OCT - 5 2011

K112715

E. GentleMAX Family of Laser Systems 510k Summary

General Information:

This 510(k) is to provide notification of substantial equivalence for the Candela GentleMAX Family of Laser Systems using 755 nm Alexandrite laser, which is substantially equivalent to previously marketed devices intended for the photocoagulation of dermatological vascular lesions (such as port-wine stains, hemangiomas, telangiectasias).

Submitted by:	Candela Corporation 530 Boston Post Road Wayland, MA 01778-1886
Contact Person:	Sam Wade, VP of Quality and Regulatory Affairs
Date prepared:	August 1, 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, GentleMAX Family of Laser Systems
Predicate Devices:	GentleLASE Family of Laser Systems (K111144) Candela 3630 Laser System (now named Candela GentleMAX Laser System) (K063074)

Description:

The Candela GentleMAX Family of Lasers contains two separate laser heads (Alexandrite and Nd:YAG), which produce laser light outputs of 755 nm and 1064 nm, respectively. The output of each laser head is optically combined on the laser rail so that their beam paths are identical as they exit the laser system. This allows the use of a single delivery system which can output either 755 nm or 1064 nm wavelengths.

Each laser head contains the appropriate solid state laser rod and high intensity xenon flashlamps to excite the laser medium. The laser heads are water cooled with a self contained circulating water system that includes a water to air heat exchanger so the system can be fully air-cooled. The temperature of the laser heads are regulated by the circulation of distilled water at a controlled temperature.

A high voltage power supply is used to charge a storage capacitor which provides energy to the flashlamps. An IGBT (high voltage switch) is used to discharge the capacitor through the flashlamp. Each laser head has its own dedicated IGBT switch which is how the system controls which wavelength is produced. The resulting flash of the flashlamp excites the laser rod which causes emission of a pulse of laser energy.

The Candela GentleMAX Laser System delivers laser energy with various pulse durations from 0.25 milliseconds to 300 milliseconds. The output of this laser is delivered to the area of treatment by means of a lens coupled user replaceable optical fiber with a treatment handpiece attached to its

distal end. A trigger switch (fingerswitch or footswitch) is used to control the delivery of laser pulses. The user may choose to deliver a single pulse each time the trigger switch is depressed, or pulses may be delivered repetitively as long as the switch is depressed, at repetition rates up to 10 pulses per second (depending on the chosen pulse duration).
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 1.5, 3, 6, 8, 10, 12, 15 and 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.
A microprocessor based system controller is used to monitor and direct all system functions. Operators of the laser select parameters such as desired energy density (fluence) level and repetition rate and monitor operation via a touch screen and display panel. The touch screen panel can also be used to enable or disable the triggering of the laser, to initiate the calibration feature and to obtain feedback from the system, such as the number of pulses delivered or spot size selected.
The GentleMAX 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 GentleMAX Family of Laser Systems are equipped with safety interlock systems to protect patients and operators.

Testing:

As laser products, the GentleMAX Family of Laser Systems conform to the Laser Performance Standard (21 CFR 1040). In addition, the GentleMAX 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, IEC 60825-1, and IEC 60601-2-22 Medical Electrical Equipment- Safety of Diagnostic and Therapeutic Laser Equip.

Summary of Substantial Equivalence;

The Candela GentleMAX Family of Laser Systems have the same intended uses, utilizes similar operating principles and matches key design aspects, including similar spot size, the same wavelengths 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 GentleMAX 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 -W066-G609
Silver Spring, MD 20993-0002

Candela Corporation
% Mr. Sam Wade
VP of Quality and Regulatory Affairs
530 Boston Post Road
Wayland, Massachusetts 01778-1886

OCT - 5 2011

Re: K112715
Trade/Device Name: GentleMAX 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: September 16, 2011
Received: September 20, 2011

Dear Mr. Wade:

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,

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): K112715

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

Indications for Use:

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

510(k) Number K112715

755nm

The GentleMAX Family of Laser Systems is indicated for temporary hair reduction. Stable long-term or permanent reduction through selective targeting of melanin in hair follicles. Permanent hair reduction is defined as long-term stable reduction in the number of hairs regrowing after a treatment regime. On all skin types (Fitzpatrick I-VI) including tanned skin.

Treatment of benign pigmented lesions.

Treatment of wrinkles.

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

1064nm

The GentleMAX Family of Laser Systems is indicated for the removal of unwanted hair, for stable long term or permanent hair reduction and for treatment of PFB. The lasers are indicated on all skin types Fitzpatrick I-VI including tanned skin. Photocoagulation and hemostasis of pigmented and vascular lesions such as but not limited to port wine stains, hemangioma, warts, telangiectasia, rosacea, venus lake, leg veins and spider veins. Coagulation and hemostasis of soft tissue. Benign pigmented lesions such as, but not limited to, lentigos (age spots), solar lentigos (sun spots), cafe au lait macules, seborrheic keratoses, nevi, chloasma, verrucae, skin tags, keratoses, tattoos (significant reduction in the intensity of black and/or blue-black tattoos) and plaques.

The laser is indicated for pigmented lesions to reduce lesion size, for patients with lesions that would potentially benefit from aggressive treatment, and for patients with lesions that have not responded to other laser treatments.
The laser is also indicated for the reduction of red pigmentation in hypertrophic and keloid scars where vascularity is an integral part of the scar.
Treatment of wrinkles.

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)

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

December 26, 2013

Candela Corporation
Mr. Sam Wade
Global Vice President, Regulatory Affairs
530 Boston Post Road
Wayland, Massachusetts 01778

Re: K133283
Trade/Device Name: Gentlemax 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: II
Product Code: GEX
Dated: December 6, 2013
Received: December 9, 2013

Dear Mr. Wade:

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.

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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 contact 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. 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.

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Sincerely yours,

David Krause -S

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section 6 – Indications for Use Statement

Indications for Use Statement

510(k) Number (if known): _____

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

Indications for Use:

755nm

The GentleMAX Family of Laser Systems is indicated for temporary hair reduction. Stable long-term or permanent reduction through selective targeting of melanin in hair follicles. Permanent hair reduction is defined as long-term stable reduction in the number of hairs regrowing after a treatment regime. Permanent hair reduction is defined as the long-term, stable reduction in the number of hairs regrowing when measured at 6, 9, and 12 months after the completion of a treatment regime. On all skin types (Fitzpatrick I- VI) including tanned skin.
Treatment of benign pigmented lesions.
Treatment of wrinkles.
The photocoagulation of dermatological vascular lesions (such as port-wine stains, hemangiomas, telangiectasias)

1064nm

The GentleMAX Family of Laser Systems is indicated for the removal of unwanted hair, for stable long term or permanent hair reduction and for treatment of PFB. Permanent hair reduction is defined as the long-term, stable reduction in the number of hairs regrowing when measured at 6, 9, and 12 months after the completion of a treatment regime. The lasers are indicated on all skin types Fitzpatrick I-VI including tanned skin. Photocoagulation and hemostasis of pigmented and vascular lesions such as but not limited to port wine stains, hemangioma, warts, telangiectasia, rosacea, venus lake, leg veins and spider veins. Coagulation and hemostasis of soft tissue. Benign pigmented lesions such as, but not limited to, lentigos (age spots), solar lentigos (sun spots), café au lait macules, seborrheic keratosis, nevi, chloasma, verrucae, skin tags, keratosis, tattoos (significant reduction in the intensity of black and/or blue-black tattoos) and plaques.
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Treatment of wrinkles.

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

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Jitendra V. Virani -S
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(Divison Sign-Off)
Division of Surgical Devices
510(k) Number K133283