

K9P0131

510(k) Summary

FEB 17 1998

Submitter: Light Age, Inc.
2 Riverview Drive
Somerset, New Jersey 08873

Contact: Rick Frost
Dir. of Sales

Date Summary Prepared: January 13, 1998

Device Trade Name: Alex Ta2 Eraser

Common Name: Medical laser system

Classification Name: Instrument, surgical, powered, laser
79-GEX
21 CFR 878.48

Equivalent Device: Medlite/755 Alexandrite Laser System, Continuum Biomedical
(K935631 and K961006).

Device Description: The Alex Ta2 Eraser is a flashlamp Q-switched solid state laser producing a broadband wavelength of $755 \pm 25\text{nm}$.

Intended Use: Light and dark ink tattoo removal and pigmented lesions removal

Comparison: The Alex Ta2 Eraser is equivalent to the Medlite/755 Alexandrite Laser System (Continuum Biomedical)

Nonclinical Performance Data: None provided at this time.

Clinical Performance Data: None provided at this time.

Conclusion: The Alex Ta2 Eraser is equivalent to the Medlite/755 Alexandrite Laser System (Continuum Biomedical)

Additional Information: None requested at this time.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Rick Frost
Director of Sales
Light Age, Incorporated
Two Riverview Drive
Somerset, New Jersey 08873

FEB 17 1998

Re: K980131
Trade Name: Alex Ta2 Eraser
Regulatory Class: II
Product Code: GEX
Dated: January 13, 1998
Received: January 15, 1998

Dear Mr. Frost:

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.

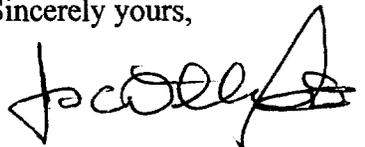
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to-895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirements, 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,



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) Premarket Notification - Original Submission

Alex Ta2 Eraser

Light Age, Inc.

January 13, 1998

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510(k) Number (if known): *pending* *K980131*

Device Name: Alex Ta2 Eraser

Indications for Use: Removal of dark and light ink tattoos and the removal of pigmented lesions.

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

[Signature]
Concurrence of CDH, Office of Device Evaluation (ODE)

(Division Sign Off) _____
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number *K980131*

Prescription Use *X* OR Over-the-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)