K133283

DEC 2 6 2013

Section 7 – 510(k) Summary

510(k) Summary
GentleMAX Family of Laser Systems

General Information:
This Special 510(k) is to provide notification of substantial equivalence for the modified GentleMAX Family of Laser Systems (GentleMax Pro Laser System) to the previously cleared GentleMAX Family of Laser Systems manufactured by Candela Corporation.

Submitted by:	Candela Corporation 530 Boston Post Road Wayland, MA 01778-1886
Contact Person:	Sam Wade, Global Vice President, Regulatory Affairs Tel: 508-358-7400 x330 Fax: 508-358-5602
Date prepared:	October 23, 2013
Trade Name:	GentleMAX Family of Laser Systems
Common Name:	Dermatology Laser System
Classification Name:	Laser surgical instrument for use in general and plastic surgery and in dermatology (21 CFR 878.4810, Product Code GEX)
Predicate Devices:	GentleMAX Family of Laser Systems (K112715)

Intended Use / Indications for Use:
The GentleMAX Family of Laser Systems is indicated for the following:

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. 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.

Treatment of benign pigmented lesions.

Treatment of wrinkles.

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

Section 7 – 510(k) Summary

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.

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.

Description:

The Candela GentleMAX Family of Laser Systems 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. The laser system creates a beam of high intensity light that penetrates deep into the skin tissue where it delivers a controlled amount of therapeutic heat. The Dynamic Cooling Device (DCD) protects the upper layers of the skin with a cooling burst of cryogen.

Technological Characteristics:

The Candela GentleMAX Family of Laser Systems delivers laser energy through an optical fiber handpiece delivery system, which can output either 755 nm or 1064 nm wavelengths. 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 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.

Section 7 – 510(k) Summary

Product	Modified GentleMAX Family of Laser Systems (GentleMax Pro Laser System)	GentleMAX Family of Laser Systems
510(k)	KXXXXXX	K112715
Manufacturer	Candela Corporation	Candela Corporation
Product Code	GEX	GEX
Regulation Number	21 CFR 878.4810	21 CFR 878.4810
Device Class	II	II
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. On all skin types (Fitzpatrick I- VI) including tanned skin. 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. 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	**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. 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. 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

Section 7 – 510(k) Summary

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Laser type	Flashlamp-excited, Solid state Alexandrite and Nd:YAG laser	Flashlamp-excited, Solid state Alexandrite and Nd:YAG laser
Wavelength	755nm/1064nm	755nm/1064nm
Pulse duration	0.25 – 100 ms	0.25 – 300 ms
Maximum fluence	53 J/cm^2 (ALEX) 80 J/cm^2 (YAG)	53 J/cm^2 (ALEX) 80 J/cm^2 (YAG)
Spot size	1.5, 3, 6, 8, 10, 12, 15, 18mm	1.5, 3, 6, 8, 10, 12, 15, 18mm
Pulse repetition rate	10 Hz, maximum	10 Hz, maximum
Pulsing control	Fingerswitch or footswitch	Fingerswitch or footswitch
Product dimensions	42" x 18" x 27"	45" x 26.5" x 38"

Section 7 – 510(k) Summary

(HxWxL)		
Product Weight	260 lbs	341 lbs

Performance Data:
Minor software and hardware modifications were made to support the changes for the modified GentleMAX Family of Laser Systems (GentleMax Pro Laser System). The testing performed to evaluate these modifications included electromagnetic compatibility (EMC), electrical safety, and software verification and validation. All performance testing demonstrated that the GentleMax Pro Laser System performs according to specifications and functions as intended.

Clinical Data:
No clinical data was required for these modifications.

Summary of Substantial Equivalence:
The modifications made to the GentleMAX Family of Laser Systems do not affect the indications for use or alter the fundamental scientific technology of the device, nor does it affect the mode of use. There are no labeling changes that affect the indications for use of the device. The modifications made to the GentleMAX Family of Laser Systems raises no new issues of safety or effectiveness. The modified 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 wavelength and the same maximum delivered fluence as the predicate devices. The non-clinical tests that were performed determined that our device is as safe, as effective, and performs as well as the predicate device. On the basis of similarities in methods of assembly, method of operation, and intended uses, as confirmed by the performance testing, Candela Corporation believes that the modified GentleMAX Family of Laser Systems is substantially equivalent to the predicate device.

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.

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 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.

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,

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

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

1064nm

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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 OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

GentleMAX Family of Laser Systems

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