K092734

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SEP 20 2010

510(k) Summary for the E-Light Line

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:	Espansione Marketing Spa is located at: Blocco 27 – Via Orefici 152 Centergross 40050 Funo – Bologna ITALY
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Summary Preparation Date:	August 28, 2009

2. Names

Device Family Name:	E-light Line
Device models:	Trinity Plus, EPI-C Plus, Evoluzione Plus
Common Name:	IPL, LED and Vacuum equipment
Classification Name:	II, Laser Surgical Instrument for use in General and Plastic Surgery and in Dermatology
Product Code:	GEX /ISA
Regulation number:	878.4810

3. Predicate Devices

The E-light line is substantially equivalent to the following legally marketed device:

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Applicant	Device name	510(k) Number
Espansione Marketing S.p.A.	EPI-C Plus	K070494
Photonova of Sweden AB	Photonova Family of pulsed light systems	K073477
Light BioScience LLC	GentleWaves Led Photomodulation	K031425
Skincare Technology Inc.	RevLigth	K042630
Photo Therapeutics Limited	Ominilux Revive	K030426
Photo Therapeutics Limited	Ominilux Blue	K030883
Quantel Derma Gmbh	LEDA	K090762
PhotoActif LLC	IllumiMed	K060792
LPG One Inc.	CELLU M6 Keymodule	K053225

4. Device Description

The E-light Line is a family of devices with three types of output emitted from different handpieces. The outputs of the E-light Line are Intense Pulsed Light (IPL), LED and Vacuum. These outputs may be issued from different handpieces. The output handpieces are:

- IPL handpiece
- Led handpiece
- Led Body Band
- Led Masks
- Vacuum handpiece

Only one output source works at a time. All the E-Light line devices include a Main Unit that controls and manages the IPL, LED or Vacuum handpiece. The Main Unit contains all circuitry to control the device as the capacitor charge system, the microcontroller and all the electronic parts.
The E-light line devices are:

- Trinity Plus
- Evoluzione Plus
- EPI-C Plus

The E-Light Trinity Plus supports all the technologies (IPL, LED and Vacuum) and therefore all the handpieces. The E-Light Evoluzione Plus and EPI-C plus support the IPL and LED Technologies and therefore all the handpiece with the exception of the Vacuum handpieces.

5. Indications for Use

The E-Light Line devices are intended for dermatological use by physicians and healthcare professionals as the following:

IPL Technology is intended for:

- Treatment of Acne (from 390 to 1200nm filter)
- Treatment of vascular and benign pigmented lesions, cutaneous lesions including warts, scars, striae , and facial and leg veins (from 550 to1200nm filter).

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- Removal of unwanted hair in all skin types (from 570- to 1200nm filter)

LED Technology is intended:

- Yellow LED 594 nm - for treatment of periorbital wrinkles and rhytides
- Blue LED 428nm - to treat dermatological conditions and specifically indicated to treat moderate inflammatory acne vulgaris
- Red LED 632nm - for treatment of superficial, benign vascular and pigmented lesions

VACUUM Technology is intended to:

- Improve Lymphatic circulation in the treated area

6. Substantial equivalence description

The E-light line is a family of device with difference energy emissions: intense pulsed light (IPL), light emitting diode (LED) and aspiration massager (Vacuum).

The IPL technology is the same of the Espansione Marketing Epi-c Plus (K070494) both for intended use and for technological characteristics, in fact the E-light line family was developed with the same hardware of the Espansione Marketing Epi-c Plus (K070494). The IPL technology is also similar to the Photonova – Photonova Family of pulsed light systems (K073477), in fact the intended use and the emission parameter are very similar to E-light line.

The LED technology is equivalent to the predicate devices K031425 – Light Bioscience LLC – Gentlewaves Led Photomodulation, K042630 – Skincare Technology Inc. – RevLight, K030426 – Photo Therapeutics Limited – Ominilux Revive, K030883 – Photo Therapeutics Limited – Ominilux Blue, K090762 – Quantel Derma Gmbh – LEDA, K060792 – PhotoActif LLC – IllumiMed. The outputs of the Led technology of the E-light line are yellow, red and blue.

The Espansione Marketing E-light line is equivalent to the K031425 – Light Bioscience LLC – Gentlewaves Led Photomodulation and to the K090762 – Quantel Derma Gmbh – LEDA because the E-light line has yellow led with the same wavelength, similar output parameters (energy density, treatment time, dose range), have the same type of application.

The Espansione Marketing E-light line is equivalent to the K030426 – Photo Therapeutics Limited – Ominilux Revive, K042630 – Skincare Technology Inc. – RevLight and to the K090762 – Quantel Derma Gmbh – LEDA because the E-light line has red led with the same wavelength, similar output parameters (energy density, treatment time, dose range), have the same type of application.

The Espansione Marketing E-light line is equivalent to the K030883 – Photo Therapeutics Limited – Ominilux Blue, the K042630 – Skincare Technology Inc. – RevLight, and to the K060792 – PhotoActif LLC – IllumiMed because the E-light line has red led with the same wavelength, similar output parameters (energy density, treatment time, dose range), have the same body application.

The Vacuum technology is equivalent to LPG One device (K053225). In fact the intended use of the E-light line massager is included in the LPG One device (K053225) intended use. The output parameters of E-light line are included in the LPG One device (K053225) parameters and the method of application is very similar for both devices.

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Then we believe that the Espansione Marketing E-light line is substantially equivalent to the predicate devices, because it have the same intended use, the similar technology characteristics and the similar application as the predicate devices and no significant differences exists between the predicate devices.

7. Performance Data

The E-Light Line devices have been successfully passed the electric safety tests in accordance with the EN 60601-1:2004 Medical Electrical Equipment - Part 1: General Requirements for Safety and the electromagnetic compatibility tests in accordance with the IEC 60601-1-2:2004 Medical Electrical Equipment - Part 1: General Requirements for Safety; Electromagnetic Compatibility -- Requirements and Tests.
The E-Light Line devices have been developed according to the following international standards too:

- EN 980:2004 Graphical symbols for use in the labeling of medical devices
- EN ISO 14971:2007 Medical devices - Application of risk management to medical devices

No clinical study was been submitted.

After an analysis of the indications and intended uses, the technology characteristics, outputs, performance and safety (both electric and electromagnetic), Espansione Marketing believes that no significant differences exist between the predicate devices listed in Section 3, above.

The E-light line 510(k) Summary includes only information that is also covered in the body of the 510(k), it does not contain any puffery or unsubstantiated labeling claims, it does not contain any raw data and contains only summary data, it does not contain any trade secret or confidential commercial information, it does not contain any patient identification information.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Espansione Marketing Spa
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Mr. Guido Bonapace
Vin Borgo Santa Cristina 12
40026 Imola, Bologna, Italy

SEP 2 0 2010

Re: K092734
Trade/Device Name: E-light Line
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general surgery and plastic surgery and in dermatology
Regulatory Class: Class II
Product Code: GEX, ISA, OPA
Dated: August 30, 2010
Received: September 01, 2010

Dear Mr. Bonapace:

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 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/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
Director
Division of Surgical, Orthopedic
And Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

SEP 2 0 2010

Indications for Use

510(k) Number (if known): **K092734**

Device Name: **E-light Line**

Indications for Use:

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VACUUM Technology is intended to:

- Improve Lymphatic circulation in the treated area

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use ___ ___ (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R. Ogden for mkm

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

510(k) Number K092734