K981351

JUL 13 1998

510(k) Summary

General Information:

This 510(k) is to provide notification of substantial equivalence for the Candela GentleLase GL Laser System, which is substantially equivalent to previously marketed devices intended for the Photocoagulation of Dermatological vascular lesions and for the removal of hair.

Classification:	Class II (21 CFR § 878.4810 Laser Surgical Instrument for use in General and Plastic Surgery and in Dermatology)
Common Name:	Dermatology Laser, Long pulse Alexandrite Laser
Predicate Devices:	Candela GentleLase GL laser cleared under 510(k) 974381, Cynosure Photogenica LP Laser cleared under 510(k) notification numbers K963094 and K971737 and the Sharplan Model 5000 Laser cleared under 510(k) number 971784

Description:

The Candela (Modified) GentleLase GL Laser utilizes an Alexandrite rod (crystal) which emits pulsed energy at 755 nanometers in the near infrared region. Energy from the laser is directed to the targeted area via an optical fiber/handpiece delivery system. The Dynamic Cooling Device functions to cool the skin prior to laser treatment, minimizing thermal damage to skin during laser treatment and reducing pain associated with laser treatment. The Candela GentleLase Lasers are designed with six major components:

1. High voltage power supply and modulator system
2. Optical laser head
3. Circulator system
4. Optical delivery system
5. Software control system
6. Dynamic cooling device

The Candela GentleLase Lasers are equipped with safety interlock systems to protect patients and operators. Users of the device make selections from an onboard control panel to regulate operation during treatment.

The intended use of the laser system is for the Photocoagulation of Dermatological vascular lesions and for hair removal.

Testing:

A clinical trial demonstrated that the GentleLase Laser System removes unwanted hair without raising any unexpected safety issues.

Summary of Substantial Equivalence:

The Candela GentleLase Lasers have the same intended use, utilize the same operating principles and match key design aspects, including similar spotsize, the same wavelength and the same maximum delivered power as the predicate devices.

On the basis of similarities in methods of assembly, method of operation, intended uses, and clinical data Candela believes that its Candela GentleLase Laser System is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 13 1998

Mr. Jay Caplan
Vice President
Candela Laser Corporation
530 Boston Post Road
Wayland, Massachusetts 01778-1886

Re: K981351
Trade Name: Candela GentleLase GL Dermatological Laser
Regulatory Class: II
Product Code: GEX
Dated: April 13, 1998
Received: April 14, 1998

Dear Mr. Caplan:

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

K981351

510(k) Number (if known):

Device Name: Candela (Modified) GentleLase GL Dermatology Laser

Indications For Use:

The Candela GentleLase GL Dermatology Laser is indicated for the following uses:

1. the Photocoagulation of Dermatological vascular lesions.

2. the removal of 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 K981351

Prescription Use ✓ OR Over-The-Counter Use ____
(Per 21 CFR 801.109)

(Optional format 1-2-96)