May 26, 2020

Candela Corporation
Yverre Bobay
Director, Regulatory Affairs
251 Locke Dr
Marlborough, Massachusetts 01752

Re: K201111
Trade/Device Name: GentleMax Pro Plus
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 24, 2020
Received: April 27, 2020

Dear Yverre Bobay:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Colin Kejing Chen
Acting Assistant Director
DHT4A: Division of General Surgery Devices
OHT4: Office of Surgical
and Infection Control Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K201111

Device Name
GentleMAX Family of Laser Systems

Indications for Use *(Describe)*

755nm:
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:
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), cafe 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.

Reduction of red pigmentation in hypertrophic and keloid scars where vascularity is an integral part of the scar. Treatment of wrinkles.

Temporary increase of clear nail in patients with onychomycosis (e.g., dermatophytes, Trichophyton rubrum and T. mentagrophytes, and/or yeast Candida Albicans, etc.)

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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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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510(k) Summary
GentleMax Pro Plus System

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of 21 CFR 807.92

1. DATE PREPARED

April 24, 2020

2. APPLICANT NAME

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3. OFFICIAL CORRESPONDENT

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4. DEVICE INFORMATION

Proprietary Name:	GentleMax Family of Laser Systems
Common/Usual Name:	Dermatology Laser System
Classification Name:	Laser surgical instrument for use in General and Plastic surgery and in dermatology (21 CFR Section 878.4810, Product Code GEX)
Product Code:	GEX
Device Classification:	Class II
Laser Classification:	Class IV

5. PREDICATE DEVICE

Candela GentleMAX Family of Lasers System (K140122).

6. INTENDED USE/INDICATION FOR USE

There are no new Intended Uses for the GentleMax Pro Plus. The Indications for Use Statement is unchanged for the GentleMax Pro Plus is as follows:

755nm:
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:
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), cafe 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.

Reduction of red pigmentation in hypertrophic and keloid scars where vascularity is an integral part of the scar. Treatment of wrinkles.

Temporary increase of clear nail in patients with onychomycosis (e.g., dermatophytes, Trichophyton rubrum and T. mentagrophytes, and/or yeast Candida Albicans, etc.)

7. DEVICE DESCRIPTION

The GentleMax Pro Plus 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.

8. TECHNOLOGICAL CHARACTERISTICS

The new GentleMax Pro Plus system has the same design, technological characteristics, operating principles, and intended use as the Candela GentleMax Family of Laser System (K140122). The devices share the same technical features, such as calibration port, wavelengths, laser medium, delivery systems, power supply, cooling system, electronics, firmware and user display screen. The devices share the same operating principles, such as energy but the Gentle Max Pro Plus offers a faster repetition rate, and offers larger spot sizes. Any minor differences do not raise any new types of safety or effectiveness questions because the GentleMax Pro Plus parameters are similar to the predicates.

Comparison Table of Technological Characteristics

Specifications	Modified Candela GentleMax Pro Plus	Current Candela GentleMax Pro
Manufacturer	Candela Corp.	Candela Corp.
K Number	Not Assigned	K140122
Product Code	GEX	GEX
Regulation Number	878.4810	878.4810
Device Class	II	II
Indications for Use	The GentleMax Family of Laser Systems is indicated for the following at the specified wavelength: **755 nm** Temporary hair reduction. Stable long-term or permanent reduction through selective targeting of melanin in hair follicles. Permanent hair reduction is defined as long-	The GentleMax Family of Laser Systems is indicated for the following at the specified wavelength: **755 nm** 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** 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 1-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 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. Reduction of red pigmentation in hypertrophic and keloid scars where vascularity is an integral part of the scar. Treatment of wrinkles. **1064nm** Temporary increase of clear nail in patients with onychomycosis (e.g., dermatophytes, Trichophyton rubrum and T. mentagrophytes, and/or yeast Candida Albicans, etc.)	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** 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 1-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 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. Reduction of red pigmentation in hypertrophic and keloid scars where vascularity is an integral part of the scar. Treatment of wrinkles. **1064nm** Temporary increase of clear nail in patients with onychomycosis (e.g., dermatophytes, Trichophyton rubrum and T. mentagrophytes, and/or yeast Candida Albicans, etc.)
Laser Type	Flashlamp-excited, Solid state Alexandrite and Nd:YAG laser	Flashlamp-excited, Solid state Alexandrite and Nd:YAG laser
Aiming Beam	Green diode laser (520-550 nm)	Green diode laser (520-550 nm)

Wavelengths (nm)	755 & 1064	755 & 1064
Maximum Energy (J)	68 Joules (J) ALEX; 90 J Nd:YAG	53 joules (J) ALEX; 80 J Nd:YAG
Accuracy of Output	± 20%	± 20%
Maximum Fluence (J/cm2)	400 J/cm2 (ALEX) 520 J/cm2 (YAG)	400 J/cm2 (ALEX) 520 J/cm2 (YAG)
Spot Size (mm)	1.5 mm, 3 mm, 3x10 mm, 5 mm, 6 mm, 8 mm, 10 mm, 12 mm, 15 mm, 18 mm, **20 mm, 22 mm, 24 mm, 26 mm**	1.5 mm, 3 mm, 3x10 mm, 5 mm, 6 mm, 8 mm, 10 mm, 12 mm, 15 mm, 18 mm
Repetition Rate (Hz)	1 – 10 Hz	1 – 10 Hz
Pulse Duration (ms)	0.25 – 100 ms (new 2ms)	0.25 – 100 ms
Operating Modes	Pulse	Pulse
Energy Delivery	Footswitch & finger switch	Footswitch & Handpiece switch
Beam Delivery	Lens-coupled optical fiber	Lens-coupled optical fiber
Voltage and Power (30A configuration)	200 V to 240 V~, 50/60 Hz, single phase, 4,600 VA or 20 A at 230 V~	200 V to 240 V~, 50/60 Hz, single phase, 4,600 VA or 20 A at 230 V~
Voltage and Power (20A configuration)	200 V to 240 V~, 50/60 Hz, single phase, 3,600 VA or 16 A at 230 V~	200 V to 240 V~, 50/60 Hz, single phase, 3,600 VA or 16 A at 230 V~
System Cooling	Ambient Air	Ambient Air
Skin Cooling	Yes Cryogen (DCD)	Yes Cryogen (DCD)
Software/GUI / Touch Screen	Yes	Yes
Dimension in Inches (H x W x L)	42 x 18 x 27	42 x 18 x 27
Weight (Pounds)	260	260
Power Supply	Yes	Yes

9. PERFORMANCE DATA

The following performance data supports the substantial equivalence determination:

Electrical Safety and Electromagnetic Compatibility Standards

- IEC 60825-1: Safety of Laser Products – Part 1: Equipment classification and requirements
- IEC 60601-1-2: Medical electrical equipment – Part 1-2: General requirements for safety – collateral standard: electromagnetic compatibility (EMC)-requirements and test
- IEC 60601-1: Medical electrical equipment – Part 1: General requirements for basic safety and essential performance
- IEC 60601-2-22: Medical electrical equipment – Part 2-22: Particular requirements for basic safety and essential performance of surgical, cosmetic, therapeutic and diagnostic laser equipment

Biocompatibility

The biocompatibility of the GentleMax Pro Plus has been established based on the predicate devices and the results of ISO 10993-5 and ISO 10993-10 series of testing.

Software Verification & Validation

Software verification and validation testing was conducted and results demonstrated that testing results were found acceptable for software release. Software testing was performed per FDA's guidance document "Guidance for the Content of Premarket Submission for Software Contained in Medical Devices".

Clinical Testing

Based on the similarities of the device specifications, intended use, indications for use between the GentleMax Pro Plus and its predicate device, no clinical studies were needed to support this 510(k) Premarket Notification.

10. STATEMENT OF SAFETY AND EFFECTIVENESS

The GentleMax Pro Plus and shares a similar design and intended use to its predicate (K140122). Additionally, technological characteristics, including wavelengths, laser mediums, pulse width, spot sizes, energy, cooling systems, and repetition rate are similar between the GentleMax Pro Plus and its predicate devices. The modifications to the device do not raise new types of questions regarding safety and efficacy, and the data presented in this 510(k) Premarket Notification supports that the device is substantially equivalent to the predicate device.