DEC 16 1998

K982316

Silver Creek SURGICAL

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510(k) SAFETY AND EFFECTIVENESS SUMMARY

Date:	July 1, 1998
Prepared By:	Loma K. Linville
Classification Name:	Instrument, surgical, powered, laser 79-GEX 21 CFR 878.48, Class II
Proprietary Name:	***LaseAway*** Alexandrite Laser System
Indications:	The ***LaseAway*** Alexandrite Laser is intended for the cosmetic removal of unwanted hair on adults (18 years or older). The ***LaseAway*** Alexandrite Laser System is intended for use only by qualified physicians trained in the safe operation of the system.
Description:	The ***LaseAway*** **Alexandrite Laser System** is a medical device which is capable of emitting an invisible treatment laser beam at a wavelength of 755 nm under the guidance of a visible aiming beam. In addition to the standard pulse width of nominally 1 Msec at 1Hz, the ***LaseAway*** **Alexandrite Laser System** will operate up to 3 Hz. Additionally, a single pulse is modulated to provide 6 x 1 Msec pulses at 1.3 Hz.
Safety Features:	The safety features of the device have been designed in accordance with relevant standards such as BS EN 60825-1 (Safety of Laser Product) and BS EN 6061-2-22 (Medical Electrical Equipment Safety). The labeling complies with 21 CFR subchapter J for a Class IV laser product.
Predicate Devices:	The ***LaseAway*** **Alexandrite Laser System** is substantially equivalent to numerous devices that are currently commercially available. These devices include the Sharplan Epitouch Alexandrite Laser System (K973354 and K971874), Medlite/755 Alexandrite Laser System (K961006), and Candella Q-Switched Alexandrite Lasers (K955662, K940173 and K944090).
Conclusion:	The ***LaseAway*** **Alexandrite Laser System** is safe and effective for the intended purpose of removal of unwanted body hair on adults 18 years of age or older.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 16 1998

Ms. Lorna K. Linville
Quality/Regulatory Specialist
Silver Creek Surgical
1310 Rockbridge Road, Suite E
Stone Mountain, Georgia 30087

Re: K982316
Trade Name: LaseAway Alexandrite Laser System
Regulatory Class: II
Product Code: GEX
Dated: October 1, 1998
Received: October 5, 1998

Dear Ms. Linville:

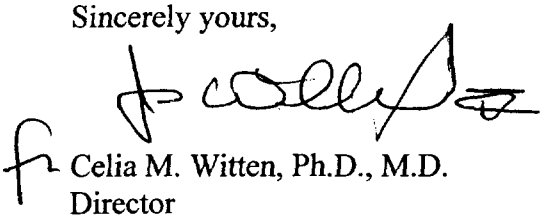
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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 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,



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): K982316

Device Name: ***LaseAway*** Alexandrite Laser System

Indications For Use:

The *LaseAway* Alexandrite Laser is intended for the cosmetic removal of unwanted hair on adults (18 years or older). The *LaseAway* Alexandrite Laser System is intended for use only by qualified physicians trained in the safe operation of the system.

(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 General Restorative Devices
510(k) Number K982316

Prescription Use X OR Over-The-Counter Use_____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)