K041242

NOV 2 2 2004

General Information:

This 510(k) is to provide notification of substantial equivalence for the Candela Smoothbeam Laser System, which is substantially equivalent to a previously marketed device and intended for use in the treatment of facial acne

Submitted by:	Candela Corporation 530 Boston Post Road Wayland, MA 01778-1886
Contact Person:	Lorraine Calzetta Patrovic
Date prepared:	April 23, 2004
Classification:	Class II (21 CFR § 878.4810 Laser Surgical Instrument for use in General and Plastic Surgery and in Dermatology)
Common Name:	Dermatology Laser, Smoothbeam Laser System
Predicate Devices:	Candela Smoothbeam 1450 nm Diode Laser System (K013825 ,K030834)

Description:

The Diode laser is a Continuous Wave, diode medical laser, controlled by an embedded processor, to be used for use in dermatology for the treatment of wrinkles. The Candela Smoothbeam Laser System is comprised of a power supply, optical delivery system, software control system and Dynamic Cooling Device. The laser output energy is delivered via an optical fiber to a handpiece, which produces circular beams on the skin. The Dynamic Cooling Device, provides a short burst of cryogen spray during the laser treatment. The cryogen is delivered via a hose to a nozzle located in the handpiece. The Dynamic Cooling Device functions to cool the skin during the laser treatment minimizing thermal damage to skin during laser treatment and reducing pain associated with laser treatment.

The Candela Smoothbeam Laser System is equipped with safety interlock systems to protect patients and operators. Users of the device, make selections from a control panel to regulate operation during the laser treatment.

Testing:

As a laser product, the Smoothbeam Laser System is required to conform and does 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 the European Community.

Safety and Effectiveness Information:

The modality of action for the treatment of sebaceous hyperplasia is similar to that of previously cleared indications in the treatment of back acne and the treatment of inflammatory acne vulgaris. Published clinical data, using t he predicate Smoothbeam Laser, cleared for use in the market, produced results that demonstrate that the Smoothbeam Laser is safe and effective for the expanded indication,- the treatment of sebaceous hyperplasia

Summary of Substantial Equivalence:

The Candela Smoothbeam Laser System described in this submission is identical to the currently marketed Candela Smoothbeam Laser System based on operating principles, materials, mechanism of action, design, construction and intended use. Candela believes that the Smoothbeam Laser is substantially equivalent to the predicate device.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 2 2 2004

Ms. Lorraine Calzetta Patrovic
Manager, Regulatory Affairs
Candela Corporation
530 Boston Port Road
Wayland, Massachusetts 01778-1886

Re: K041242
Trade/Device Name: Candela Smoothbeam Laser System
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: August 24, 2004
Received: August 26, 2004

Dear Ms. Patrovic:

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/dsma/dsmamain.html

Sincerely yours,

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

Indications for Use

510(k) Number (if known): K041242

Device Name: ***Candela Smoothbeam Laser (aka Candela MID IR Laser)***

Indications For Use:

The Candela Smoothbeam Laser is indicated for the following uses :

For use in dermatology: incision, excision, ablation, and vaporization with hemostasis of soft tissue,

Treatment of back acne

Treatment of atrophic acne scars

Treatment of facial wrinkles

Treatment of mild to moderate acne vulgaris

New indication : Treatment of Sebaceous Hyperplasia

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)

Mark N. Melkerson

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K041242

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