K993209



DEC 23 1999

# 510(k) Summary
# ThermoLase SoftLight™ Laser Tattoo Removal

| | |
|---|---|
| Submitter: | ThermoLase Corporation<br>10455 Pacific Center Court<br>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 (and accessories). |
| Legally marketed predicate: | ThermoLase SoftLight Q-Switched Nd:YAG Laser with optional SofTouch™ Scanner accessory. The predicate device is a dermal laser for use in combination with a ThermoLase supplied topical lotion for removal or lightening of unwanted facial or body hair. It is also indicated for use with the same lotion for laser skin resurfacing. The operating wavelength is 1064nm and is typically operated at a fluence of up to 3.0 J/cm$^2$. |
| Device description: | The SoftLight Q-Switched Nd:YAG Laser Tattoo Removal System consists of the laser device and a beam-shrinking handpiece which is attached to the aperture of the laser.<br><br>The handpiece focuses the beam from the laser. The absorption of energy from the beam by the dyes in the tattoo results in the formation and liberation of mechanical and heat energy sufficient to lighten the pigment of the tattoo. |
| Indications for Use: | The ThermoLase SoftLight Q-Switched Nd:YAG Laser is indicated for use with the beam-shrinking handpiece for the removal or significant reduction in intensity of black and/or blue-black tattoos. The laser, without the beam-shrinking handpiece is also indicated for use in combination with the ThermoLase supplied topical lotion in removing or lightening unwanted facial or body hair and for laser skin resurfacing. |
| Technological characteristics: | Laser<br>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 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 seven mirror articulated arm and beam delivery handpiece which allows 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 keypad 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.

Beam-shrinking Handpiece

The accessory beam-shrinking handpiece reduces the aperture to 5 mm. The 5mm spot size will convert the fluence of a 2.9 J/cm$^2$ setting to 5.68 J/cm$^2$. This is the setting used most frequently for the tattoo removal application.

Performance data:

Clinical trials involving human subjects subjected to two laser treatments, four weeks apart and followed for an additional eight weeks showed no safety issues. The treatments were shown to reduce the intensity of tattoos in the treated areas.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 23 1999

Mr. Gerald Feldman, MPH, MBA
President and Chief Executive Officer
ThermoLase Corporation
6 Westminster Place
Monmouth Junction, New Jersey 08852

Re: K993209
Trade Name: SoftLight Q-Switched Nd:YAG Laser
Regulatory Class: II
Product Code: GEX
Dated: September 17, 1999
Received: September 24, 1999

Dear Mr. Feldman:

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,

for James E. Dillard III
Acting Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K993209

Device Name: ThermoLase SoftLight Q-Switched Nd:YAG Laser
Tattoo Removal System

Indications for Use:

The ThermoLase SoftLight Q-Switched Nd:YAG Laser is indicated for use with the beam-shrinking handpiece for the removal or significant reduction in intensity of black and/or blue-black tattoos. The laser, without the beam-shrinking handpiece is also indicated for use in combination with the ThermoLase supplied topical lotion in removing or lightening unwanted facial or body hair and for laser skin resurfacing.

(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 K993209

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The Counter Use ____