr>
<tr>
<td>14</td>
<td>59.7μm</td>
<td>86.8μm</td>
<td>-</td>
<td>-</td>
</tr>
</tbody>
</table>

### 800μm Results

<table>
<thead>
<tr>
<th>Day</th>
<th>Energy</th>
<th>50 mJ</th>
<th>100 mJ</th>
<th>200 mJ</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Depth</td>
<td>Width</td>
<td>Depth</td>
<td>Width</td>
</tr>
<tr>
<td>0</td>
<td>50.06μm</td>
<td>296μm</td>
<td>69.2μm</td>
<td>360.5μm</td>
</tr>
<tr>
<td>3</td>
<td>36.06μm</td>
<td>256.01μm</td>
<td>41.03μm</td>
<td>285.5μm</td>
</tr>
<tr>
<td>14</td>
<td>31.02μm</td>
<td>170.40μm</td>
<td>25.30μm</td>
<td>105.01μm</td>
</tr>
</tbody>
</table>

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.
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 I
- 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 CO2 laser when used in traditional non-fractionated scanner mode is indicated for incision, excision, ablation, vaporization, and coagulation of body soft tissues.

The Equinox CO2 laser when used in fractionated mode is indicated for ablative skin resurfacing.

Prescription Use xx AND/OR Over-The-Counter Use
(Part 21 CFR 801 Subpart D)
(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
2013.09.18 15:07:08-04'00'
(Division Sign-Off) for MXM
Division of Surgical Devices
510(k) Number K131903