JAN 24 2000

K993671

510(k) Summary

General Information:
This 510(k) is to provide notification of substantial equivalence for the Candela Sclero Long Pulse Laser System, which is substantially equivalent to previously marketed devices.

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 Dye Laser System
Predicate Devices:	Candela SPTL Long Pulse/Tunable Pulse Dye Laser cleared under 510(k) number K954934, Candela SPTL (K931762), Coherent Argon/Dye Laser (K882160), Cynosure LPIR, Apogee 40 (K971737), Coherent VersaPulse Laser (K972347), Instruments for Medicine and Diagnostics Spectrum VeinLase (K981952), and Altus CoolGlide (K991234)

Description:
The Sclero LP laser is a pulsed, flash lamp excited dye, medical laser, controlled by an embedded processor, to be used for the treatment of telangiectasia, port wine stains, benign cutaneous lesions and other benign cutaneous vascular lesions. The laser system has a Dynamic Cooling Device built into it which provides a short burst of cryogen spray prior to firing the laser pulse. The laser output energy is delivered via an optical fiber to a handpiece on to the skin. The cryogen which is housed within the laser enclosure is delivered via a hose to a nozzle located in the handpiece. 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 Sclero Long Pulse system is comprised of the following components:
1. High voltage power supply (HVPS)
2. Flashlamp laser head
3. Circulatory System
4. Dye fluid system
5. Optical delivery system
6. Software control system
7. Dynamic Cooling Device

The Candela Sclero Long Pulse 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.

Indication for Use:
The Candela Sclero Long Pulse Laser System is indicated for use in photocoagulation of benign cutaneous vascular lesion, benign cutaneous lesion, and benign cutaneous vascular lesion in gynecology.

Testing:
As a laser product, the Sclero Long Pulse is required to conform and does conform to the Laser Performance Standard (21 CFR 1040). In addition the device conforms to the UL 544 electrical safety standard and the Essential Requirements of the European Union Medical Device Directives.

Summary of Substantial Equivalence:
The Candela Sclero Long Pulse Laser has the same intended use, utilizes the same operating principles and match key design aspects, including similar spot size, the same wavelength and / or the same maximum delivered power as the predicate devices.

On the basis of similarities in methods of assembly, method of operation, intended uses Candela believes that its Candela Sclero Long Pulse 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

JAN 24 2000

Ms. Joan Clifford
Clinical Research Manager
Candela Corporation
530 Boston Post Road
Wayland, Massachusetts 01778

Re: K993671
Trade Name: Candela Sclero Long Pulse Laser System
Regulatory Class: II
Product Code: GEX
Dated: October 29, 1999
Received: November 1, 1999

Dear Ms. Clifford:

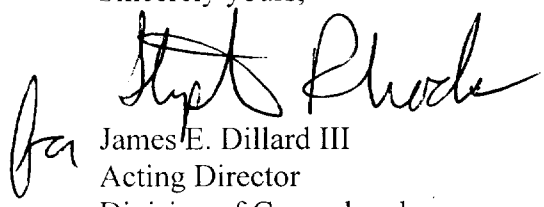
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of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



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): K993671

DEVICE NAME: Candela Sclero Long Pulse

INDICATIONS FOR USE:

The Candela Sclero Long Pulse Laser is indicated for the following uses:

General Surgery: Photocoagulation of benign cutaneous vascular lesion and benign cutaneous lesions.

Dermatology/Plastic Surgery: For treatment of benign cutaneous vascular lesion, such as facial and leg telangiectasia, rosacea, port wine stains, hemangiomas, angioma, spider angioma, poikiloderma of Civatte and benign cutaneous lesion, such as warts, scars, striae.

Gynecology: Photocoagulation of benign cutaneous lesion and benign vascular lesion in gynecology

Podiatry: Treatment of benign cutaneous lesion, such as warts.

The Candela Sclero Long Pulse Laser includes an integrated Dynamic Cooling Device, which is indicated for:

1. the reduction in pain.
2. cooling of the 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)

Prescription Use X OR Over-The-Counter-Use
(Per 21 CFR 801.109) (Optional Format 1-2-96)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K993671