JUN 7 1999

K 983984

Attachment I
510(K) Summary
COOLTOUCH "V" Nd:YAG Laser System

This 510(K) Summary of safety and effectiveness for the COOLTOUCH "V" Nd:YAG Surgical Laser system is submitted in accordance with the requirements of the SMDA 1990 and following guidance concerning the organization and content of a 510(K) summary.

Applicant:	Laser Aesthetics
Address:	11802 Kemper Road Auburn, CA 95603
Contact Person:	Jonathan M. Baumgardner
Telephone:	(916) 823-1434 Fax (916) 823-1446
Preparation Date:	11-6-98
Device Trade Name:	COOLTOUCH "V" Nd:YAG Surgical Laser
Common Name:	Nd:YAG Pulsed Surgical Laser
Classification Name:	Instrument, Surgical, Powered, laser 79-GEX 21 CFR 878-48
Legally Marketed Predicate Device:	Laser Aesthetics NS 130 "CoolTouch" Nd:YAG Laser System, HGM Veinlase Nd:YAG Laser System, Laserscope Orion Nd:YAG Laser System
Description of the Laser Aethetics COOLTOUCH "V" Nd:YAG Surgical Laser:	The Laser Aesthetics COOLTOUCH "V" Nd:YAG Surgical Laser is an Nd:YAG laser producing laser emission at 1064nm. The laser consists of three interconnected sections: The cabinet which houses the power supply, the cooling system, the microcontroller and the laser, the fiber optics and the handpiece.
Intended use of the Laser Aesthetics COOLTOUCH "V" Nd:YAG Surgical Laser:	The Laser Aesthetics COOLTOUCH "V" Nd:YAG laser is indicated for use in surgical procedures for the coagulation and hemostasis of vascular lesions and soft tissue.
Nonclinical Performance Data:	None
Clinical Performance Data:	None
Conclusion:	The Laser Aesthetics COOLTOUCH "V" Nd:YAG Surgical Laser System is substantially equivalent to other existing surgical laser systems in commercial distribution.
Additional Information:	None requested at this time

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 7 1999

Mr. Jonathan M. Baumgardner
Project Manager
Laser Aesthetics, Inc.
11802 Kemper Road
Auburn, California 95603

Re: K983984
Trade Name: CoolTouch "V" Nd: YAG Laser
Regulatory Class: II
Product Code: GEX
Dated: March 5, 1999
Received: March 9, 1999

Dear Mr. Baumgardner:

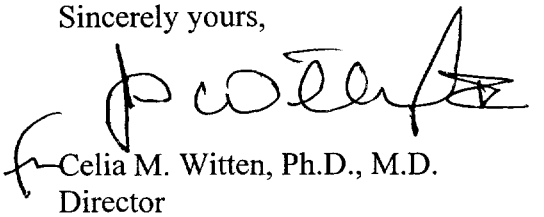
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of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

INDICATION FOR USE STATEMENT

510(k) Number: K 983984

Device Name: Laser Aesthetics Nd:YAG Surgical Laser Model COOLTOUCH "V"

Indications for Use:

The Laser Aesthetics Nd:YAG Surgical Laser Model COOLTOUCH "V" is indicated for the coagulation and hemostasis of vascular lesions and soft tissue.

(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 K983984

Prescription Use X OR Over-the-Counter Use ____
(per 21 CFR 801.109)