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

July 5, 2016

Syneron Candela Corporation
c/o Ms. Janice M. Hogan
Hogan Lovells US LLP
1835 Market Street, 29th Floor
Philadelphia, PA 19103

Re: K160607
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: May 19, 2016
Received: May 19, 2016

Dear Ms. Hogan:

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,

Jennifer R. Stevenson -A

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: January 31, 2017
See PRA Statement on last page

510(k) Number *(if known)*

K160607

Device Name

PicoWay Laser System

Indications for Use *(Describe)*

The PicoWay laser system is indicated for the following at the specified wavelength:

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

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

1064nm: 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.

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.

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510(k) Summary
PicoWay Laser System

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

Contact Person: Ruthie Amir
Global Vice President of Clinical, Regulatory, and Education
Tel: 508-358-7400 x330
Fax: 508-358-5602

Date prepared: July 1, 2016

Trade Name: PicoWay Laser System

Common Name: Dermatology Laser System

Classification: Class II
Laser surgical instrument for use in general and plastic surgery and in dermatology (21 CFR 878.4810)
Product Code GEX

Predicate and Reference Devices:

Predicate Devices: Cynosure PicoSure™ workstation (K143105, K140719, K133364, K121346) (Primary Predicate); Syneron-Candela's PicoWay Laser System (K153527, K150326, K142372)

Reference devices: Syneron Medical Ltd.'s Transcend System (K120510), Candela Corporation's GentleMAX Pro laser system (K140122, K133283, K112715), Candela Corporation's VBeam Laser System (K033461)

Intended Use / Indications for Use:

The PicoWay Laser System is indicated for the following at the specified wavelength:

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

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

1064nm
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.

Description:

The PicoWay Laser System is a solid state laser capable of delivering energy at wavelengths of 1064 nm, 785 nm, or 532 nm at short durations of 240–750 picoseconds (ps) at repetition rates up to 10 Hz (1064 nm, 532 nm) or 5 Hz (785 nm). The device system is comprised of a system console, an articulated arm, and an attached Handpiece. The laser output at each wavelength is generated within the laser chassis and delivered to the skin through an articulated arm delivery system terminated by a Handpiece. The light-weight and ergonomic Handpieces allow the spot size on the skin to be easily adjusted. A range of spot sizes is available for the PicoWay System (up to 10 mm). The system includes an internal calibration port with an internal meter located on the control panel of the system console, which is used to verify the transmission of the laser beam into the articulated arm. The PicoWay system control panel enables the user to select the desired energy density level and repetition rate. The control panel is also used to obtain feedback from the system, such as the number of pulses delivered or spot size selected.

Technological Characteristics:

The PicoWay Laser System has the same intended use and similar indications for use, technological characteristics and operating principles as the Cynosure PicoSure™ workstation (K143105, K140719, K133364, K121346) and the PicoWay Laser System (K153527, K150326, K142372). The PicoWay design and components are very similar to those of the previously cleared predicates. The primary purpose of this submission is to add an additional 785 nm wavelength. For each of these device systems, the treatment Handpiece is 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. For the PicoWay and predicate devices, the laser output at each wavelength is generated within the laser chassis and delivered to the skin through an articulated arm delivery system with a Handpiece attached to the end. Treatment parameters can be adjusted according to device specifications. Each system thus 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 PicoWay provides similar key design aspects, including the same or similar spot sizes, laser wavelengths, pulse width, and laser types, as its predicate devices. The frequency (repetition rate) of the PicoWay System is the same as or within the frequency range of the predicates. Further, each of the devices presents a range of spot sizes to allow the user to choose the most appropriate spot size for each patient. The wavelengths available with the PicoWay are the same as or similar to those presented by the predicates. Therefore, the minor differences do not raise any new types of safety or effectiveness questions because the PicoWay parameters are the same as or within the range of the predicates.

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 requirements for basic safety and essential performance and with IEC 60601-1-2, Collateral Standard: Electromagnetic Compatibility - Requirements and Tests, 3rd 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 PicoWay device has also been established per ISO 10993 guidelines based on the biocompatibility of the PicoWay predicate.

Software: Software verification and validation testing was conducted and results demonstrated that testing results were found acceptable for software release.

Bench Testing: Testing verified that energy measurements met specifications. Bench testing also demonstrated that the Resolve handpieces of the PicoWay System clear pigment particles in a similar manner compared to the previously cleared Zoom handpiece. Bench testing was also conducted to evaluate the tattoo ink absorption achieved with the 785 nm handpiece of the PicoWay as compared to other legally marketed tattoo and pigmented lesions clearance devices. 100 pulses of PicoWay 785nm treatment resulted in greater ink clearance compared to 200 pulses of another legally marketed device for the treatment of pigmented lesions and tattoos. Clearance results demonstrated that the picosecond laser pulses achieve ink particle fracturing and/or de-aggregrating pigment particles in at least a substantially equivalent manner compared to other laser systems similarly cleared for tattoo clearance.

Clinical Data: Several prospective studies have been conducted to evaluate the PicoWay System, and results consistently demonstrate the favorable safety and performance profiles of the PicoWay System for its indicated uses. In support of the proposed additional wavelength in this 510(k), a single arm, self-controlled study was conducted to evaluate the safety of the PicoWay System for the previously cleared indication of tattoo removal. The clinical evaluation of 15 subjects (22 tattoos) after up to 2 treatments demonstrated that the PicoWay performs as intended and presents a favorable safety profile when used with the 785 nm wavelength. Treatments were administered following enrollment, completion of screening and obtaining informed consent from each subject. Each treatment session was 11±5 weeks (6-16 weeks) apart. Study results were evaluated at the post treatment 2 visit (10-16 weeks after the first treatment). The majority of subjects were female, Caucasian, with a mean age of 36 years. Clinical data were available from a large majority of the treated tattoos through the third visit (post second treatment). Subjects were treated using 2-4 mm spot sizes at pulse repetition rates up to 5 Hz. Treatment with the PicoWay device using the added wavelength achieved substantial clearance of blue and green tattoos. Based on independent review by 3 blinded reviewers, the reviewers correctly identified the pre and post treatment photographs for all (100%) of the tattoos. In addition, 83% of the blue/green tattoos demonstrated at least 50% clearance compared to baseline after only 2 treatments. In addition, investigator assessments of tattoo clearance also demonstrated that substantial to complete clearance was achieved with the PicoWay when using the added 785 nm wavelength in 83% (15/18) of the blue/green tattoos.

PicoWay treatment also demonstrated a positive safety profile, with no device related serious adverse events. Mild erythema, edema, and pinpoint bleeding following treatments were observed and considered to be anticipated responses. Treatments resulted in none to moderate discomfort/pain, consistent with the results observed with the PicoWay predicate. Therefore, the study results did not present any new types of safety questions as compared to the predicate devices.

Additional data from two separate clinical investigations of treatment on the face, an additional histology evaluation, and bench testing demonstrated the safety of the Resolve handpieces. The clinical studies together provide safety data from 114 subjects, and the investigations included both wavelengths of the Resolve handpieces (1064 nm, 532 nm). In both of the clinical studies providing

additional safety data, there were no adverse events following PicoWay treatment throughout the course of the study and anticipated treatment-associated responses were all transient and resolved.

Histological evaluation of 19 treated areas from 9 subjects demonstrated that the effects on the treated area using picosecond laser energy using the Resolve handpieces are equivalent between the PicoWay and PicoSure devices.

Based on the clinical data, the PicoWay System with the added wavelength and Resolve handpieces performs as intended with a positive safety profile. Results were similar to the predicate devices, and further support substantial equivalence. All performance testing demonstrated that the PicoWay Laser System performs according to specifications and functions as intended.

Summary of Substantial Equivalence:

The PicoWay and the predicate devices have the same intended use with similar indications for use. The PicoWay Laser System presents the same or similar technological characteristics as its predicate devices, including the laser type, wavelengths, device design, pulse width, frequency, spot sizes and system components. Any minor differences do not present any new types of safety or effectiveness questions since the PicoWay parameters are similar to or within the range of the predicates. Further, PicoWay performance has been demonstrated in clinical and non-clinical investigations, and results confirm the safety and performance of the device. The PicoWay device and its predicates all operate with the same mechanism of action based on selective photothermolysis of pigment particles using laser energy. Therefore, the PicoWay has the same intended use and similar indications for use, technological characteristics, and principles of operation as the predicate devices. The PicoWay is substantially equivalent to the predicate devices.

Conclusions:

Testing of the PicoWay device demonstrated that the device performs as intended with a favorable safety profile. Results in the clinical studies were similar to those reported for the predicate device, in support of substantial equivalence. The non-clinical data further support the safety of the device, and software verification and validation testing demonstrates that the PicoWay device is expected to perform as intended. The PicoWay System is substantially equivalent to the predicate devices.