MAY 13 1998

K971207

510(k) Summary
ThermoLase SoftLight™ Laser

Submitter:	ThermoLase Corporation 10455 Pacific Center Court San Diego, CA 92121-4339
Trade name:	SoftLight Q-Switched Nd:YAG Laser
Common name:	Q-Switched Nd: YAG Laser
Classification name:	Instrument, Surgical, Laser Powered (Laser Surgical instrument for use in General and Plastic Surgery and Dermatology)
Legally marketed predicate:	ThermoLase SoftLight Q-Switched Nd:YAG Laser. The predicate device is a dermal laser indicated for use in removing or lightening unwanted facial or body hair. The operating wavelength is 1064 nm and is typically operated at a fluence of 2.8 J/cm^2.
Device description:	The SoftLight Q-Switched Nd:YAG Laser Skin Treatment System consists of the laser device and a topical lotion. The topical lotion is massaged into the skin and absorbs energy from the laser. The interaction between the laser and the lotion results in formation and liberation of mechanical and heat energy sufficient to ablate epidermal skin layers.
Indications for Use:	The ThermoLase SoftLight laser is indicated for use in combination with a ThermoLase-supplied topical lotion in removing or lightening unwanted facial or body hair. It is also indicated for use with the same lotion for laser skin resurfacing.
Technological characteristics:	Laser The ThermoLase SoftLight Q-Switched Nd:YAG Laser is designed to deliver a nominal output of 1.0 Joule per pulse at a fixed operating wavelength of 1064 nm in a collimated beam. The pulse repetition rate is 1, 2, 5 or 10 pulses per second

(Hz) and single shot. The Q-Switched output pulses are nominally 6-20 nsec in duration. The output beam is delivered through a 7 mirror articulated arm and beam delivery handpiece which allows an easy access to the treatment site. The collimated laser beam gives a fixed spot size of between 6 and 7 mm at the treatment site. This laser can be set to deliver fluences of between approximately 1 to 3.5 J/cm^2.

The laser energy and repetition rate settings are adjusted and monitored through a microprocessor-controlled key pad on the control panel of the laser. These operating parameters are virtually identical to the operating parameters of the ThermoLase SoftLight Q-Switched Nd:YAG Laser System on which substantial equivalence is based.

Topical Lotion
The accessory topical lotion is a suspension of carbon powder, in a base of Light Mineral Oil, NF.

Performance data

Clinical trials involving human subjects followed for 8 months showed no safety issues. The treatment was shown to remove or ablate skin epidermis in the treatment area.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 13 1998

Mr. Robert van Osdel, R.A.C.
Regulatory Affairs Manager
ThermoLase Corporation
10455 Pacific Center Court
San Diego, California 92121-4339

Re: K971207
Trade Name: SoftLight Q-switched Nd:YAG Laser
Regulatory Class: II
Product Code: GEX
Dated: February 4, 1998
Received: February 12, 1998

Dear Mr. van Osdel:

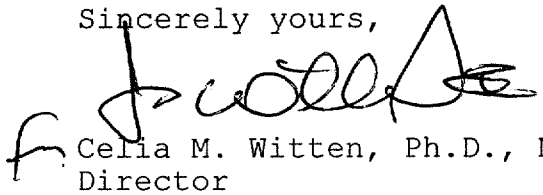
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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): K971207

Device Name: SoftLight Q-switched Nd:YAG Laser

Indications for Use:

The SoftLight Q-switched Nd:YAG laser is indicated for use in combination with the supplied lotion for skin resurfacing. It is also indicated for the removal or lightening of unwanted facial or body hair.

(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 K971207

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____
(Optional Format 1-2-96)