September 16, 2019

Candela Corporation
Brenda M Geary
Senior Regulatory Affairs Specialist
530 Boston Post Road
Wayland, MA 01778 US

Re: K191685
Trade/Device Name: PicoWay 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: June 21, 2019
Received: June 26, 2019

Dear Brenda M Geary:

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,

Purva Pandya
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)*
K191685

Device Name
PicoWay Laser System

Indications for Use *(Describe)*

The PicoWay laser system is indicated for the following at the specified wavelength
532 nm: Removal of tattoos for Fitzpatrick skin types I-III to treat the following tattoo colors: red, yellow and orange.
730 nm: Removal of tattoos for Fitzpatrick skin types II-IV to treat the following tattoo colors: green and blue.

785 nm: Removal of tattoos for Fitzpatrick skin types II-IV to treat the following tattoo colors: green and blue.
1064 nm: Removal of tattoos for all skin types (Fitzpatrick I-VI) to treat the following tattoo colors: black, brown, green, blue and purple.

The Picoway laser system is also indicated for benign pigmented lesions removal for Fitzpatrick Skin Types I-IV.
The Resolve handpiece (1064 nm) is also indicated for the treatment of acne scars in Fitzpatrick Skin Types II-V.

The Resolve handpieces (532 nm HE, 532nm, 1064nm) are also indicated for treatment of wrinkles in Fitzpatrick Skin Types I-IV

The Resolve Fusion handpiece (1064 nm) is indicated for the treatment of wrinkles as well as benign pigmented lesions in Fitzpatrick Skin Types I-IV

The Resolve Fusion handpiece (532 nm) is indicated for the treatment of benign pigmented lesions in Fitzpatrick Skin Types I-IV

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"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."

K191685

510(k) Summary

August 23, 2019

Submitter
Candela Corporation
530 Boston Post Road
Wayland, MA 01788 USA

Authorized Contact
Brenda M Geary
Senior Regulatory Affairs Specialist
e: brendag@candelamedical.com
p: 508.974.3556

Trade Name
PicoWay Laser System

Device Classification
Class II
Laser Surgical Instrument for use in General and Plastic Surgery and in Dermatology (21 CFR 878.4810)
Product Code: GEX

Predicates
Primary Predicate: Candela Corporation's PicoWay Laser System (K170597)
Reference Predicates: Cynosure PicoSure (K160480), Cutera Enlighten III (K172077), Syneron-Candela PicoWay (K160607)

Intended Use/Indications for Use
The PicoWay laser system is indicated for the following at the specified wavelength:

532 nm: Removal of tattoos for Fitzpatrick skin types I-III to treat the following tattoo colors: red, yellow and orange.

730 nm: Removal of tattoos for Fitzpatrick skin types II-IV to treat the following tattoo colors: green and blue.

785 nm: Removal of tattoos for Fitzpatrick skin types II-IV to treat the following tattoo colors: green and blue.

1064 nm: Removal of tattoos for all skin types (Fitzpatrick I-VI) to treat the following tattoo colors: black, brown, green, blue and purple.

The PicoWay laser system is also indicated for benign pigmented lesions removal for Fitzpatrick Skin Types I-IV.

The Resolve handpiece (1064 nm) is also indicated for the treatment of acne scars in Fitzpatrick Skin Types II-V.

The Resolve handpieces (532 nm HE, 532 nm, 1064 nm) are also indicated for treatment of wrinkles in Fitzpatrick Skin Types I-IV

The Resolve Fusion handpiece (1064 nm) is indicated for the treatment of wrinkles as well as benign pigmented lesions in Fitzpatrick Skin Types I-IV.

The Resolve Fusion handpiece (532 nm) is indicated for the treatment of benign pigmented lesions in Fitzpatrick Skin Types I-IV.

Description

The PicoWay System has been previously cleared (K170597, K162454, K160607, K150326, K142372 and K153527) for tattoo removal and treatment/removal of benign pigmented lesions as well as treatment of acne scars and wrinkles. There are minor modifications to the current system to add four (4) new handpieces, minor system specifications, and new wavelengths. The additional new handpieces will work in the same way as the currently cleared PicoWay handpieces as in they will operate in the same manner as the predicate devices.

The PicoWay Laser System is a solid-state laser capable of delivering energy at wavelengths of 1064 nm, 532 nm, 730 nm (new) or 785 nm at extremely short duration in the range of 240-500 ps. The laser system contains one 755 nm (Alexandrite) laser head which is used to 'pump' (create) the 1064 nm picosecond wavelength. The 1064 nm wavelength can be frequency-doubled to 532 nm as desired. The outputs of the two lasers are designed to be co-linear 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 the 532 nm or 1064 nm wavelengths. The current 785 nm and new 730 nm wavelength contain a Ti:Sapphire laser rod that is pumped with the 532 nm energy. All these energies are delivered through an articulated arm and corresponding handpiece. Currently there are two cleared Resolve handpieces (1064 nm and 532 nm), a 785 nm handpiece and a Zoom handpiece that works on two wavelengths (532 nm and 1064 nm).

Technological Characteristics

The new handpieces and wavelength all have similar technological characteristics as the predicate PicoWay Laser System handpieces including the laser types, wavelengths, device design, pulse width, frequency, spot sizes, fluence, energy and system components. Any minor differences do not raise different questions of safety or effectiveness since the PicoWay handpieces are similar to or within the range of the cleared predicate device. The verification and validation testing have confirmed the safety and performance of these new handpieces and wavelength. With the same intended use and indications for use, technological characteristics, and principles of operation as the currently marketed PicoWay Laser System, the handpieces can be considered substantially equivalent to the predicate device.

Apart from the addition of four new handpieces, the software and user interface were revised, to include the updates for the inclusion of new handpieces. The PicoWay design and components of the new handpieces are very similar to the cleared handpieces. The primary purpose of this submission is to

add the four handpieces to the PicoWay Laser System and update to the indications for use for those new handpieces. As with the original cleared handpieces these new treatment handpieces are attached to an articulating arm that is connected to the main system console. For each system, the user interface is located at the front/top of the console. The laser output at each wavelength is generated within the laser chassis and delivered to the skin through an articulated arm deliver system with a handpiece attached to the end. Treatment parameters can be adjusted according to the device specifications. Each system consists of the articulating arm (and attached handpiece), as well as an electrically powered system console that houses the software, user interface and produces the laser energy. The addition of the new handpieces will work in the same way as the currently cleared PicoWay handpieces. The PicoWay handpieces will be in the same frequency range as the predicate, the previously cleared PicoWay Laser System handpieces. Therefore, the new handpieces do not raise different questions of safety of effectiveness because the parameters are the same or within the range of the primary predicate.

Performance Data

Electrical Safety and Electromagnetic Compatibility: Electrical safety and electromagnetic compatibility (EMC) testing for the PicoWay Laser System was conducted by an independent test laboratory in accordance with IEC 60601-1, Medical electrical equipment, Part 1: General requirement for basic safety and essential performance and with IEC 60601-1-2, Collateral Standard: Electromagnetic Compatibility – requirements and testes, 4th ed. The PicoWay System was determined to be in conformance with applicable IEC standards (IEC 62366, IEC 60601-1, IEC 60601-1-2, IEC 60601-1-6, IEC 60601-2-22 and IEC 60825-1).

Biocompatibility: The biocompatibility of the patient-contacting materials of the PicoWay device is based on the established biocompatibility of the previous cleared PicoWay predicates (K170597, K162454, K160607, K150326, K142372 and K153527). There are no changes in the material for the new handpiece distance gauges (patient contacting materials) as well as manufacturing process, therefore the biocompatibility of the PicoWay device is based on the established biocompatibility of the predicate.

Software: Software for the PicoWay Laser System has been updated to implement the functionality of the new handpieces. The software verification and validation testing results were found acceptable for according to ISO 62304 for the new software release. The PicoWay Laser System is a closed loop system with no network connectivity; therefore, software cybersecurity standards do not apply to this system.

Bench Testing:

The four additional handpieces being added to the PicoWay Laser System family, were extensively tested through bench testing. The results of the bench testing verified that the laser system specifications were met, and the handpieces performed as intended.

Ship Testing

The new handpieces were subjected to ISTA 2A testing to ensure that the current case and configurations would continue to protect the devices during transport from the manufacturing floor to the warehouse and eventually to the customer for use. The same pelican case that is used to ship previously cleared devices is used to ship the new additional handpieces. The packaging passed the testing and was proven to protect the devices.

Clinical Data: The PicoWay Laser System did not require clinical performance data.

Summary of Substantial Equivalence

The four additional handpieces for the PicoWay Laser System have the same intended use as its predicate device. The handpieces have similar technological characteristics as the predicate including the laser types, wavelengths, device design, pulse width, frequency, spot sizes and system components. Any minor differences do not present different types of safety or effectiveness questions since the PicoWay handpieces are similar to or within the range of the cleared predicate device. The verification and validation testing have confirmed the safety and performance of the handpieces. All handpieces have the same mechanism of action based on the selective photo thermolysis of pigment particles using the laser energy. Therefore, with the same intended use and indications for use, technological characteristics, and principles of operation as the currently marketed PicoWay Laser System the handpieces can be considered substantially equivalent to the predicate device.