Cutera, Inc.
Julia Brown
Manager, Regulatory Affairs
3240 Bayshore Blvd.
Brisbane, California 94005

December 12, 2018

Re: K182997
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 29, 2018
Received: October 30, 2018

Dear Julia Brown:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Neil R Ogden -S

Digitally signed by Neil R Ogden -S
Date: 2018.12.12 13:52:37 -05'00'

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K182997

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)
• treatment of acne scars on patients with Fitzpatrick skin types II-V when used with the Micro Lens Array handpiece attachment

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:
70 nm wavelength of the enlighten family of 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.

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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:	Julia Brown 415-657-5575 – phone 415-715-3575 – fax jbrown@cutera.com
Preparation Date:	December 11, 2018
Device Trade Name:	enlighten III Laser System
Common Name:	Dermatology Laser
Classification Name:	Powered Laser Surgical Instrument, GEX, 21 CFR 878.4810
Legally Marketed Predicate Devices:	Cutera enlighten III Laser System (K172077) Syneron Candela PicoWay Laser System (K170597)
Legally Marketed Reference Device:	Cynosure PicoSure Workstation (K173199)
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, as well as an optional Micro Lens Array handpiece attachment, which can be attached to the distal end of the handpiece to fractionate the treatment beam. The beam of a low-power blue diode laser is also transmitted through the arm to provide an aiming beam.
Indications for Use:	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. **<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)
- treatment of acne scars on patients with Fitzpatrick skin types II-V when used with the Micro Lens Array handpiece attachment

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: There are no changes to the software, electrical safety, electromagnetic compatibility, or biocompatibility associated with this submission. Therefore, no additional performance testing is necessary for the expanded indications for use.

Results of Clinical Study: An IRB-approved, open-label, prospective, multicenter, pivotal study was conducted to assess the safety and efficacy of the Cutera enlighten III laser system with the Cutera Micro Lens Array handpiece attachment for the treatment of acne scars.

Thirty-three subjects received treatment with the 1064 nm laser. 93.9% of subjects showed improvement in acne scars as assessed by correct identification of the temporal order of randomized baseline and follow-up visit images by at least two of three blinded dermatologist evaluators.

Based on subject questionnaires, 76% percent of subjects reported that they were very satisfied or satisfied with the treatment results, and 91% of subjects would likely have the investigational treatment again.

The primary and secondary efficacy endpoints were therefore met. The safety endpoints of the clinical study were also met, with subjects experiencing no unexpected adverse events.

In conclusion, the study results demonstrate that the 1064 nm wavelength of the enlighten III laser system, when equipped with a

Micro Lens Array handpiece attachment, can safely and effectively be used for the treatment of acne scars.

Summary of Technological Characteristics:

The Cutera enlighten III laser system that was used in the clinical study and is the subject of this submission is identical to the previously cleared enlighten III laser system (K172077). There are no hardware or software changes to the enlighten III laser system associated with this submission.

The device design and specifications of the enlighten III laser system with the Micro Lens Array handpiece attachment are also very similar to those of the previously cleared Syneron Candela PicoWay Laser System (K170597) with the Resolve handpiece and the Cynosure PicoSure Workstation (K173199) with the Focus Lens Array handpiece attachment. All of these systems feature a picosecond laser with a fractionated beam, and all have similar mechanisms of action, although beam-splitting mechanisms vary. Beam fractionation is achieved via a micro lens array for the Micro Lens Array handpiece attachment; via a diffractive lens array for the Focus Lens Array handpiece attachment; and via holographic diffractive beam-splitting technology for the Resolve handpiece.

The enlighten III laser system with the Micro Lens Array handpiece attachment shares similar key design aspects with its predicate device, including the same or similar laser wavelengths, pulse energy, fluence, spot sizes, and laser types. The minor differences do not raise any new safety or effectiveness questions.

Conclusion:

Clinical testing of the enlighten III laser system with the Micro Lens Array handpiece attachment demonstrated that the device performs as intended with a favorable safety profile. Results in the study were similar to those reported for the PicoWay with the Resolve handpiece, in support of substantial equivalence. The enlighten III laser system with the Micro Lens Array handpiece attachment is substantially equivalent to the predicate devices.