DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

March 2, 2016

Syneron Candela Corporation
% Ms. Janice Hogan
Regulatory Counsel
Hogan Lovells US LLP
1835 Market Street
29th Floor
Philadelphia, Pennsylvania 19103

Re: K153527
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: December 9, 2015
Received: December 9, 2015

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" (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 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)*

K153527

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.

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: February 29, 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: Syneron-Candela's PicoWay Laser System (K150326, K142372) (Primary Predicate); Cynosure PicoSure™ workstation (K143105, K140719, K133364, K121346); Cutera enlighten Laser System (K140727)

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

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.

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 or 532 nm at short durations of 240-750 picoseconds (ps) at repetition rates up to 10 Hz. 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 zoom handpiece (HP). The light-weight and ergonomic zoom handpiece allows the spot size on the skin to be easily adjusted from 2 mm to 10 mm in steps of 1 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 (fluence) 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 indications for use, as well as the same or very similar technological characteristics and operating principles as Syneron-Candela's PicoWay Laser System (K150326, K142372) (Primary Predicate); Cynosure PicoSure™ workstation (K143105, K140719, K133364, K121346); Cutera enlighten Laser System (K140727). The PicoWay device design and components are very similar to those of the previously cleared PicoWay System, where the only key differences are in the increased range of spot sizes and repetition rates available with the modified system. The technological characteristics are also very similar to those of the PicoSure and enlighten predicates. 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. The handpiece allows the spot size on the skin to 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 PicoSure and enlighten 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. 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.

Clinical Data: A single arm, self-controlled study was conducted to evaluate the safety and effectiveness of the PicoWay System for the previously cleared indications for removal of tattoos and benign pigmented lesions. The clinical evaluation of 60 subjects (69 tattoos/pigmented lesions) demonstrated that the PicoWay performs as intended and presents a favorable safety profile for its indications. The majority of subjects were female, Caucasian, with a mean age of 33 years.

The results of the clinical study demonstrated the favorable safety and effectiveness profile for the PicoWay for tattoo removal. As discussed above, the PicoWay device successfully met the primary hypothesis for tattoo clearance, where 86% of the treated tattoos achieved 50% or more clearance after up to 3 treatments based on blinded, independent review, exceeding the endpoint threshold of 85%. Consistent with the results observed for the primary endpoint, the study results under the secondary efficacy endpoint demonstrated a substantial degree of tattoo clearance based on investigator assessment after up to 3 treatments, where the majority of subjects (97%) achieved at least 50% tattoo clearance after up to 3 treatments. Results of the blinded review and investigator review were also consistent with results reported in the prior PicoWay studies submitted to FDA, further confirming the favorable device effectiveness data in the PicoWay study.

Treatment with the PicoWay device also demonstrated a positive safety profile, with no device related serious adverse events after the 138 treatments for the 69 tattoos/ pigmented lesions evaluated. The few device related adverse events were all mild and all resolved during the course of the study. Erythema and edema following treatments were observed and considered to be anticipated responses. Subjects did not receive any anesthesia before or during treatment, and reported that the treatments resulted in none to moderate discomfort/pain. Therefore, the study results did not present any new types of safety or effectiveness questions as compared to the predicate devices.

Based on the clinical performance in the study, the PicoWay System with the increased ranges of spot sizes and repetitions rates was found to have a safety and effectiveness profile that is similar to the predicate devices. 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 the same or 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 investigations, and results confirm the safety and effectiveness profile 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 the same or similar indications for use, technological characteristics, and principles of operation as the predicate devices. The PicoWay is substantially equivalent to the predicate devices.

Conclusions:

Clinical testing of the PicoWay device demonstrated that the device performs as intended with a favorable safety profile. Results in the study 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 in the specified use conditions. The PicoWay System is substantially equivalent to the predicate devices.