JUN 13 2005

510(k) Summary

General Information:

This 510(k) is to provide notification of substantial equivalence for the Candela Family of Pulsed Dye Lasers which is substantially equivalent to previously marketed devices indicted for the following uses:
General Surgery: Photocoagulation of benign cutaneous vascular lesions and benign cutaneous lesions.
Dermatology/Plastic Surgery: For treatment of benign cutaneous vascular lesions, such as facial and leg telangiectasia, rosacea, port wine stains, hemangiomas, angioma, spider angioma, Poikiloderma of Civatte, and benign cutaneous lesions, such as warts, scars, striae and psoriasis and the treatment of wrinkles. Treatment of Benign Epidermal Pigmented Lesions. Treatment of Inflammatory Acne Vulgaris
Gynecology: Photocoagulation of benign cutaneous lesions and benign vascular lesions in gynecology.
Podiatry: Treatment of benign cutaneous lesions, such as warts.

Submitted by:	Candela Corporation 530 Boston Post Road Wayland, MA 01778-1886
Contact Person:	Lorraine Calzetta
Date prepared:	March 11, 2005
Classification:	Class II (21 CFR § 878.4810 Laser Surgical Instrument for use in General and Plastic Surgery and in Dermatology)
Common Name:	Dermatology Laser, Candela Family of Pulse Dye Laser Systems
	Predicate Devices:
	Candela Family of Pulsed Dye Lasers - K043251 Cynosure VStar (Tristar PDL) - K033176, K032565

Description:

The Candela Family of Pulsed Dye Laser Systems are 585, 595nm flash-lamp excited pulse dye medical lasers, indicated for the following uses:

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

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Summary cont.

Dermatology/Plastic Surgery: For treatment of benign cutaneous vascular lesions, such as facial and leg telangiectasia, rosacea, port wine stains, hemangiomas, angioma, spider angioma, Poikiloderma of Civatte, and benign cutaneous lesions, such as warts, scars, striae and psoriasis and the treatment of wrinkles. Treatment of Benign Epidermal Pigmented lesions. Treatment of Inflammatory Acne Vulgaris
Gynecology: Photocoagulation of benign cutaneous lesions and benign vascular lesions in gynecology.
Podiatry: Treatment of benign cutaneous lesions, such as warts.

The laser output energy is delivered via an optical fiber to a handpiece, which produces circular beams with diameters of 3 5, 7 or 10, 12 or 3x10 millimeters on the skin..

The Candela Family of Pulsed Dye Laser Systems is 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.

Testing:

As a laser product, the Candela Family of Pulsed Dye Laser Systems conforms to the CDRH Laser Performance Standard (21 CFR 1040). In addition the laser conforms to UL/IEC 60601-1. Electrical Safety Standard.

Summary of Substantial Equivalence:

The Candela Family of Pulsed Dye Laser Systems, has the same intended use, utilizes similar operating principles and matches key design aspects, as the predicate devices.

On the basis of similarities in methods of assembly, method of operation, and intended uses, Candela Corporation believes that its Candela Family of Pulsed Dye Laser Systems 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

JUN 13 2005

Ms. Lorraine Calzetta
Manager, Regulatory Affairs
Candela Corporation
530 Boston Post Road
Wayland, Massachusetts 01778

Re: K050673
Trade/Device Name: Candela Family of Pulsed Dye Laser Systems
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: II
Product Code: GEX
Dated: March 11, 2005
Received: March 15, 2005

Dear Ms. Calzetta:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate 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) that do not require approval of a premarket approval application (PMA). 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 (PMA), 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 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 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), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Miriam C. Provost, Ph.D.
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K050673

Device Name: Candela Family of Pulsed Dye Laser Systems

Indications For Use:

The Candela Family of Pulse Dye Laser Systems is indicated for the following uses :

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

Dermatology/Plastic Surgery: For treatment of benign cutaneous vascular lesions, such as facial and leg telangiectasia, rosacea, port wine stains, hemangiomas, angioma, spider angioma, Poikiloderma of Civatte, and benign cutaneous lesions, such as warts, scars, striae and psoriasis and the treatment of wrinkles. Treatment of Benign Epidermal Pigmented Lesions.

Treatment of Inflammatory Acne Vulgaris

Gynecology: Photocoagulation of benign cutaneous lesions and benign vascular lesions in gynecology.

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

Prescription Use _X_____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(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
and Neurological Devices
510(k) Number K050673

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