DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
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November 6, 2014

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

Re: K140727
Trade/Device Name: enlighten 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 28, 2014
Received: October 29, 2014

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" (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,

David Krause -S

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

Section 4
Indications for Use

510(k) Number (if known): K140727

Device Name: enlighten Laser System

Indications for Use:

The enlighten 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 laser system is indicated for 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 laser system is indicated for tattoo removal for lighter colored tattoo inks, including red and yellow inks, on patients with Fitzpatrick skin types I-III.

Prescription Use ___xx___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Section 5
510(K) Summary

This 510(K) Summary of safety and effectiveness for the enlighten 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
Telephone: Fax: Email:	415-657-5568 – phone 415-715-3568 – fax brenton@cutera.com
Preparation Date:	October 21, 2014
Device Trade Name:	enlighten Laser System
Common Name:	Dermatology Laser
Classification Name:	Instrument, Surgical, Powered, laser 79-GEX, 21 CFR 878.4810
Legally Marketed Predicate Devices:	Cutera Q-Switch Laser System (K102954) Quanta System Q-Plus T (K073549) Cynosure PicoSure (K121346)
Device Description:	The enlighten laser system is a multi-wavelength, pulsed laser system designed for tattoo removal. A key feature of the device is its ability to produce multiple laser wavelengths (1064 nm and 532 nm) and pulse widths (750 ps and 2 ns, nominal). 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. The system is operated using 110 V mains AC power. 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 a detachable tip that determines the spot size of the laser beam on the treatment surface. Multiple tips are provided to vary the spot size as desired for treatment. The beam of a low-power red diode laser is also transmitted through the arm to provide an aiming beam.
Intended Use:	The enlighten laser system is intended for use in surgical and aesthetic applications in the medical specialties of dermatology and general and plastic surgery.

Specific Indications:

1064 nm:

The 1064 nm wavelength of the enlighten laser system is indicated for 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 laser system is indicated for tattoo removal for lighter colored tattoo inks, including red and yellow inks, on patients with Fitzpatrick skin types I-III.

Performance Data:

IEC 60601-1 Medical Electrical Equipment – Part 1: General Requirements for Safety

IEC 60601-1-2 Medical Electrical Equipment – Part 1-2: General Requirements for Safety – Collateral Standard: Electromagnetic Compatibility

Nova Software Verification and Validation Testing Report (V0083 r1)

Results of Clinical Study:

An IRB-approved multicenter prospective clinical study was conducted to assess the safety and efficacy of the enlighten laser system for tattoo removal. Forty-two subject tattoos of black/blue ink, alone or with other colors, older than one year and 2 to 12 square inches in size were enrolled. Forty-one subject tattoos completed the study with 1 lost to follow-up. Subject tattoos were divided into 2 portions for treatment with the Cutera Investigational Q-Switched Nd:YAG laser and a comparator Q-switched Nd:YAG laser respectively, based on randomization assignment. Subject tattoos received 2 to 3 treatments with both laser systems performed 6 weeks apart. Subject tattoos were followed for 6 weeks following final laser treatment.

Standardized photographs were taken at baseline and 6 weeks following the final treatment. Primary efficacy assessments were performed through review of tattoo photographs taken at baseline and 6 weeks post-final treatment by a panel of independent, blinded reviewers (dermatologists). Safety was assessed by the investigator at each visit and via phone surveys (subject reporting) conducted at 3 and 14 days following each laser treatment.

Blinded review of baseline and post-treatment tattoo photographs resulted in a clinically and statistically significant mean improvement of 2.54 (95% CI: 2.13–2.94) and 2.17 (95% CI: 1.77–2.57) for the Cutera Investigational device and comparator device, respectively, at 6 weeks post-final treatment. The mean difference in reviewer's global assessment of improvement scores between the Investigational and comparator devices was 0.37 (95% CI: 0.20–0.53), indicating that the Investigational device resulted in more clearing than the comparator device at 6 weeks following 2 to 3

treatment sessions. This result was statistically significant ($p<0.001$).

All subjects tolerated treatments well and pain scores were similar with both the investigational and comparator devices (mean pain scores of 4.1 (0.9-0) and 4.4 (0-9) respectively). As expected, subjects experienced erythema, edema and pin-point bleeding in both treatment arms following laser treatment. No serious adverse events were noted.

Subgroup analysis was performed looking at pulse duration, wavelength, and patient skin type. The first subgroup analysis divided subjects into cohorts based on pulse duration: (1) subjects treated with the investigational device using ps pulse durations only; (2) subjects treated with a combination of ps and ns pulse durations in the investigational arm; (3) subjects treated only with ns pulse durations in the investigational arm. The second subgroup analysis divided subjects into cohorts based upon treatment wavelength: (1) treatments were administered using the 532 nm wavelength; (2) only the 1064 nm wavelength was used during laser treatments. The final subgroup analysis divided subjects into cohorts based upon patient skin type: (1) Fitzpatrick skin type IV-VI; (2) Fitzpatrick skin type I-III.

Blinded Reviewer assessment of tattoo clearing at 6 weeks post-treatment for subgroup analysis 1 (Pulse Duration) for the subjects in cohort 1 (treated only with ps pulses) resulted in a clinically and statistically significant mean improvement score of 3.2 (95% CI: 2.54 – 3.86, $p<0.001$) in the investigational arm. Subjects in cohort 2 (treated with combination of ps and ns pulses) had a clinically and statistically significant mean improvement score of 2.77 (95% CI: 2.23 – 3.32, $p<0.001$). Subjects assigned to cohort 3 (ns pulse only) had a clinically and statistically significant mean improvement score of 2.3 (95% CI: 1.91 – 2.69, $p<0.001$). In all cohorts, the investigational device showed a statistically significant higher clearance than the comparator device, with ps pulses only having the greatest difference [0.7 (95% CI: 0.22 – 1.18, $p=0.01$)], followed by ps and ns [0.46 (95% CI: 0.10 – 0.81, $p=0.015$)], and then ns pulses only [0.26 (95% CI: 0.05 – 0.47, $p=0.018$)].

Blinded Reviewer assessment results for subgroup analysis 2 (Wavelength) for subjects in cohort 1 of subgroup 2, who were treated with the 532 nm wavelength of the investigational and comparator devices, and cohort 2 of subgroup 2, who were treated with only the 1064 nm wavelength of the investigational and comparator devices, demonstrated clinically and statistically significant mean improvement scores for the investigational treatment arm of 2.6 (95% CI: 1.91 – 3.29, $p<0.001$) and 2.53 (95% CI: 2.21 – 2.85, $p<0.001$) respectively based on blinded reviewers' photographic assessments of tattoo clearing at 6 weeks post-treatment. These improvement scores were consistent with the overall study population.

Subgroup analysis was performed based on patient skin type (subgroup analysis 3). At 6 weeks post-final treatment, subjects in cohort 1 of subgroup 3 had a clinically and statistically significant mean improvement score of 2.33 (95% CI: 1.55 – 3.12, $p<0.001$) in the investigational arm based on blinded reviewers' photographic assessment. The mean clearing score for the investigational arm in this cohort is slightly lower than the overall study population; however, the mean score in the comparator arm for this cohort was also 0.5 less than that of the comparator arm for the total study population. Subjects with FST I-III had mean tattoo clearing scores in the investigational and comparator arms consistent with the total study population. Safety data showed equivalent adverse event profiles for subjects for both patient cohorts. There were no significant differences in the incidence and severity of adverse events occurring in the investigational treatment arm versus the comparator arm.

Data for 19 additional unilateral picosecond-only treatment sessions was also presented. The blinded reviewers' photographic assessments of subject tattoos at 12 weeks post-final treatment relative to baseline resulted in a mean tattoo clearance rating of 3.4. This clearance is consistent with the 3.2 clearance rating achieved in subjects in cohort 1 subgroup analysis 1, who also received picosecond treatments only. All subjects experienced edema and erythema following laser treatment; the incidence and severity were consistent with those observed in the comparator-controlled clinical study. No unexpected or serious adverse events were reported.

The treatment outcomes observed were consistent with the results of published studies for tattoo removal with nanosecond QS lasers. The comparative results between the investigational and active comparator arms of this study showed substantially equivalent outcomes and adverse events for both treatment arms.

Tattoo removal with the enlighten laser system was found to be safe and effective allowing the conclusion that the enlighten laser system is substantially equivalent to the predicate devices for the requested indication.

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

Section 5
510(K) Summary

	enlighten Laser System	Cutera Q-Switch Laser System (K102954)	Quanta System Q-Plus T (K073549)	Cynosure PicoSure (K121346)
Wavelength	1064 nm Nd:YAG laser 532 nm Nd:YAG laser	1064 nm Nd:YAG laser 532 nm Nd:YAG laser	1064 nm Nd:YAG laser 532 nm Nd:YAG laser	755 nm Alexandrite laser
Max Pulse Energy	1064 nm: 600 mJ 532 nm: 300 mJ	1064 nm: 1600 mJ 532 nm: 500 mJ	1064 nm: 1000 mJ 532 nm: 500 mJ	200 mJ
Max Fluence	1064 nm: 10 J/cm² 532 nm: 2.5 J/cm²	1064 nm: 12 J/cm² 532 nm: 5 J/cm²	1064 nm: 22 J/cm² 532 nm: 11 J/cm²	6.37 J/cm²
Pulse Duration (nominal)	750 ps or 2 ns	5-20 ns	6 ns	≤ 900 ps
Spot Size	2, 3, 4, 6 or 8 mm	2-8 mm	Up to 6 mm	Zoom 2-6 mm; fixed 2, 3, 4, 6, 8 or 10 mm
Output Mode	Pulsed	Pulsed	Pulsed	Pulsed
Repetition Rate	≤ 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	Q-switched Alexandrite 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
Treatment Beam Activation	Footswitch	Footswitch	Footswitch	Footswitch
Delivery System	Articulated arm with user-detachable handpiece tips	Articulated arm with user-detachable handpiece tips	Articulated arm with user-detachable handpiece tips	Articulated arm with user-detachable handpiece tips
Aiming Beam	635 nm	635-655 nm	635 nm	630-690 nm
Handpiece Tips (How Supplied)	Non-sterile, reusable, cleanable	Non-sterile, reusable, cleanable	Non-sterile, reusable, cleanable	Non-sterile, reusable, cleanable