DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

April 25, 2017

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

Re: K170936
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: March 29, 2017
Received: March 30, 2017

Dear Dr. 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 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 -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

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)*
K170936

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-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.

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
Special 510(K) Summary – Device Modification

This 510(K) Summary of safety and effectiveness for the modified Cutera 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:	April 19, 2017
Device Trade Name:	Cutera 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 (K160488)
Legally Marketed Reference Devices:	Quanta Systems SpA, Discovery Pico Family (K163222) Cynosure, RevLite (K133254)

Device Description: The modified Cutera 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.

Indications for Use:

1064 nm

The 1064 nm wavelength of the Cutera 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 Cutera 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 Cutera enlighten III laser system is indicated for treatment of benign pigmented lesions on patients with Fitzpatrick skin types I-III.

Device Modifications

The purpose of this submission is to modify the control software of the previously cleared Cutera enlighten III laser system to enable access to the full parameter range of the enlighten III laser system. The modified and unmodified systems are identical in mechanical, electrical, and thermal design. The modified software will:

- Change the maximum delivered energy from 600 mJ to 800 mJ for the 1064 nm wavelength and from 300 mJ to 400 mJ for the 532 nm wavelength, while maintaining the previously cleared maximum treatment fluences of 10 J/cm^2 and 2.5 J/cm^2 for the 1064 nm and 532 nm wavelengths, respectively.
- Add 9 and 10 mm incremental spot sizes for the 1064 and 532 nm wavelengths.
- Add 2 ns pulse duration for the 670 nm wavelength.

Cutera has determined that no new risks have been introduced due to the above changes, as the maximum treatment fluence for all wavelengths remains unchanged and there are no changes to the intended use or indications for use.

Performance Data:

enlighten III Software Verification and Validation Testing Report (V0140 rA1)

The modified and unmodified devices are electrically, mechanically, and thermally identical and comply with the following standards:

- IEC 60601-1 Medical Electrical Equipment – Part 1: General Requirements for Safety (Edition 3.1, 2012), including:
  - IC 60601-1-6 Medical Electrical Equipment – Part 1-6: General Requirements for Safety - Collateral Standard:

Usability (Edition 3.1, 2013)

- IEC 62366 Medical Devices – Application of Usability Engineering to Medical Devices (Edition 1.1, 2014)
- 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)
- IEC 60825-1 Safety of Laser Products – Part 1: Equipment Classification and Requirements (Edition 2.0, 2007)

- 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)

Summary of Technological Characteristics:

The modified Cutera enlighten III laser system has the same intended use and indications for use and the same fundamental scientific technology as the previously cleared unmodified Cutera enlighten III laser system (K160488), Quanta System Q-Plus T (K073549), and Cynosure RevLite (K133254). The device design and components are also very similar to these devices. For each of these devices:

- 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 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 modified Cutera 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 and reference devices. The repetition rate of the enlighten III laser system is the same as or within the repetition rate range of the

predicate device. 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 predicate and reference devices.

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