October 27, 2017

Cutera, Inc.
Bradley Renton
Vice President, Regulatory and Medical Affairs, & Compliance Officer
3240 Bayshore Blvd.
Brisbane, California 94005

Re: K172077
Trade/Device Name: Cutera enlighten III 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: October 5, 2017
Received: October 6, 2017

Dear Bradley Renton:

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 (DICE) 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 (DICE) 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,

Jennifer R. Stevenson -S3

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 below.

510(k) Number *(if known)*
K172077

Device Name
Cutera enlighten III Laser System

Indications for Use *(Describe)*
The enlighten III laser system is intended for use in surgical and aesthetic applications in the medical specialties of dermatology and general and plastic surgery.

1064 nm:
The 1064 nm wavelength of the enlighten III laser system is indicated for:
• treatment of benign pigmented lesions on patients with all skin types (Fitzpatrick I-VI)
• tattoo removal for dark colored tattoo inks and for multicolored tattoos containing dark colored tattoo inks on patients with all skin types (Fitzpatrick I-VI)

532 nm:
The 532 nm wavelength of the enlighten III laser system is indicated for:
• treatment of benign pigmented lesions on patients with Fitzpatrick skin types I-IV
• tattoo removal for lighter colored tattoo inks, including red and yellow inks, on patients with Fitzpatrick skin types I-III

670 nm:
The 670 nm wavelength of the enlighten III laser system is indicated for:
• treatment of benign pigmented lesions on patients with Fitzpatrick skin types I-III
• tattoo removal for lighter colored tattoo inks, including green and blue inks, on patients with Fitzpatrick skin types II-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."

Section 5
510(K) Summary

This 510(K) Summary of safety and effectiveness for the enlighten III laser system is submitted in accordance with the requirements of the SMDA 1990 and following guidance concerning the organization and content of a 510(K) summary.

Applicant:	Cutera, Inc.
Address:	3240 Bayshore Blvd., Brisbane, CA 94005
Contact Person:	Bradley Renton 415-657-5568 – phone 415-715-3568 – fax brenton@cutera.com
Preparation Date:	October 5, 2017
Device Trade Name:	enlighten III Laser System
Common Name:	Dermatology Laser
Classification Name:	Instrument, Surgical, Powered, laser 79-GEX, 21 CFR 878.4810
Legally Marketed Predicate Devices:	Cutera enlighten III Laser System (K170936) Cynosure PicoSure (K160480) Syneron Candela PicoWay (K170597) Cynosure RevLite (K133254)
Device Description:	The enlighten III laser system is a multi-wavelength, pulsed laser system. A key feature of the device is its ability to produce multiple laser wavelengths and pulse widths (1064 and 532 nm: 750 ps and 2 ns; 670 nm: 660 ps and 2 ns). The laser, power supplies, and control electronics are housed inside a console equipped with a touchscreen control panel. The laser treatment parameters are selected using the control panel. Laser emission is activated by depressing a footswitch. An articulated arm with rotational mirror knuckles delivers the laser beam from a laser head inside the console to a handpiece. The handpiece is equipped with an optical zoom assembly that determines the spot size of the laser beam on the treatment surface. The beam of a low-power diode laser is also transmitted through the arm to provide an aiming beam.

Section 5
510(K) Summary

Indications for Use:

1064 nm

The 1064 nm wavelength of the enlighten III laser system is indicated for:

- treatment of benign pigmented lesions on patients with all skin types (Fitzpatrick I-VI)
- tattoo removal for dark colored tattoo inks and for multicolored tattoos containing dark colored tattoo inks on patients with all skin types (Fitzpatrick I-VI)

532 nm

The 532 nm wavelength of the enlighten III laser system is indicated for:

- treatment of benign pigmented lesions on patients with Fitzpatrick skin types I-IV
- tattoo removal for lighter colored tattoo inks, including red and yellow inks, on patients with Fitzpatrick skin types I-III

670 nm

The 670 nm wavelength of the enlighten III laser system is indicated for:

- treatment of benign pigmented lesions on patients with Fitzpatrick skin types I-III
- tattoo removal for lighter colored tattoo inks, including green and blue inks, on patients with Fitzpatrick skin types II-IV

Performance Data:

IEC 60601-1 Medical Electrical Equipment – Part 1: General Requirements for Safety (Edition 3.1, 2012), including:

- IEC 60601-1-6 Medical Electrical Equipment – Part 1-6: General Requirements for Safety - Collateral Standard: Usability (Edition 3.1, 2013) – Test Report Attachment 4
- IEC 62366 Medical Devices – Application of Usability Engineering to Medical Devices (Edition 1.1, 2014) – Test Report Attachment 5
- IEC 60601-2-22 Medical Electrical Equipment – Part 2: Particular Requirements for Basic Safety and Essential Performance of Surgical, Cosmetic, Therapeutic and Diagnostic Laser Equipment (Edition 3.1, 2012) – Test Report Attachment 6
- IEC 60825-1 Safety of Laser Products – Part 1: Equipment Classification and Requirements (Edition 2.0, 2007) – Test Report Attachment 7

The product also fulfills the requirements of AAMI/ANSI ES60601-1:2005+A2 (R2012) + A1.

IEC 60601-1-2 Medical Electrical Equipment – Part 1-2: General Requirements for Safety – Collateral Standard: Electromagnetic Compatibility (Edition 3, 2007)

Results of Clinical Study:

An IRB-approved, prospective, two-center clinical study was conducted to assess the safety and efficacy of the 670 nm wavelength of the enlighten III laser system for the clearing of tattoos containing green and/or blue ink.

Twenty-seven subjects with Fitzpatrick skin types II-V with unwanted tattoos containing green and/or blue ink, either alone or in combination with other ink colors were enrolled. The subjects received nanosecond and/or picosecond treatments with the Cutera enlighten III laser system with the 670 nm wavelength used to target green and blue inks; the 1064 nm wavelength used to target black and gray inks; and the 532 nm wavelength used to target lighter red and yellow inks. All wavelengths of the system could be used as required by the ink colors contained within the tattoo; however, only the clearing of green and blue inks were graded by blinded dermatologists. Standardized photographs were taken prior to and immediately after all study visits. Pain levels during treatment and adverse events were recorded during all visits.

An analysis of data was conducted on twenty-five of the twenty-seven subjects originally enrolled (two subjects had voluntarily withdrawn from the study after receiving one and two treatments respectively, but prior to attending the required follow-up visits for photography). Before and after images of the twenty-five subject tattoos were randomized and sent to three blinded dermatologists for correct identification of the before from after image, and grading of the clearing of the green and/or blue ink. All blinded dermatologists correctly identified the before image for all subjects. Greater than 50% clearing was seen in green and blue ink in the tattoos for 84% of subjects indicating that the primary efficacy endpoint for the study (≥ 50% clearing of green and blue inks in ≥ 80% of patients) had been met.

Blinded photographic assessment of the 25 subject tattoos resulted in a clinically and statistically significant improvement score of 3.24 on a 0-4 point scale. The mean and standard deviation were 3.24 ±0.71. Investigator assessment of tattoo clearing at six-week post treatment resulted in a mean improvement score of 3.43 ± 0.7.

Based on subject questionnaires, sixty-nine percent of subjects reported that they were “extremely satisfied” or “satisfied” with the level of clearing and thirty-one percent of subjects reported they were neutral. No patients reported dissatisfaction. Eighty-five percent of subjects would have the investigational treatment again.

All subjects tolerated treatments well with few requests for topical anesthetic and without any requests for local infiltration of anesthetic even though allowed by protocol (mean pain score 4.2 ± 2.9 [0-9] on a 10-point scale). As expected, all subjects experienced erythema, edema and frosting immediately following laser treatment, and most experienced crusting in the treated area. All adverse effects resolved with no required intervention. No

unexpected device related serious adverse events were noted.

The 670 nm wavelength of the enlighten III laser system was found to be safe and effective, with acceptable adverse effects, for tattoo removal for lighter colored tattoo inks including green and blue inks, in patients with skin types II-IV, allowing the conclusion that the enlighten laser system is substantially equivalent to the predicate devices for the requested indications.

Summary of Technological Characteristics:

The Cutera enlighten III laser systems used at each site in the clinical trial had identical device design, components, and performance specifications as the currently cleared enlighten III laser system (K170936). The enlighten III device design and components are also very similar to those of the Cynosure PicoSure, Syneron Candela PicoWay, and Cynosure RevLite predicates. For each of these systems:

- the user interface is located at the front/top of the console;
- the treatment handpiece is attached to an articulating arm that is connected to the main system console;
- laser energy is generated within the console and is transmitted through the articulated arm to the handpiece; and
- the handpiece allows the spot size on the skin to be adjusted according to device specifications.

Each system thus consists of an articulating arm and attached handpiece, as well as an electrically powered system console that produces the laser energy and houses the software and user interface.

The enlighten III laser system provides similar key design aspects, including the same or similar spot sizes, laser wavelengths, pulse widths, and laser types as its predicate devices. The repetition rate of the enlighten III laser system is the same as or within the repetition rate range of the predicate devices. 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 safety or effectiveness questions, because the enlighten III parameters are the same as or within the range of the predicates.

Conclusion:

Clinical testing of the enlighten III laser system demonstrated that the device performs as intended with a favorable safety profile. Results in the study were similar to those reported for the predicate devices, 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 enlighten III is expected to perform as intended in the specified use conditions. The Cutera enlighten III laser system is substantially equivalent to the predicate devices.