June 6, 2023

Cutera, Inc.
Amogh Kothare
VP, Clinical and Regulatory Affairs
3240 Bayshore Blvd.
Brisbane, California 94005

Re: K230660
Trade/Device Name: AviClear 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 10, 2023
Received: March 10, 2023

Dear Amogh Kothare:

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/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Jianting Wang -S

Jianting Wang
Acting Assistant Director
DHT4A: Division of General Surgery Devices
OHT4: Office of Surgical
and Infection Control Devices
Office of Product Evaluation and Quality
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K230660

Device Name

AviClear Laser System

Indications for Use *(Describe)*

The AviClear Laser System is indicated for the long-term treatment of mild to severe inflammatory acne vulgaris.

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.

K230660
510(k) Summary

This 510(k) Summary of safety and effectiveness for the AviClear 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:	Amogh Kothare akothare@cutera.com m. (415) 690-6796 o. (415) 657-5730 f. (415) 715-3730
Preparation Date:	March 10, 2022
Device Trade Name:	AviClear Laser System
Common Name:	Dermatology Laser
Classification Name:	Powered Laser Surgical Instrument, GEX, 21 CFR 878.4810
Legally Marketed Predicate Device:	AviClear Laser System (K213461)
Indications for Use:	The AviClear Laser System is indicated for the long-term treatment of mild to severe inflammatory acne vulgaris.
Device Description:	The AviClear Laser System is an infrared diode laser device with a nominal wavelength of 1726 nm. Similar to other well-established infrared laser devices, the device uses a combination of the treatment spot size, beam characteristics, and tissue absorption and scattering coefficients at the output wavelength to deliver energy to tissues at depth. The wavelength of the laser energy, when combined with the pre, parallel (during energy delivery), and post cooling of epidermal and superficial dermal structures, causes selective heating of dermal tissue at different depths. The 1726 nm laser energy heats the chromophore, sebum within sebaceous glands, which results in controlled thermal injury of the sebaceous glands, the ultimate treatment target, thus reducing or eliminating sebum production and causing an improvement in acne vulgaris. The diode laser and associated beam delivery optics, laser and electronics power supplies, control electronics, and cooling system are housed inside a console equipped with a touchscreen user interface. The laser treatment parameters are selected using the touchscreen. The treatment handpiece has an integrated scanner for delivering treatment spot(s) in an operator-selected pattern; a temperature-controlled skin-contact cooling window to provide thermal protection for the epidermis and superficial dermis and through which energy is delivered to the patient; and skin-contact pressure sensors that enable laser energy delivery when the system is in Ready mode and the footswitch is depressed.

Performance Data:

- IEC 60601-1/A1:2012 Medical Electrical Equipment – Part 1: General Requirements for Safety
  - IEC 60601-1-6:2010/A1:2013 Medical electrical equipment – Part 1-6: General Requirements For Basic Safety And Essential Performance – Collateral Standard: Usability
  - IEC 60601-2-22:2007/A1:2012 Medical Electrical Equipment – Part 2-2: Particular Requirements for the Basic Safety and Essential Performance of High Frequency Surgical Equipment and High Frequency Surgical Accessories
  - IEC 60825-1:2014 Safety of laser products – Part 1: Equipment classification and requirements
- IEC 60601-1-2:2014 Medical Electrical Equipment – Part 1-2: General Requirements for Safety – Collateral Standard: Electromagnetic Disturbances
- Software Verification and Validation Testing
- Biocompatibility testing of patient-contact materials according to ISO-10993-1:2018 Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process

Results of Clinical Study:

Data for the clinical study was previously submitted under K213461, resulting in FDA 510k clearance for the treatment of mild to severe inflammatory acne vulgaris. This is a prospective, multi-center, clinical study to assess the safety and effectiveness of the Cutera AviClear Laser System for the treatment of mild to severe acne vulgaris. The study's primary effectiveness objective was to show more that than 50% of subjects enrolled were Responders who achieved Treatment Success, where Treatment Success was defined as a subject with ≥50% fewer inflammatory acne lesions with respect to baseline. Safety was assessed by a review of the totality of all reported adverse events and their resolutions, including assessments of treatment discomfort.

104 subjects, 57% female and 43% male, 16 to 40 years (avg. 22.2 ± 5.5), diagnosed with mild, moderate, and severe acne vulgaris were enrolled. Subjects received up to 3 treatments and were followed up through 52-weeks post final treatment, with 12-weeks being primary end-point.

Details surrounding the Primary, Secondary Effectiveness as well as Safety Analysis have been outlined in the previous 510(K) summary submitted under K213461.

- **Long Term Effectiveness Analysis:** At the 52-week post-final-treatment follow-up visit, 91.5% of subjects achieved treatment success ($p<0.001$); thereby showing durable and efficacious results from the 12-week post-final-treatment follow-up visit.
- **Secondary Effectiveness Analyses:**

  Improvement in Investigator's Global Assessment
  - By the 52-week follow-up visit, the number of subjects had increased to 66.2% for the Clear or Almost Clear skin categories.

Improvement from Baseline in Non-Inflammatory Lesion Counts

- The non-inflammatory lesion counts reduced from 25% (p=0.001) at 12-week mark to 57.6% reduction from Baseline at the 52-week follow-up assessment (p<0.001).

Subject Satisfaction

- Approximately 70% of subjects reported they were either “Very likely” or “Likely” to have the laser treatment again at both the 12- and 52-week follow-up visits.

- **Safety Variable Analysis:** All treatment sessions were well tolerated with an average discomfort score of 5.23 ± 1.15. No treatment sessions ended prematurely due to excessive treatment discomfort. No reports of serious adverse events (SAEs) and unanticipated adverse device effects of any severity (SUADEs/UADEs).

  There were no residual adverse events at the 52-week mark. Adverse events through 12-week follow-up can be found outlined in previous 510(K) summary submitted under K213461. Most commonly reported adverse events from the 12-week mark are summarized below:

  - As is expected with laser procedures, all subjects experienced mild, transient erythema, while 98.1% of subjects experienced edema. Erythema self-resolved within minutes to hours, while edema self-resolved within hours to days.
  - 45.2% of subjects experienced mild acne purging / flare-up; typically resolving with no medical intervention.
  - 18.3% of subjects experienced mild dryness; typically resolving with application of topical skin moisturizers.
  - There were no reports of blistering, hyper- or hypopigmentation, or scarring adverse events in any subjects.

As demonstrated by the results of the clinical study, the AviClear Laser System continues to demonstrate safe and effective performance at the one-year follow-up, thus supporting the claim for long-term treatment of mild to severe inflammatory acne vulgaris.

Comparison of the Proposed Device and Predicate Device:

The technical specifications of the previously cleared AviClear Laser System and the subject device are identical, as tabulated below. However, the following minor design modifications were made to the subject device:

- Slimmer handpiece body (no change to patient contact end of handpiece)
- Updated touchscreen user interface

Technical Specification Comparison

	AviClear Laser System (current submission)	AviClear Laser System K213461
Wavelength	1726 nm	1726 nm
Max Fluence	Single pulse mode: 30 J/cm² Double pulse mode: 20 J/cm^2	Single pulse mode: 30 J/cm² Double pulse mode: 20 J/cm^2
Max Pulse Energy	5 J	5 J
Pulse Duration	Up to 50 ms	Up to 50 ms
Spot Size	3 mm or 10 mm 7-spot hexagonal array	3 mm or 10 mm 7-spot hexagonal array
Laser Type	Diode	Diode
Output Mode	Quasi-CW	Quasi-CW
User Interface	Touchscreen	Touchscreen
Treatment Beam Activation	Footswitch and handpiece contact sensors verifying firm and even contact between cooling window and skin is made and maintained	Footswitch and handpiece contact sensors verifying firm and even contact between cooling window and skin is made and maintained
Delivery System	Optical fiber handpiece	Optical fiber handpiece
Skin Cooling	0°C to 5°C, Sapphire window	0°C to 5°C, Sapphire window
Aiming Beam	650 nm	650 nm
Handpiece	Non-sterile, reusable, cleanable	Non-sterile, reusable, cleanable

Conclusion: As demonstrated by the results of the clinical study, the AviClear Laser System is safe and effective for the requested indication for use. The clinical study also confirmed that there are no new concerns for safety or efficacy for the updated indication for use. The minor cosmetic design changes to the handpiece and touchscreen do not impact the technical specifications nor the safety and effectiveness of the device.