OCT 11 2001

K 013043

510(k) Summary

General Information:

This 510(k) is to provide notification of substantial equivalence for the Candela Clearbeam Pulse Dye Laser System, which is substantially equivalent to previously marketed devices intended for photocoagulation of benign cutaneous vascular lesion, such as facial and leg telangiectasia, rosacea, port wine stains, hemangiomas, angioma, spider angioma, poikiloderma of Civatee and benign cutaneous lesion, such as warts, scars, striea and psoriasis. Photocoagulation of benign cutaneous lesion and benign vascular lesion in gynecology. Treatment of wrinkles.

Submitted by:	Candela Corporation 530 Boston Post Road Wayland, MA 01778-1886
Contact Person:	Joan M. Clifford
Date prepared:	August 3, 2001
Classification:	Class II (21 CFR § 878.4810 Laser Surgical Instrument for use in General and Plastic Surgery and in Dermatology)
Common Name:	Dermatology Laser, Clearbeam Pulse Dye Laser System
Predicate Devices:	Candela SPTL-1e Pulse Dye Laser (K011092), SLS Biophile Ltd NLite (K000811)

Description:
The Clearbeam Pulse Dye laser is a 585 nm pulsed, flash lamp excited dye, medical laser, controlled by an embedded microprocessor, to be used for the treatment of psoriasis, telangiectasia, port wine stains, benign cutaneous lesions and other dermatologic applications. The laser system may be used with the Candela Dynamic Cooling Device, 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, which produces circular beams with diameters of 5, 7 or 10 millimeters on the skin. The cryogen, which is housed within the laser enclosure, is delivered via a hose to a nozzle located in the handpiece.

The Candela Clearbeam Pulse Dye 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.

Testing:
As a laser product, the Clearbeam Pulse Dye Laser is required to conform and will conform to the Laser Performance Standard (21 CFR 1040). In addition the device will conform to the UL 2601 Electrical Safety Standard and with the Harmonized Standard EN 60601-1-2, Part 2 established by and required by the European Community.
Summary of Substantial Equivalence:

Summary of Substantial Equivalence:
The Candela Clearbeam Laser has the same intended use, utilizes similar operating principles and matches 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, and intended uses, Candela believes that its Candela Clearbeam 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

OCT 1 1 2001

Candella Corporation
c/o Mr. Donald J. Sherratt
Medical Stream Director
Intertek Testing Services
70 Codman Hill Road
Boxborough, Massachusetts 01779

Re: K013043
Trade/Device Name: Candela Clearbeam Pulse Dye Laser System
Regulation Number: 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: II
Product Code: GEX
Dated: September 27, 2001
Received: September 28, 2001

Dear Mr. Sherratt :

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 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. 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" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained 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/dsma/dsmamain.html

Sincerely yours,

Susan Walter, MD

for

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

CANDELA

510(k) Number (if known): K013043

Device Name: Candela Clearbeam Pulse Dye Laser System

Indications For Use:

The Candela Clearbeam Pulse Dye Laser is indicated for the following uses in:

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, striea and psoriasis. Treatment of periocular wrinkles.

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

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

(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 K013043

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

(Optional format 1-2-96)