This 510(K) Summary of safety and effectiveness for the E-Beam Nd:YAG 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
Fax: 972-380-2953 – fax
Email: tobrien@eclipsemed.com
Preparation Date: September 12, 2012
Device Trade Name: E-Beam Nd:YAG Laser System
Common Name: Nd:YAG Q-Switch Laser
Classification Name: Instrument, Surgical, Powered, laser 79-GEX, 21 CFR 878-48
Legally Marketed Predicate Device: Lutronic Spectra Laser System K113588

Description of the E-Beam Nd:YAG Laser System: The E-Beam Nd:YAG Laser System is a Q-Switch laser with wavelengths of 1064nm and 532nm. Optional Dye attachments to the handpiece add additional wavelengths of 585nm and 650nm. This system consists of main body, color touch screen, articulated arm hand-piece and Foot switch.

The E-Beam Nd:YAG Laser System can also be used in a long pulse mode.


532nm Wavelength (nominal delivered energy of 585 nm and 650 nm with optional dye handpieces):

- Tattoo removal: light ink (red, tan, purple, orange, sky blue, green)
- Removal of Epidermal Pigmented Lesions
- Removal of Minor Vascular Lesions including but not limited to telangiectasias
- Treatment of Lentigines
- Treatment of Cafe-Au-Lait
- Treatment of Seborrheic Keratoses
Attachment 5
510(K) Summary
E-Beam Nd:YAG Laser System

- Treatment of Post Inflammatory Hyper-Pigmentation
- Treatment of Becker's Nevi, Freckles and Nevi Spilus

1064nm Wavelength:
- Tattoo removal: dark ink (black, blue and brown)
- Removal of Nevus of Ota
- Removal or lightening of unwanted hair with or without adjuvant preparation.
- Treatment of Common Nevi
- Skin resurfacing procedures for the treatment of acne scars and wrinkle

Performance Data:
None

Results of Clinical Study:
None

Conclusion: The E-Beam Nd:YAG Laser System is substantially equivalent to the previously cleared predicate devices that are currently in commercial distribution.

Technical Comparison for the Q-Switch Laser

<table>
<thead>
<tr>
<th>Feature</th>
<th>Wavelength</th>
<th>E-Beam (Subject of this submission)</th>
<th>Spectra (K113588) (Predicate Device)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Laser Medium</td>
<td>Nd:YAG</td>
<td>Nd:YAG</td>
<td>Nd:YAG</td>
</tr>
<tr>
<td>Wavelengths</td>
<td>1064nm / 532nm (Option: 585nm, 650nm)</td>
<td>1064nm / 532nm (Option: 585nm, 650nm)</td>
<td></td>
</tr>
<tr>
<td>Operating Mode</td>
<td>Q-Switched</td>
<td>Top Hat Mode</td>
<td>Q-Switched</td>
</tr>
<tr>
<td>Beam Profile</td>
<td>Top Hat Mode</td>
<td>Top Hat Mode</td>
<td>Top Hat Mode</td>
</tr>
<tr>
<td>Pulse Energy</td>
<td>1064nm</td>
<td>1200mJ</td>
<td>1200mJ</td>
</tr>
<tr>
<td></td>
<td>532nm</td>
<td>400mJ</td>
<td>400mJ</td>
</tr>
<tr>
<td></td>
<td>585nm</td>
<td>250mJ</td>
<td>250mJ</td>
</tr>
<tr>
<td></td>
<td>650nm</td>
<td>150mJ</td>
<td>150mJ</td>
</tr>
<tr>
<td>Pulse Width</td>
<td>5ns – 10ns</td>
<td>5ns – 10ns</td>
<td>5ns – 10ns</td>
</tr>
<tr>
<td>Spot Size</td>
<td>1064nm</td>
<td>2-8mm Colimated: 6mm</td>
<td>3,4,5,6,7,8,9mm Optional: 1,2,3,4,6,7,8mm</td>
</tr>
<tr>
<td></td>
<td>532nm</td>
<td>6.9mm</td>
<td>2.6, 3.4, 4.3, 5.2, 6.0, 6.9mm Optional: 0.8, 1.7, 2.6, 3.4, 4.3, 5.2, 6.0mm</td>
</tr>
<tr>
<td></td>
<td>585nm</td>
<td>2mm</td>
<td>2mm</td>
</tr>
<tr>
<td></td>
<td>650nm</td>
<td>2mm</td>
<td>2mm</td>
</tr>
<tr>
<td>Pulse Duration</td>
<td>1064nm</td>
<td>Single, 1,2,5,10 Hz</td>
<td>Single, 1,2,5,10 Hz</td>
</tr>
<tr>
<td></td>
<td>532nm</td>
<td>Single, 1,2,4,5Hz</td>
<td>Single, 1,2,4,5Hz</td>
</tr>
<tr>
<td></td>
<td>585nm</td>
<td>Single, 1,2,4,5 Hz</td>
<td>Single, 1,2,4,5 Hz</td>
</tr>
<tr>
<td></td>
<td>650nm</td>
<td>Single, 1 and 2Hz</td>
<td>Single, 1 and 2Hz</td>
</tr>
<tr>
<td>Beam Delivery</td>
<td>Articulated Arm</td>
<td>Articulated Arm</td>
<td>Articulated Arm</td>
</tr>
<tr>
<td>Aiming Beam</td>
<td>Diode 655nm (Red) 1mW</td>
<td>Diode 655nm (Red) 1mW</td>
<td>Diode 655nm (Red) 1mW</td>
</tr>
</tbody>
</table>
Technical Comparison for the Long Pulse Nd:YAG Laser System

<table>
<thead>
<tr>
<th>Feature</th>
<th>E-Beam (Subject of this submission)</th>
<th>Spectra (K113588) (Predicate Device)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Laser Medium</td>
<td>Nd:YAG</td>
<td>Nd:YAG</td>
</tr>
<tr>
<td>Wavelengths</td>
<td>1064nm</td>
<td>1064nm</td>
</tr>
<tr>
<td>Operating Mode</td>
<td>Long Pulse</td>
<td>Long Pulse</td>
</tr>
<tr>
<td>Beam Profile</td>
<td>Top Hat Mode</td>
<td>Top Hat Mode</td>
</tr>
<tr>
<td>Pulse Energy</td>
<td>1500mJ</td>
<td>1500mJ</td>
</tr>
<tr>
<td>Pulse Width</td>
<td>300us</td>
<td>300us</td>
</tr>
<tr>
<td>Spot Size 1064nm</td>
<td>2-8mm</td>
<td>3,4,5,6,7,8mm</td>
</tr>
<tr>
<td></td>
<td>Collimated 6mm</td>
<td>Optional: 1,2,3,4,6,7,mm</td>
</tr>
<tr>
<td>Pulse Duration</td>
<td>Single, 1,2,5,10 Hz</td>
<td>Single, 1,2,5,10 Hz</td>
</tr>
<tr>
<td>Optical Deliver</td>
<td>Articulated Arm</td>
<td>Articulated Arm</td>
</tr>
<tr>
<td>Aiming Beam</td>
<td>Diode 655nm (Red) 1mW</td>
<td>Diode 655nm (Red) 1mW</td>
</tr>
</tbody>
</table>

Conclusion: The E-Beam Nd:YAG Laser System is substantially equivalent to the previously cleared predicate devices that are currently in commercial distribution.
Eclipse Aesthetics, LLC
% Mr. Tom O'Brien
Chief Executive Officer
13998 Diplomat Drive
Dallas, Texas 75234

Re: K122922
   Trade/Device Name: Tri-Beam Nd: YAG 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: GEX
   Dated: December 05, 2012
   Received: December 11, 2012

Dear Ms. O'Brien:

We have reviewed your Section 510(k) premarket notification of intent to market the device
referred to 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" (21 CFR 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

510(k) Number (if known): K122922

Device Name: Tri-Beam Nd:YAG Laser System

Indications for Use:

The Tri-Beam Nd:YAG Laser System is indicated for: the incision, excision, ablation, vaporization of soft tissues for general dermatology, dermatologic and general surgical procedures for coagulation and hemostasis.

532nm Wavelength (nominal delivered energy of 585 nm and 650 nm with optional dye handpieces):

- Tattoo removal: light ink (red, tan, purple, orange, sky blue, green)
- Removal of Epidermal Pigmented Lesions
- Removal of Minor Vascular Lesions including but not limited to telangiectasias
- Treatment of Lentigines
- Treatment of Café Au Lait
- Treatment of Seborrheic Keratoses
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- Removal of Nevus of Ota
- Removal or lightening of unwanted hair with or without adjuvant preparation.
- Treatment of Common Nevi
- Skin resurfacing procedures for the treatment of acne scars and wrinkle

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)

Neil R Ogden
2013.01.04/14:51:12 -05'00'
(Division Sign-Off) for MXM
Division of Surgical Devices
510(k) Number K122922