



Food and Drug Administration
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November 7, 2014

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

Re: K140732
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: October 9, 2014
Received: October 10, 2014

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 Industry and Consumer Education 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 Industry and Consumer Education 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.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section 6 – Indications for Use Statement

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration
Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number (if known)

K140732

Device Name

GentleLASE Family of Laser Systems

Indications for Use (Describe)

The GentleLASE 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)

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D) Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary
GentleLASE Family of Laser Systems

General Information:

This Special 510(k) is to provide notification of a software change made for the modified GentleLASE Family of Laser Systems (GentleLase Pro and GentleLase Pro LE Laser Systems) to the previously cleared GentleMAX Family of Laser Systems (K133283) manufactured by Candela Corporation.

Submitted by: Candela Corporation
530 Boston Post Road
Wayland, MA 01778-1886

Contact Person: Sam Wade,
Vice President, Regulatory Affairs and Quality Assurance
Tel: 508-358-7400 x330
Fax: 508-358-5602

Date prepared: March 14, 2014

Trade Name: GentleLASE 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 (K133283)

Intended Use / Indications for Use:

The GentleLASE Family of Laser Systems is indicated for the following:

The GentleLASE 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).

Description:

The Candela GentleLASE Family of Laser Systems contains an alexandrite laser head, which produces laser energy emitted at nominal wavelength of 755 nm. The output of the energy is then delivered to the skin through an optical fiber delivery system which also cools the surface of the skin through either air or cryogen cooling. 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. The GentleLase Pro and GentleLase Pro LE laser systems both have the same technological and performance specifications, the same indications for use, the same principles of operation, and the same energy type. The only difference between these two systems is the color of the side panels.

Technological Characteristics:

Product	Modified GentleLASE Family of Laser Systems (GentleLase Pro and GentleLase Pro LE Laser Systems)	GentleMAX Family of Laser Systems
510(k)	KXXXXXX	K133283
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	<p>The GentleLASE 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</p>	<p><u>755nm</u> 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</p>

Product	Modified GentleLASE Family of Laser Systems (GentleLase Pro and GentleLase Pro LE Laser Systems)	GentleMAX Family of Laser Systems
	<p>dermatological vascular lesions (such as port-wine stains, hemangiomas, telangiectasias).</p>	<p>dermatological vascular lesions (such as port-wine stains, hemangiomas, telangiectasias).</p> <p><u>1064nm</u></p> <p>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.</p> <p>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.</p> <p>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.</p> <p>The laser is also indicated for the</p>

Product	Modified GentleLASE Family of Laser Systems (GentleLase Pro and GentleLase Pro LE Laser Systems)	GentleMAX Family of Laser Systems
		reduction of red pigmentation in hypertrophic and keloid scars where vascularity is an integral part of the scar. Treatment of wrinkles.
Laser type	Flashlamp-excited, Solid state Alexandrite laser	Flashlamp-excited, Solid state Alexandrite and Nd:YAG laser
Wavelength	755nm	755nm/1064nm
Pulse duration	3 – 300 ms	0.25 – 100 ms
Maximum fluence	53 J/cm ²	53 J/cm ² (ALEX) 80 J/cm ² (YAG)
Spot size	6, 8, 10, 12, 15, 18, 20, 22, 24mm	1.5, 3, 6, 8, 10, 12, 15, 18mm
Pulse repetition rate	2 Hz, maximum	10 Hz, maximum
Pulsing control	Fingerswitch or footswitch	Fingerswitch or footswitch
Laser Cooling Method	Self-contained internally circulated liquid to air	Self-contained internally circulated liquid to air
Product dimensions (HxWxL)	42” x 18” x 27”	42” x 18” x 27”
Product Weight	250 lbs	260 lbs

Performance Data:

A software update is being made to the modified GentleLASE Family of Laser Systems (GentleLase Pro and GentleLase Pro LE) due to a recall, therefore software verification and validation have been performed. Testing to the third edition of IEC 60601-1, IEC 60601-1-2, and IEC 60601-2-22 has been conducted on the GentleLase Pro and GentleLase Pro LE laser systems. All performance testing demonstrated that the GentleLase Pro and GentleLase Pro LE laser systems perform 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 GentleLASE 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 GentleLASE Family of Laser Systems raises no new issues of safety or effectiveness. The modified GentleLASE Family of Laser Systems have the same intended uses, utilizes similar operating principles, and matches key design aspects, including

Section 7 – 510(k) Summary

similar spot size, similar wavelength and the same maximum delivered fluence as the predicate device. 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 GentleLASE Family of Laser Systems is substantially equivalent to the predicate device.