Candela Corp.
Sharon Timberlake
Vice President Global Clinical and Regulatory Affairs
530 Boston Post Road
Wayland, Massachusetts 01778

February 1, 2019

Re: K183452
Trade/Device Name: Vbeam Prima Laser System
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: January 16, 2019
Received: January 17, 2019

Dear Sharon Timberlake:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Neil R Ogden -S

Digitally signed by Neil R Ogden -S
Date: 2019.02.01 14:50:42 -05'00'

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

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)*

K183452

Device Name
Vbeam Prima Laser System

Indications for Use *(Describe)*

1,064nm:
The Vbeam® Prima Laser System is intended for the coagulation and hemostasis of benign vascular lesions such as, but not limited to, port wine stains, hemangiomas, warts, telangiectasia, rosacea, venus lakes, leg veins, spider veins, and poikiloderma of civatte and treatment of benign cutaneous lesions such as, but not limited to lentigos (age spots), solar lentigos (sun spots), cafe au lait manules, seborrheic keratoses, nevi, chloasma, verrucea, skin tags, and keratoses. The laser is also indicated for the treatment of wrinkles such as, but not limited to, periocular and perioral wrinkles.

595 nm:
General Surgery: Photocoagulation of benign cutaneous vascular lesions and benign cutaneous lesions.

Dermatology/Plastic Surgery: For treatment of benign cutaneous vascular lesions, such as facial and leg telangiectasia, rosacea, port wine stains, hemangiomas, angioma, spider angioma, poikiloderma of civatte, and benign cutaneous lesions, such as warts, scars, striae, psoriasis and the treatment of wrinkles. Treatment of benign epidermal pigmented lesions. Treatment of inflammatory acne vulgaris.

Gynecology: Photocoagulation of benign cutaneous lesions and benign vascular lesions in gynecology.

Podiatry: Treatment of benign cutaneous lesions, such as warts.

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
Vbeam® Prima Laser 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

December 12, 2018

2. APPLICANT NAME

Candela Corporation
530 Boston Post Road
Wayland, MA 01778
P: (508) 358-0304
M: (617) 957-1434

3. OFFICIAL CORRESPONDENT

Sharon Timberlake, MSHS, RAC, CCRA
VP, Global Clinical & Regulatory Affairs
Candela Corporation
530 Boston Post Road
Wayland, MA 01778
P: (508) 358-0304
M: (617) 957-1434
sharont@syneron-candela.com

4. DEVICE INFORMATION

Proprietary Name:	Vbeam® Prima Laser System
Common/Usual Name:	Pulse Dye and Nd: YAG Laser
Classification Name:	Laser surgical instrument for use in General and Plastic surgery and in dermatology (21 CFR Section 878.4810)
Product Code:	GEX
Device Classification:	Class 2
Laser Classification:	Class IV

5. PREDICATE DEVICE

Candela Vbeam Prima Laser System (K180593) and Candela GentleMAX Family of Pulse Dye Laser Systems (K140122).

6. INTENDED USE

1,064 nm:

The Vbeam® Prima Laser System is intended for the coagulation and hemostasis of benign vascular lesions such as, but not limited to, port wine stains, hemangiomas, warts, telangiectasia, rosacea, venus lakes, leg veins, spider veins, and poikiloderma of civatte and treatment of benign cutaneous lesions such as, but not limited to lentigos (age spots), solar lentigos (sun spots), cafe au lait manules, seborrheic keratoses, nevi, chloasma, verrucea, skin tags, and keratoses.

The laser is also indicated for the treatment of wrinkles such as, but not limited to, periocular and perioral wrinkles.

595 nm:

General Surgery: Photocoagulation of benign cutaneous vascular lesions and benign cutaneous lesions.

Dermatology/Plastic Surgery: For treatment of benign cutaneous vascular lesions, such as facial and leg telangiectasia, rosacea, port wine stains, hemangiomas, angioma, spider angioma, Poikiloderma of Civatte, and benign cutaneous lesions, such as warts, scars, striae and Psoriasis and the treatment of wrinkles. Treatment of Benign Epidermal Pigmented Lesions.

Treatment of Inflammatory Acne Vulgaris.

Gynecology: Photocoagulation of benign cutaneous lesions and benign vascular lesions in gynecology.

Podiatry: Treatment of benign cutaneous lesions, such as warts.

7. DEVICE DESCRIPTION

The Vbeam Prima Laser system is designed as a transportable device that delivers laser energy at wavelengths of 595 nm (pulse-dye) or 1064 nm (Nd: YAG). The device is comprised of a main console, power supply, controlled electronics, firmware, software, cooling system, and handpieces. There is also an internal calibration port with an internal meter located in the system. The handpiece offers a set of distance gauges available in the following spot ranges: 3-7 mm, 7-11 mm, 11-15 mm, and 3 X 10 mm. The user selects treatment settings, such as fluence, number of pulses, and spot size selection via a color touch screen. The handpiece incorporates a Dynamic Cooling Device (DCD) into its handpiece that is designed to cool the skin surface during treatment, which consists of an electrically controlled spray nozzle, cryogen reservoir canister and an electronic control circuitry. The Vbeam Prima Laser System also offers an optional EverCool Delivery System Handpiece for skin cooling during treatment.

8. TECHNOLOGICAL CHARACTERISTICS

The modified Vbeam Prima Laser System has the same design, technological characteristics, operating principles, and intended use as the Candela Vbeam Prima Laser System (K180593). The devices share the same technical features, such as calibration port, wavelengths, laser medium, delivery systems, cooling system, user display screen, with changes to the power supply, electronics, firmware and software. The devices share the same operating principles, such as repetition rate, and availability of a range of spot sizes. Any minor differences including input voltage, pulse duration and pulse energy do not raise any new types of safety or effectiveness questions because the Vbeam Prima Laser System parameters are similar to the predicates.

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 Vbeam Prima Laser System 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 Vbeam Prima Laser System and its predicate devices, no clinical studies were needed to support this 510(k) Premarket Notification.

10. STATEMENT OF SAFETY AND EFFECTIVENESS

The modified Vbeam Prima Laser System has the same design, technological characteristics, operating principles, and intended use as the Candela Vbeam Prima Laser System (K180593). The devices share the same technical features, such as calibration port, wavelengths, laser medium, delivery systems, cooling system, user display screen, with changes to the power supply, electronics, firmware and software. The devices share the same operating principles, such as repetition rate, and availability of a range of spot sizes. Any minor differences including input voltage, pulse duration and pulse energy do not raise any new types of safety or effectiveness questions because the Vbeam Prima Laser System parameters are similar to the predicates.