K 111144

E. GentleLASE Family of Laser Systems 510k Summary

JUL 18 2011

General Information:

This 510(k) is to provide notification of substantial equivalence for the Candela GentleLASE Family of Laser Systems, which is substantially equivalent to previously marketed devices intended for photocoagulation of dermatological vascular lesions.

Submitted by:	Candela Corporation 530 Boston Post Road Wayland, MA 01778-1886
Contact Person:	Scott Blood, VP of Quality and Regulatory Affairs
Date prepared:	April 5, 2011
Classification:	Class II GEX Product Code (21 CFR § 878.4810 Laser Surgical Instrument for use in General and Plastic Surgery and in Dermatology)
Common Name:	Dermatology Laser, GentleLASE Family of Laser Systems
Predicate Devices:	GentleLASE Family of Laser Systems (K024371, K024335, K024260) Candela GentleLASE GL and previous Candela GentleLASE models (K994260, K981351, K974381, K972767)

Description:

The Candela GentleLASE Family of Lasers utilizes an Alexandrite rod (crystal) which emits pulsed energy at 755 nanometers in the near infrared region. Energy from the laser is directed to the target area via optical fiber handpiece delivery system. The Dynamic Cooling Device 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 6, 8, 10, 12, 15, 18 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 GentleLASE Family of Laser Systems are designed with six major components:

1. High voltage power supply and modulator system
2. Optical laser head
3. Circulator system
4. Optical delivery system
5. Software control system
6. Dynamic cooling device

The Candela GentleLASE Family of Laser Systems 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 laser products, the GentleLASE Family of Laser Systems conform to the Laser Performance Standard (21 CFR 1040). In addition, the GentleLASE Family of Laser Systems conform to IEC (EN) 60601-1 Medical Electrical Equipment- Gen'l Requirements for Safety, IEC 60601-1-2 Medical Electrcal Equipment- Electromagnetic Compatibility, IEC 60601-1-4 Medical Electrical Equipment- Programmable Electrical Medical Systems, and IEC 60601-2-22 Medical Electrical Equipment- Safety of Diagnostic and Therapeutic Laser Equip.

Summary of Substantial Equivalence;

The Candela GentleLASE Family of Laser Systems have the same intended uses, utilizes similar operating principles and matches key design aspects, including similar spot size, the same wavelength and the same maximum delivered fluence as the predicate devices.
On the basis of similarities in methods of assembly, method of operation, and intended uses, Candela Corporation believes that the Candela GentleLASE Family of Laser Systems are substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

JUL 18 2011

Candela Corporation
% Mr. Scott Blood
530 Boston Post Road
Wayland, Massachusetts 01778-1886

Re: K111144
Trade/Device Name: GentleLASE Family of 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: Class II
Product Code: GEX
Dated: April 12, 2011
Received: April 22, 2011

Dear Mr. Blood:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Mark N. Melkerson
Director
Division of Surgical, Orthopedic
And Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K111144

Device Name: **GentleLASE Family of Laser Systems**

Indications for Use:

The photocoagulation of dermatological vascular lesions (such as port-wine stains, hemangiomas, telangiectasias).

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 IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K111144

Modified 7/15/2011 Candela