CANDELA

K 063800

510(k) Summary

This 510(k) summary of safety and effectiveness information is submitted in accordance with the requirements of the Safe Medical Devices Act (SMDA) of 1990. The contents of the 510(k) summary have been provided in conformance with 21 CFR §807.92.

Submitter Information

FEB 05 2007

Company Name:	Candela Corporation
Company Address:	530 Boston Post Road Wayland, MA 01778
Company Phone:	508-358-7400
Company Facsimile:	508-358-5602
Contact Person:	Mr. Jeffrey Roberts Manager, Regulatory Affairs
Date summary Prepared:	12/14/06

Device Identification

Device Trade/Proprietary Name: Candela Fluorescent Pulsed Light System

Common Name:	Fluorescent Pulsed Light System
Classification Name:	Laser Surgical Instrument, for use in General and Plastic Surgery and Dermatology
Classification Regulation:	21 CFR § 878.4810
Device Classification:	II

Identification of Predicate Device

Predicate Device(s): Luxsano AB OmniLight Fluorescent Pulsed Light System, K032191
Palomar Medical Technologies, Inc. StarLux Pulsed Light System, K041086

Device Description

The Candela Fluorescent Pulsed Light System is designed for selective photothermolysis in aesthetic treatments. The technology is based on a unique combination of patented fluorescent filter technology, selected spectrums of light source emission; pulse forming and sapphire based skin cooling system. It operates through creation of a directed incoherent light beam of spectrally balanced light. The light is spectrally filtered to remove the shorter wavelength portions (UV) most likely to cause harm to the skin. A sapphire crystal light guide is used to transport the resultant longer wavelength light to a laser-dye impregnated polymer filter sheet, which absorbs the part of the lamp light spectrum below it's emission and emits the selected wavelength band (417- 1200 nm) to 615 – 1200 nm, and non fluorescent 650 nm – 1200 nm and 850 – 1200 nm..

A liquid-to-air cooling system, including a fluid pump, fluid reservoir, deionization filter, interlocks and forced convection liquid-to-air heat exchanger and a water to water ThermoElectrical cooler is used to maintain the hand piece components at the proper temperature. The electronic components of the system include multiple safety features to protect both the user and patient, and the pulsed-light system itself.

A microprocessor based system controller is used to monitor and direct all system functions. Users of the Candela Fluorescent Pulsed Light System select parameters such as desired energy density (fluence) level and filter wavelength and monitor operation via electronic controls and a display panel. The control panel is also used to enable or disable the triggering of the Candela Fluorescent Pulsed Light System, and to obtain feedback from the system, such as the number of pulses delivered or spot size selected. The Candela Fluorescent Pulsed Light System supports 40mm x 20mm, 20mm x 20mm, 10mm x 20mm, 7mm x 15mm, 7mm x 7mm.

Description of Intended Use

The Candela Fluorescent Pulsed Light System is indicated for treatment in the following uses:

Hair removal in all skin types according to the Fitzpatrick scale. Permanent Hair Reduction
Treatment of Vascular Lesions
Treatment of Inflammatory Acne (acne vulgaris)
Treatment of Benign Pigmented Epidermal and Cutaneous Lesions including warts, scars and striae.

Rationale for Substantial Equivalence

The Candela Fluorescent Pulsed Light System, has the same intended use and utilizes similar functional features (including power output, spot size, repetition rate, energy, and fluence) and matches key design aspects (including wavelength, light generation medium, power supply, cooling and controls system) as the currently legally marketed predicate devices.

The Candela Fluorescent Pulsed Light System shares similar methods of operation, and intended uses, and therefore is substantially equivalent to the currently legally marketed OmniLight Fluorescent Pulsed Light System K032191 held by Luxsano AB and the StarLux Pulsed Light System K041086 held by Palomar Medical Technologies predicate devices.

Safety and Effectiveness Information

The Candela Fluorescent Pulsed Light System is substantial equivalent to the currently legally marketed Luxsano AB OmniLight Fluorescent Pulsed Light System, K032191 and the Palomar Medical Technologies, Inc. StarLux Pulsed Light System, K041086 predicate devices in intended use and technological features and therefore the risks and benefits are comparable to the predicate devices.

We therefore believe that there are no new questions of safety or effectiveness raised by the introduction of the Candela Fluorescent Pulsed Light System.

Conclusion

Base on the similarities in indications for use, design features, and functional features the Candela Fluorescent Pulsed Light System has been shown to be substantially equivalent to the current legally marketed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Candela Corporation
% Mr. Jeffrey Roberts
Manager, Regulatory Affairs
530 Boston Post Road
Wayland, Massachusetts 01778

FEB 5 2007

Re: K063800
Trade/Device Name: Candela Fluorescent Pulsed Light 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: December 21, 2006
Received: December 22, 2006

Dear Mr. Roberts:

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.

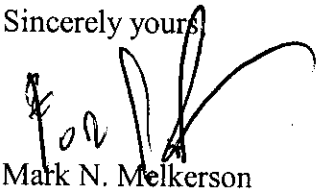
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Mark N. Melkerson
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): ~~K063072~~ K063810

Device Name: Candela Fluorescent Pulsed Light System

Indications for Use:

The Candela Fluorescent Pulsed Light System is indicated for the following uses:

Hair removal in all skin types to the Fitzpatrick scale. Permanent Hair Reduction.

Treatment of Vascular Lesions

Treatment of Inflammatory Acne (acne vulgaris)

Treatment of Benign Pigmented Epidermal and Cutaneous Lesions including warts, scars and striae.

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

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number K063810