

JAN 7 1999

K983977

**510(k) Summary of Safety and Effectiveness
Light Age, Inc. EpiCare™ Alexandrite Laser**

In response to the Safe Medical Devices Act of 1990, the following is a summary of the safety and effectiveness information on which the substantial equivalence determination is based.

The safety and effectiveness of the Light Age EpiCare™ Alexandrite Laser is based upon a determination of the substantial equivalence as well as the safety and effectiveness of its predicate device, which is the Sharplan Model 5000 Alexandrite Laser System.

1. Light Age, Inc.
2 Riverview Drive
Somerset, NJ 08873
Susan Laufer, Director of Regulatory Affairs
November 5, 1998
2. **Model:** Light Age EpiCare™ Alexandrite Laser
3. **Predicate Device:** The Sharplan Model 5000 Alexandrite Laser System (K973354, K971874)
4. **Description:** The Light Age EpiCare™ Alexandrite Laser is a medical device capable of emitting an invisible pulsed treatment laser beam with a wavelength of 755 nm under the guidance of a visible aiming beam. This laser can be utilized in either a continuous or timed-exposure mode of operation.
5. The Light Age EpiCare™ Alexandrite Laser is intended for use in dermatology for the removal of dark, unwanted body hair.
6. From both a design and clinical perspective, **the predicate and candidate devices are of identical design and have the same intended use.** Light Age has been supplying Laser Industries, Ltd. with the internal components of the Sharplan Model 5000 Alexandrite Laser System and integrating them into the basic Laser Industries chassis and power supply since the start of the Model 5000 project. Light Age is now taking over the final assembly, sales, and distribution of this laser. **No changes will be made to the product, and Light Age is seeking no new indications in this 510(k) submission.**
A letter of authorization from ESC Medical Systems (the parent company of Laser Industries, Ltd. and Sharplan Lasers, Inc.) is provided in Section A of this document, to permit the FDA to access the data contained in K973354 and K971874 in support of this premarket notification.

As the predicate and candidate devices are identical in design and overall performance characteristics, the Light Age EpiCare™ Alexandrite Laser should not raise any concerns regarding its overall safety or effectiveness.

Advisory: This information was prepared for the sole purpose of compliance with the Safe Medical Devices Act of 1990. It does not imply that the procedures described herein can be performed with the equipment described without substantial risk of personal injury or death to patients due to operator error or in procedures requiring a high degree of skill.



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Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Susan Laufer
Director of Regulatory Affairs
Light Age, Inc.
Two Riverview Drive
Somerset, New Jersey 08873

Re: K983977
Trade Name: Light Age EpiCare™ Alexandrite Laser
Regulatory Class: II
Product Code: GEX
Dated: November 5, 1998
Received: November 9, 1998

Dear Ms. Laufer:

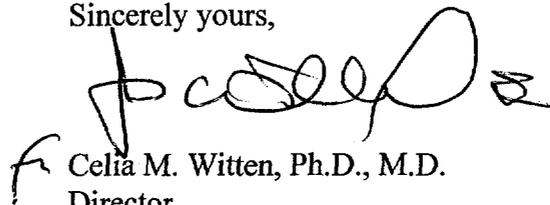
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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). 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 (Pre-market Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,

A handwritten signature in black ink, appearing to read 'Celia M. Witten', with a stylized flourish at the end.

f Celia M. Witten, Ph.D., M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (If known): K983977

Device Name: Light Age EpiCare™ Alexandrite Laser

Indications for Use:

The Light Age EpiCare™ Alexandrite Laser is intended for use in dermatology for the removal of dark, unwanted body hair.

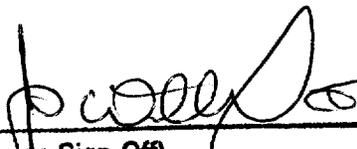
(Please Do Not Write Below This Line – Continue on Another Page If Needed)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use


(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K983977

(Optional Format 1-2-96)