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

October 28, 2016

Cutera Incorporated
Mr. Bradley Renton
Vice President, Regulatory Affairs and Medical Affairs, & Compliance Officer
3240 Bayshore Boulevard
Brisbane, California 94005

Re: K160488
Trade/Device Name: 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, 2016
Received: October 6, 2016

Dear Mr. 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 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,

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 below.

510(k) Number *(if known)*
K160488

Device Name
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-III
• 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.

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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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 25, 2016
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 Laser System (K133945 and K140727) Cynosure PicoSure (K121346) Quanta System Q-Plus T (K073549) 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). 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.
Indications for Use:	**<u>1064 nm</u>** 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-III
- 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.

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)

enlighten III Software Verification and Validation Testing Report (V0141 r2)

Results of Clinical Study:

An IRB-approved prospective clinical study was conducted to assess the safety and efficacy of the 670 nm wavelength of the enlighten III laser system for the treatment of benign pigmented lesions.

Forty-eight subjects with Fitzpatrick skin types I-III diagnosed with benign pigmented lesions of the hands, body, or face were enrolled and received a single picosecond 670 nm treatment. Subjects were enrolled in two primary cohorts: 25 subjects with 32 subject-treatment-areas were enrolled in cohort 1; 3 additional subjects with

5 subject-treatment-areas were enrolled between the two primary cohorts; and 20 subjects with a single subject-treatment-area were enrolled in cohort 2. Forty-six subjects completed the study; one patient was lost to follow-up from the 3 subjects enrolled between the two primary cohorts; and one subject was lost to follow-up from the 2nd cohort.

The first cohort of 25 subjects and the 3 additional subjects were enrolled under protocol Ver. 1, and standardized photographs were taken at baseline and 12 weeks following treatment. The 2nd cohort of 20 subjects was enrolled under protocol Ver. 2, and standardized photographs were taken at baseline and 6 weeks following treatment. Blinded assessment of improvement (clearing) in the benign pigmented lesions was completed by three independent dermatologists. Pain levels during treatment and adverse events were recorded during all visits.

For cohort 1, to create a dataset with 25 observations, one from each subject, a single treatment area was randomly selected from each subject for whom multiple treatments were done. This dataset with 25 observations was then created 100 times using a different randomization each time. Greater than 50% BPL lightening was observed in 66% of treated BPL areas, and the median improvement score of 2.00 was statistically significant (one-sample Wilcoxon Signed Test, 95% CI: 1.67 – 2.67, $p<0.0001$). Investigator and subject subjective assessments of improvement were consistent with the blinded review.

For cohort 2, greater than 50% BPL lightening was observed in 74% of treated subjects, and the median improvement score of 2.33 was statistically significant (one-sample Wilcoxon Signed Test, 95% CI: 1.67 – 2.67, $p<0.001$). The mean and standard deviation were 2.12 ± 0.61. Investigator and subject subjective assessments of improvement were consistent with the blinded review.

For cohort 1, the reviewers were consistent (kappa of 0.874) and accurate (kappa of 0.833) in identification of the baseline and post-treatment photographs. Seventy-eight percent of the subject photographs were scored identically or within one grade difference. For cohort 2, the reviewers were consistent (kappa of 1.0) and accurate (kappa of 1.0) in identification of the baseline and post-treatment photographs. Ninety-five percent of the subject photographs were scored identically or within one grade difference. The 3 blinded reviewers' scores were an exact match in 16% of BPL photographs, and in 79% of photographs the 3 scores were within one grade difference.

For cohort 1, 96% percent of subjects were satisfied or extremely satisfied with the results of a single treatment and would repeat the treatment or recommend it to others. For cohort 2, 85% of subjects were satisfied or extremely satisfied with the results of a single treatment, 90% percent of the subjects would repeat the treatment,

and 95% would recommend it to others.

All subjects tolerated treatments well (cohort 1, mean pain score of 1.0 ± 0.2 [1-2]; cohort 2, mean pain score of 0.96 ± 0.37 [0-2] on a 10-point scale). As expected, all subjects experienced minor erythema, edema, and lesion frosting immediately following laser treatment, and most experienced mild crusting of treated lesions. All adverse effects resolved or improved during the study period with no required intervention. No serious adverse events were noted.

Treatment of benign epidermal pigmented lesions with the 670 nm output wavelength of the enlighten III laser system was found to be safe and effective, with minimal discomfort and adverse effects, allowing the conclusion that the enlighten III laser system is substantially equivalent to the predicate devices for the requested indications.

Summary of Technological Characteristics:

The Cutera enlighten III 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 the Cutera enlighten laser system (primary predicate: K133945 and K140727), Cynosure PicoSure (K121346), Quanta System Q-Plus T (K073549), and Cynosure RevLite (K133254). The enlighten III device design and components are very similar to those of the previously cleared enlighten laser system, where the only key difference is the addition of components to produce the 670 nm wavelength. The device design and components are also very similar to those of the Cynosure PicoSure, Quanta System Q-Plus T, 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;
- the laser output at each wavelength is generated within the laser chassis and delivered to the skin through the handpiece attached to the articulated arm; 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.

See Table 5A below.

Conclusion: The enlighten III laser system is substantially equivalent to the predicate devices in terms of indications for use, technical specifications, operating performance features, and general design.

Table 5A—Technical Specification Comparison

	enlighten III Laser System (K160488 current submission)	Cutera enlighten Laser System (K133945 and K140727)	Quanta System Q-Plus T (K073549)	Cynosure PicoSure (K121346)	Cynosure RevLite (K133254)
Wavelength	1064 nm 532 nm 670 nm	1064 nm 532 nm	1064 nm 532 nm 694 nm	755 nm	1064 nm 532 nm 585 nm (with optional dye handpiece) 650 nm (with optional dye handpiece)
Max Pulse Energy	1064 nm: 600 mJ 532 nm: 300 mJ 670 nm: 125 mJ	1064 nm: 600 mJ 532 nm: 300 mJ	1064 nm: 1000 mJ 532 nm: 500 mJ 694 nm: 1000 mJ	200 mJ	1064 nm: 1.6 J 532 nm: 500 mJ 585 nm: unknown 650 nm: 170 mJ
Max Fluence	1064 nm: 10 J/cm² 532 nm: 2.5 J/cm² 670 nm: 4.0 J/cm²	1064 nm: 10 J/cm² 532 nm: 2.5 J/cm²	1064 nm: 22 J/cm² 532 nm: 11 J/cm² 694 nm: 25 J/cm²	6.37 J/cm²	1064 nm: 12 J/cm² 532 nm: 5 J/cm² 585 nm: 10 J/cm² 650 nm: 6 J/cm²
Pulse Duration (nominal)	1064 nm: 750 ps or 2 ns 532 nm: 750 ps or 2 ns 670 nm: 660 ps	750 ps or 2 ns	1064 nm: 6 ns 532 nm: 6 ns 694 nm: 30 ns	450 - 900 ps	1064 nm: 7-20 ns 532 nm: 7-20 ns 585 nm: <7 ns 650 nm: <7 ns
Spot Size	1064 nm and 532 nm: 2, 3, 4, 5, 6, 7, and 8 mm 670 nm: 2, 3, 4, 5, and 6 mm	2, 3, 4, 6, or 8 mm	Up to 6 mm	Zoom 2-6 mm; fixed 2, 3, 4, 6, 8 or 10 mm	Zoom 2-8.5 mm
Output Mode	Pulsed	Pulsed	Pulsed	Pulsed	Pulsed
Repetition Rate	1, 2, 3.3, 5, and 10 Hz or single shot	≤10 Hz or single shot	≤10 Hz or single shot	≤10 Hz or single shot	≤10 Hz or single shot
Laser Media	Q-switched Nd:YAG laser	Q-switched Nd:YAG laser	Q-switched Nd:YAG laser and Q-switched Ruby laser	Q-switched Alexandrite laser	Q-switched Nd:YAG laser
User Interface	Push-button control or LCD color touchscreen	Push-button control or LCD color touchscreen	Push-button control or LCD color touchscreen	Push-button control or LCD color touchscreen	Push-button control or LCD color touchscreen
Treatment Beam Activation	Footswitch	Footswitch	Footswitch	Footswitch	Footswitch
Delivery System	Articulated arm with laser handpiece	Articulated arm with laser handpiece	Articulated arm with laser handpiece	Articulated arm with laser handpiece	Articulated arm with laser handpiece
Aiming Beam	≤1 mW Max at 450 nm	≤1 mW Max at 635 nm	635 nm	630-690 nm	650 nm
Handpiece (How Supplied)	Non-sterile, reusable, cleanable	Non-sterile, reusable, cleanable	Non-sterile, reusable, cleanable	Non-sterile, reusable, cleanable	Non-sterile, reusable, cleanable