July 11, 2025

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

Re: K251149
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: April 11, 2025
Received: April 14, 2025

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

TANISHA L. HITHE -S

Digitally signed by TANISHA L. HITHE -S
Date: 2025.07.11 13:52:34 -04'00'

Tanisha Hithe
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: 07/31/2026
*See PRA Statement below.*

510(k) Number *(if known)*
K251149

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.**

510(k) Summary
K251149

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.

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| Applicant: | Cutera, Inc. |
| Address: | 3240 Bayshore Blvd., Brisbane, CA 94005 |
| Contact Person: | Julia Brown<br><br>jbrown@cutera.com<br>(415) 657-5575 |
| Preparation Date: | July 9, 2025 |
| Device Trade Name: | AviClear Laser System |
| Common Name: | Laser surgical instrument for use in general and plastic surgery and in dermatology |
| Classification Name: | Powered Laser Surgical Instrument |
| Regulation Number: | 878.4810 |
| Product Code: | GEX |
| Legally Marketed Predicate Device: | AviClear Laser System (K230660) |
| Device Description Summary: | 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.<br><br>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. Two treatment handpieces are available. Each 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. |
| Intended Use/ Indications for Use: | The AviClear Laser System is indicated for the long-term treatment of mild to severe inflammatory acne vulgaris. |

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| Indications for Use Comparison: | The requested indication for use is identical to that of the predicate device. |
| Technological Comparison: | The majority of technological characteristics of the modified AviClear Laser System are identical to the previously cleared AviClear Laser System. However, the modified device has a new Large handpiece with a 3 mm x 3 mm square spot and rectangular arrays of up to 25 spots; and the post-treatment skin cooling duration was reduced from 2 seconds to 1 second. The differences in technological characteristics do not raise different questions of safety and effectiveness, as demonstrated in the clinical study. |
| Nonclinical Testing Summary: | The AviClear Laser System was tested according to the following standards:<br>• IEC 60601-1 Ed. 3.2 2020 Medical electrical equipment – Part 1: General requirements for basic safety and essential performance<br>• IEC 60601-1-6 Ed. 3.2 2020 Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral standard: Usability<br>• IEC 60601-2-22 Ed. 4.0 2019 Medical electrical equipment – Part 2-22: Particular requirements for basic safety and essential performance of surgical, cosmetic, therapeutic and diagnostic laser equipment<br>• IEC 60825-1 Ed. 3.0 2014 Safety of laser products – Part 1: Equipment classification and requirements<br>• IEC 60601-1-2 Ed. 4.1 2020 Medical electrical requirement – Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic Disturbances.<br>• Software Verification and Validation Testing |
| Clinical Testing Summary: | A multi-center, prospective, comparative double-arm safety study was conducted to evaluate the incidence and severity of reported adverse events from dose-ranging treatments delivered with the modified device, with Large and Universal handpieces and 1-second post-cool, to the previously cleared device, with Universal handpiece and 2-second post-cool; and to compare through histological tissue evaluation the modified device to the previously cleared device.<br>A total of 10 subjects were enrolled across two study arms, and all completed the study per protocol. The mean age of subjects was 53.9 ± 11.7 years [range: 33 to 70 years]. The majority of the subjects were female (90%) and White/Caucasian (70%). Subjects with Fitzpatrick Skin Types II (30%), III (40%), and IV (30%) were enrolled. The enrolled subjects, scheduled for abdominoplasty and/or rhytidectomy surgeries, underwent laser treatments with varying parameters on their pre-excised skin prior to their respective surgeries.<br>In the first arm, subjects scheduled for abdominoplasty procedures received dose-ranging treatments with the previously cleared and modified devices on their pre-excised skin. Subjects were monitored for adverse events immediately post-treatment and throughout a 2 (+1) week period. The primary outcome measure of the first arm of the study was evaluated by |

totality of all reported adverse events (AEs) and adverse device effects (ADEs) throughout the study duration to determine if the modified device had incidence of new ADEs when compared to the previously cleared device.

Overall, no new or unexpected adverse device effects ADEs were observed with the modified device. The reported ADEs were consistent with those of the previously cleared device, and no cases of blistering or scarring were reported in any subjects.

In the second arm, subjects scheduled for rhytidectomy procedures received treatments with the previously cleared and modified devices on their periauricular pre-excised skin. Subjects returned 2- or 3-days post-treatment, on the day of their scheduled rhytidectomy surgery. During surgery, the treated skin was excised and preserved in formalin for histological assessment. A comparative analysis was conducted via histological tissue assessment by an independent dermatopathologist to determine the extent of thermal impact (i.e., epidermal and dermal changes, cellular changes, inflammatory changes, and overall tissue architecture) delivered by each device.

Histological assessment of the laser-treated tissue revealed comparable thermal effects at the highest available settings for both the previously cleared and modified devices. No treatments resulted in epidermal injury; all demonstrated similar depths of selective, noninvasive sebaceous gland destruction; and no associated inflammation was observed. Additionally, all adjacent cellular structures remained intact and there was no denaturation of the adjacent collagen.

The findings of the clinical study demonstrate that the thermal safety profile of the modified device, with Large and Universal handpieces and 1-second post-cool, is not significantly different from that of the previously cleared device, with Universal handpiece and 2-second post-cool. Accordingly, the modified device can be safely and effectively used for the long-term treatment of mild to severe inflammatory acne vulgaris.

Conclusion: The modified AviClear Laser System is substantially equivalent to the predicate device, the previously cleared AviClear Laser System (K230660).