

FEB 10 1998

K974381

510(k) Summary

General Information:

This 510(k) is to provide notification of substantial equivalence for the Candela (Modified) Gentlelase GL Laser System, which is substantially equivalent to previously marketed devices intended for the photocoagulation of dermatological vascular lesions.

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 Device: Candela Gentlelase GL laser cleared under 510(k) 972767.

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 Candela Gentlelase Lasers are designed with five 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

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.

The Candela (Modified) Gentlelase GL Laser also includes the Candela Dynamic Cooling Device integrated into the laser system. The DCD consists of 1) a source of skin refrigerant fluid, 2) an electronically controlled solenoid delivery valve, and 3) electronic timing circuitry. The Dynamic Cooling Device is connected in line with the laser's triggerswitch system so that activation of the triggerswitch controls the delivery of a pulsed spray of refrigerant, just prior to the delivery of the laser pulse. The pulsed spray of skin refrigerant cools the skin as it evaporates.

The intended use of the Dynamic Cooling Device is to cool the skin prior to laser treatment, to minimize thermal damage to skin during laser treatment and to reduce pain associated with laser treatment.

Testing:

Testing of the GentleLase Laser System, including the Dynamic Cooling Device, consists of component testing and functional testing of the completed Laser.

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 device.

The Dynamic Cooling Device, which is part of the Candela GentleLase Laser System, has the same intended use, utilizes the same operating principles, and has the same technological and performance characteristics as the predicate device, the Candela Dynamic Cooling Device.

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



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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

FEB 10 1998

Re: K974381
Trade Name: Candela (Modified) GentleLase GL Dermatological Laser
Regulatory Class: II
Product Code: GEX
Dated: November 17, 1997
Received: November 20, 1997

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.

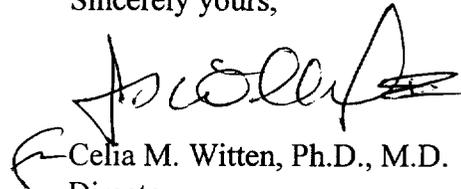
If your device is classified (see above) into either class II (Special Controls) or class III (Pre-market Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirements, 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,

A handwritten signature in black ink, appearing to read "Celia M. Witten", with a stylized flourish at the end.

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): K974381

Device Name: Candela (Modified) GentleLase GL Dermatology Laser

Indications For Use:

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

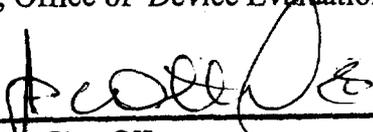
1. the photocoagulation of dermatological vascular lesions.

The Candela GentleLase GL Dermatology Laser includes an integrated Dynamic Cooling Device, which is indicated for:

1. the reduction of pain.
2. cooling of skin prior to laser treatment.

(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 K974381

Prescription Use
(Per 21 CFR 801.109)

OR

Over-The-Counter Use