510(k) Summary

EpiCare-DUO™ Laser System

June 1, 2009

NOV - 8 2009

Submittal Information

Post Approval Contact:
Dr. Donald F. Heller
Chief Executive Officer
Betsy Reddington
Director of Regulatory Affairs
Light Age, Inc.
500 Apgar Drive
Somerset, NJ 08873
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Fax: 732-563-1571

Device Name and Classification

510(k) Number:	K091625
Proprietary Name:	Light Age EpiCare-DUO™ Laser System
Common Name:	Alexandrite and Nd:YAG Laser System
Classification Name:	Class IV Laser Surgical Instrument
Classification Panel :	General & Plastic Surgery Devices
C.F.R. Section	878.4810
Device Class:	II
Product Code:	GEX

Predicate Devices:

- Light Age, Inc. EpiCare™ Alexandrite Laser System [K032991],
- Cynosure Apogee Elite [K034030],
- Candela Corp GentleLase Family of Lasers [K063074]

Device Description:

The Light Age EpiCare-DUO™ Laser is a Class IV Laser Surgical Instrument for use in General medical/cosmetic procedures, General and Plastic surgery, Podiatry, and Dermatology. Using alexandrite and neodymium (Nd) YAG crystal rods, pulsed energy is emitted at 755 and 1064 nanometers in the near infrared portion of the spectrum under the guidance of a visible aiming beam. The device consists of the following components and accessories:

1. Laser Source and Onboard Microprocessor Based Control unit
2. Laptop User Interface

3. Flexible Optical Fiber and handpiece delivers energy from the laser to the target area via optical fiber with handpiece, which produces a circular beam on the skin.
4. Foot Pedal Switch activates delivery when lasers are enabled.

Intended Use:

The Light Age EpiCare-Duo™ Laser System delivers variable pulse laser light in the near infrared portion of the spectrum during procedures. The Light Age, Inc. EpiCare-DUO™ Laser System is intended for use in general and plastic surgery, dermatology, and podiatry for the treatment of vascular lesions, benign pigmented lesions, wrinkles, for removal of dark tattoo inks and reduction of hypertrophic and keloid scars and for hair removal, and stable long-term, or permanent hair reduction. Permanent hair reduction is defined as long-term stable reduction in the number of hair regrowth after a treatment regime on all skin types (Fitzpatrick I-VI) including tanned skin. No new indications were sought in this 510(K) and no clinical data is presented.

Performance Standards

- The EpiCare-DUO™ complies with applicable performance standards for light emitting products as outlined in 21 CFR1040.10 and 21 CFR1040.11.
- The device also conforms to the voluntary electrical equipment standards: IEC 60601-1, IEC 60601-1-1, IEC 60601-1-2, and IEC 60601-1-22.

Substantial Equivalence:

The reason for this 510(k) is a design change. Light Age, Inc. is adding a (Nd:YAG) capability to our EpiCare™ alexandrite laser system that has been cleared and in use since 2001.

The candidate device is identical in design and operation to the previously cleared EpiCare™ laser system when operated in the 755 nm wavelength mode. In the 1064 nm mode the candidate device is substantially equivalent in operation and efficacy to the other predicate devices.

Safety and Effectiveness:

The Light Age, Inc. EpiCare-DUO™ Laser System should not raise any concerns regarding its overall safety and effectiveness. In the nearly one decade of use with over 1 million treatments performed the EpiCare™ product family has been proven to be clinically safe with no reports of significant patient or operator injury.

The Light Age, Inc. EpiCare-DUO™ is designed in accordance with both mandatory and voluntary standards ensuring it is both safe and effective for cosmetic/medical procedures indicated above. No new clinical indications are to be provided by the introduction of this device as compared to the predicate devices, identified above, which have previously demonstrated clinical effectiveness..

Indications for Use:

The Light Age, Inc. EpiCare-DUO™ Laser System is intended for use in general and plastic surgery, dermatology, and podiatry for the treatment of vascular lesions, benign pigmented lesions, for removal of dark tattoo inks and reduction of hypertrophic and keloid scars, hair removal, and for stable long-term, or permanent hair reduction. Permanent hair reduction is defined as long-term stable reduction in the number of hair regrowth after a treatment regime on all skin types (Fitzpatrick I-VI including tanned skin.) No new indications were sought in this 510(K) and no clinical data is presented.

Light Age, Inc. is providing more specialized indications, which are a subset of the previously cleared indications. From both a design and clinical perspective, the predicate and candidate laser devices, are of the same technology and have the same intended use. Based upon an analysis of the overall performance characteristics for the devices, Light Age, Inc. believes that no significant differences exist.

755nm – Specifically the 755 nm mode is indicated

- Hair removal, and stable long-term or permanent hair reduction through selective targeting of melanin in hair follicles on all skin types (Fitzpatrick I-VI) including tanned skin. Permanent hair reduction is defined as long-term stable reduction in the number of hair regrowth after a treatment regime. The number of hairs re-growing must be stable over a time greater than the duration of the complete growth cycle of hair follicles, which varies from 4-12 months according to body location. Permanent hair reduction does not necessarily imply the elimination of all hairs in the treated area.
- Treatment of vascular lesions
- Treatment of benign pigmented lesions.
- Treatment of wrinkles.

1064nm –

- Removal of unwanted hair, for stable long term or permanent hair reduction on all skin types Fitzpatrick I-VI including tanned skin.
- Photocoagulation and hemostasis of pigmented and vascular lesions such as but not limited to port wine stains, hemoangioma, warts, telangiectasia, rosacea, venus lake, leg veins, and spider veins and poikiloderma of civatte. Coagulation and hemostasis of soft tissue.
- Benign cutaneous lesions such as warts, scars striac and psoriasis.
- Benign pigmented lesions such as, but not limited to, lentigos (age spots), solar lentigos (sun spots), café au lait macules, seborrheic keratoses,

nevi, chloasma, verrucae, skin tags, keratoses, tattoos (significant reduction in the intensity of black and/or blue-black tattoos) and plaques.

- Pigmented lesion size reduction in patients with lesions who would potentially benefit from aggressive treatment, and for patients with lesions that have not responded to other laser treatments.
- Reduction of red pigmentation in hypertrophic and keloid scars where vascularity is an integral part of the scar.
- Treatment of pseudofolliculitis barbae (PFB).
- Treatment of wrinkles including but not limited periocular wrinkles and perioral wrinkles.

No new indications were sought in this premarket notification and no clinical data is presented.

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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

Light Age, Inc.
% Ms. Elizabeth Reddington
Director of Regulatory Affairs
500 Apgar Drive
Somerset, New Jersey 08873

NOV - 3 2009

Re: K091625
Trade/Device Name: Light Age, EpiCare-Duo™ 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: October 16, 2009
Received: October 19, 2009

Dear Ms. Reddington:

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

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INDICATIONS FOR USE STATEMENT

Device Name: Light Age, Inc EpiCare-DUO™ Laser System

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neil R. O'Leary for mxm
(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use __X____ OR Over the Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-06)

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

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