K093465

JAN - 5 2010

Attachment 5
510(K) Summary
Fusion System

This 510(K) Summary of safety and effectiveness for the Fusion 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: | Eclipsemed Global, Inc |
| Address: | 16850 Dallas Parkway<br>Dallas, TX 75248<br>972-380-2911 – phone<br>972-380-2953 – fax |
| Contact Person: | Mr. Igor Gradov |
| Telephone:<br>Fax:<br>Email: | 972-380-2911 – Phone<br>972-380-2953 – Fax<br>igorg@eclipsemed.com |
| Preparation Date: | October 31, 2009 |
| Device Trade Name: | Fusion System |
| Common Name: | Intense Pulse Light (IPL) System |
| Classification Name: | Instrument, Surgical, Powered, laser<br>79-GEX, 21 CFR 878-48 |
| Legally Marketed Predicate Device: | Lumenis One Family of Systems<br>K060448<br><br>Alma Harmony XL (for treatment of Acne)<br>K072564 |
| Description of the Fusion System: | The Fusion System consists of:<br>• The main console unit that incorporates the touch-screen control panel, power supply module, cooling system, switching module and isolation transformer<br>• Variety of handpieces<br>• Footswitch |
| Intended use of the Fusion System: | The 500 – 1200nm intense pulsed light wavelengths are indicated for:<br>• The treatment of benign pigmented epidermal lesions, including dyschromia, hyperpigmentation, melasma, ephelides (freckles)<br>• The treatment of cutaneous lesions, including warts, scars and striae<br><br>The 560 – 1200nm intense pulsed light wavelengths are indicated for:<br>• The treatment of benign cutaneous vascular lesions, including port wine stains, hemangiomas, facial, truncal and leg telangiectasias, rosacea, erythema of rosacea, angiomas and spider angiomas, poikiloderma of Civatte, leg veins and venous malformations |

Attachment 5
510(K) Summary
Fusion System

| | |
|---|---|
| Intended use of the Fusion System: | The 600 – 1200nm intense pulsed light wavelengths are indicated for:<br>• The removal of unwanted hair from all skin types and to effect stable, long-term or permanent hair reduction in skin types I-V through selective targeting of melanin in hair follicles.<br><br>The 400 – 1200nm intense pulsed light wavelengths are indicated for:<br>• The treatment of moderate inflammatory acne vulgaris. |
| Performance Data: | None |
| Results of Clinical Study: | None |
| Conclusion: | The Fusion 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 Room W-O66-0609
Silver Spring, MD 20993-0002

JAN - 5 2010

Eclipsemed Global, Inc.
% Mr. Igor Gradov
16850 Dallas Parkway
Dallas, Texas 75248

Re: K093465
Trade/Device Name: Fusion 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: ONF
Dated: December 16, 2009
Received: December 22, 2009

Dear Mr. Gradov:

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 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.

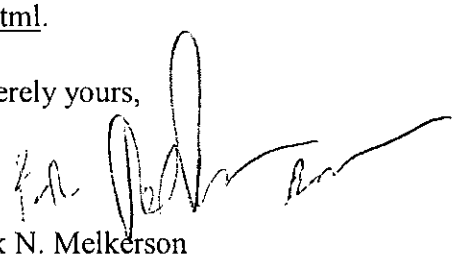
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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/cdrh/mdr/ 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/cdrh/industry/support/index.html.

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

510(k) Number (if known): K093465

Device Name : Fusion System

Indications for Use:

The 500 – 1200nm intense pulsed light wavelengths are indicated for:

- The treatment of benign pigmented epidermal lesions, including dyschromia, hyperpigmentation, melasma, ephelides (freckles)
- The treatment of cutaneous lesions, including warts, scars and striae

The 560 – 1200nm intense pulsed light wavelengths are indicated for:

- The treatment of benign cutaneous vascular lesions, including port wine stains, hemangiomas, facial, truncal and leg telangiectasias, rosacea, erythema of rosacea, angiomas and spider angiomas, poikiloderma of Civatte, leg veins and venous malformations

The 600 – 1200nm intense pulsed light wavelengths are indicated for:

- The removal of unwanted hair from all skin types and to effect stable, long-term or permanent hair reduction in skin types I-V through selective targeting of melanin in hair follicles.

The 400 – 1200nm intense pulsed light wavelengths are indicated for:

- The treatment of moderate inflammatory acne vulgaris.

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)



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

510(k) Number K093465