



March 24, 2022

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

Re: K213461

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: October 26, 2021

Received: October 27, 2021

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,

Purva Pandya, D.Eng.
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

Indications for Use

510(k) Number (if known)
K213461

Device Name
AviClear Laser System

Indications for Use (Describe)

The AviClear Laser System is indicated for the 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.

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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.

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Preparation Date: March 21, 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: Candela Smoothbeam Laser System (K041242)

Indications for Use: The AviClear Laser System is indicated for the treatment of mild to severe inflammatory acne vulgaris.

Device Description: The AviClear Laser System is an infrared Indium Phosphide (InP) 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.

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- 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

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Results of Clinical Study:

An IDE-approved, prospective, multi-center, significant-risk clinical study was conducted under IRB oversight to assess the safety and effectiveness of the AviClear Laser System for the treatment of mild to severe acne vulgaris. The study's primary effectiveness objective was to show more than 50% of subjects enrolled were Responders who achieved Treatment Success, where Treatment Success was defined a subject with $\geq 50\%$ fewer inflammatory acne lesions 12 weeks after their final treatment visit than at baseline.

104 subjects, 59 female (57%) and 45 male (43%), aged 16 to 40 years (avg. 22.2 ± 5.5 years), diagnosed with Mild ($n=1$), Moderate ($n=81$), or Severe ($n=22$) acne vulgaris were enrolled and entered the Treatment Phase of the study at 7 US sites. In the Treatment Phase, subjects received a total of 304 treatments, spaced 2 to 5 weeks apart, to facial skin and were followed 10 (± 5) days after each treatment visit via phone and at 4 ($-1/+2$) weeks and 12 (± 2) weeks after their final treatment visit. After completing the 12-week follow-up visit, the subjects entered the Follow-up Phase of the study and are scheduled for follow-up visits at 26 (± 3) weeks and 52 (± 4) weeks post-final treatment.

Standardized photographs of subjects were taken at baseline and at 4- and 12-week follow-up visits. Prior to a subject being formally enrolled, baseline photographs of the subject were sent to a panel of three trained expert physicians for Investigator Global Assessment (IGA) grading and, if the median of the three baseline IGA grades was at least Mild, the subject was enrolled. Subject photographs taken at the 4- and 12-week follow-up visits were sent to the same panel of trained expert physicians for independent IGA grading with the median of the three IGA grades being assigned to the subject for that study timepoint.

Study-timepoint randomized (baseline, 4-week follow-up, and/or 12-week follow-up) sets of left and right 45° frontal photographs of each subject were sent to three trained and experienced acne lesion counters for independent counting of inflammatory (papules, pustules, and nodules) and noninflammatory (open and closed comedones) acne lesions. The acne lesion counters were blinded to the study design, including the success criteria and study timepoints being evaluated. The median of the three count values for each facial side and lesion type was assigned to the subject for each study timepoint.

All subjects who were enrolled and received at least one treatment with the investigational Cutera 1726 nm laser system were included in the Safety/Intent-to-Treat (ITT) Cohort. The Per-Protocol (PP) Cohort was defined as the group of subjects who completed all treatment procedures and who completed the 12-week post-final treatment visit without any major protocol deviations.

Subjects were also assigned into subgroups by Age (16-19 years, 20-35 years, or >35 years), Sex (female or male), Fitzpatrick Skin Type (FST I-III, FST IV-V, or FST VI), and baseline IGA (Mild, Moderate, or Severe), and Responder rates and the frequency of device related adverse events within these subgroups were compared.

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Primary Effectiveness Analysis

For the ITT cohort (n=104), the median and mean inflammatory lesion counts at baseline were 56 (Min 14, Max 297) and 63.4 ± 40.2 , respectively. There were median and mean reductions of 41.5% and $37.1\% \pm 28.5\%$, respectively, in the inflammatory lesion counts from baseline ($p < 0.001$) at the 4-week follow-up visit, which increased to median and mean reductions of 55.9% and $49.5\% \pm 26.5\%$, respectively, at the 12-week follow-up visit ($p < 0.001$). At the 4-week follow-up visit, 35.6% (n=37) of subjects had achieved Treatment Success, and at the 12-week follow-up visit, 77.9% (n=81; 95% CI 69%-85%) of subjects had achieved Treatment Success; therefore, the Primary Effectiveness Endpoint of the study was met.

Supportive Analysis of the Primary Effectiveness Endpoint (PP Cohort)

For the PP cohort (n=89), the median and mean inflammatory lesion counts at baseline were 56 (Min 14, Max 297) and 61.4 ± 38.4 , respectively. There were median and mean reductions of 37.8% and $34.7\% \pm 28.4\%$, respectively, in the inflammatory lesion counts from baseline ($p < 0.001$) at the 4-week follow-up visit, which increased to median and mean reductions of 55.9% and $49.4\% \pm 26.8\%$, respectively, at the 12-week follow-up visit ($p < 0.001$). At the 4-week follow-up visit, 32.6% (n=29) of subjects in the PP cohort had achieved Treatment Success, at the 12-week follow-up visit, 79.8% (n=71; 95% CI 70%-88%) of subjects had achieved Treatment Success; therefore, the Primary Effectiveness Endpoint of the study was also met in the PP cohort.

Sensitivity Analyses of the Primary Effectiveness Endpoint (ITT Subgroups)

Responder rates in Age subgroups 16-19 years (n=42) and 20-35 years (n=60) were 83.3% (95% CI: 69%, 93%) and 75.0% (95% CI: 62%, 85%), respectively. Both results were statistically significant ($p < 0.001$) for the Responder rate being greater than 50%. The Responder rate in subgroup >35 years (n=2) was 50%; however, the result was not statistically significant ($p > 0.999$).

Responder rates in Sex subgroups female (n=59) and male (n=45) were 76.3% (95% CI: 63%, 86%) and 80% (95% CI: 65%, 90%), respectively. Both results were statistically significant ($p < 0.001$) for the Responder rate being greater than 50%.

Responder rates in FST subgroups Grades I-III (n=45) and Grades IV-V (n=54) were 77.8% (95% CI: 63%, 89%) and 75.9% (95% CI: 62%, 86%), respectively. Both results were statistically significant ($p < 0.001$) for the Responder rate being greater than 50%. The Responder rate in FST subgroup Grade VI (n=5) was 100%; however, the result was not statistically significant ($p > 0.999$).

Responder rates in Baseline IGA subgroups Moderate (n=81) and Severe (n=22) were 82.2% (95% CI: 70%, 88%) and 72.7% (50%, 89%), respectively. Both results were statistically significant ($p < 0.001$ and $p = 0.033$, respectively) for the Responder rate being greater than 50%. Only one subject with Mild acne severity at baseline was enrolled in the study and the subject was not a Responder.

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**Secondary Effectiveness Analysis (IGA Clear/Almost Clear;
% Change in Noninflammatory Lesion Count; Subject Satisfaction)**

For the ITT cohort, 1, 81, and 22 subjects were graded IGA Mild, Moderate, and Severe, respectively, at baseline. By the 4-week follow-up visit, 1, 9, and 45 subjects were graded IGA Clear, Almost Clear, and Mild, respectively, which further improved to 2, 30, and 41 subjects graded IGA Clear, Almost Clear, and Mild, respectively, by the 12-week follow-up visit. For subjects in the PP cohort (n=89), 1, 69, and 19 subjects were graded IGA Mild, Moderate, and Severe, respectively, at baseline. By the 4-week follow-up visit, 1, 7, and 39 subjects were graded IGA Clear, Almost Clear, and Mild, respectively, which further improved to 2, 30, and 39 subjects graded IGA Clear, Almost Clear, and Mild, respectively, by the 12-week follow-up visit. By the 12-week follow-up visit, 31% and 36% of subjects in the ITT and PP cohorts, respectively, had achieved a two or more IGA grade improvement and had Clear or Almost Clear skin.

In both the ITT and PP cohorts, statistically significant reductions were seen at 4-week and 12-week follow-up visits in noninflammatory lesion counts ($p < 0.001$ at both time points for both cohorts). For the ITT cohort, there was a 15% median reduction in non-inflammatory lesion counts at 4 weeks, which further increased to a 25% median reduction from baseline at the 12-week follow-up assessment ($p < 0.001$ and $p = 0.002$, respectively). For the PP cohort, there was a 13.3% median reduction in non-inflammatory lesion counts at 4 weeks, which further increased to a 25% reduction from baseline at the 12-week follow-up assessment ($p = 0.003$ and $p = 0.002$, respectively).

At the 4-week post-final treatment follow-up visit, 18 (17.3%) subjects were extremely satisfied, 48 (46.2%) subjects were satisfied, 27 (26%) subjects were neutral, and 5 (4.8%) were unsatisfied. By the 12-week follow-up visit, subject satisfaction had improved to 26 (25%) and 44 (42.3%) subjects being extremely satisfied and satisfied, respectively, with the results they achieved by participating in the study.

Safety Variable Analysis

All 304 treatment sessions were well tolerated with subjects reporting an average discomfort score of 5.6 ± 1.16 [median: 5.7; min, max: 2, 8] during treatment visit 1, 5.1 ± 1.30 [median: 5.2; min, max: 2, 9] during treatment visit 2, and 5.0 ± 1.28 [median: 5.2; min, max: 1, 9] during treatment visit 3. No treatment sessions were ended prematurely due to excessive treatment discomfort.

No serious adverse events (SAEs) related to the device or protocol and no unanticipated adverse device effects of any severity (SUADEs/UADEs) occurred during the study through 12-weeks post-final treatment.

The most commonly reported adverse events were erythema and edema. All subjects experienced erythema, while 98.1% of subjects experienced edema. All reported erythema and edema events were "Mild" in nature and the rates were equivalent for all Age, Sex, FST, and Acne Severity subgroups. Erythema and edema are expected and typical for laser therapy, and the occurrences were transient and self-resolved within several hours to several days of ending treatment. There was one report of "prolonged"

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erythema of “Mild” severity, in which the subject stated, “a few red patches around the upper lip, chin, and ear persisted for 4 days” after their “overall erythema had resolved within 24 hours” (5 days total).

Acne purging was the third most commonly reported adverse event (45.2%). All but one of the acne purging events were reported as “Mild” and the single event reported as “Moderate” occurred in a subject with IGA Severe at baseline after the subjects 1st study treatment. The rates of acne purging event were equivalent for all Age, Sex, and FST subgroups, and similar for Acne Severity subgroups; however, a trend of higher frequency of acne purging with higher baseline acne severity was observed.

Dryness was the next most commonly reported adverse event (18.3%). All events were “Mild” in nature. The rates of Dryness adverse event were equivalent for all Age and Acne Severity subgroups, and similar for Sex and FST subgroups; however, a trend of higher frequency in female subjects than in male subjects was observed (female: 22% [n=59]; male: 13.3% [n=45]). The rates of Dryness events were equivalent in FST subgroups Grades I-III and IV-V, but no events were reported in subgroup Grade VI [n=5]; however, the small enrollment number makes it difficult to ascertain the true rate for this subgroup.

There were no reports of blistering, hyper- or hypopigmentation, or scarring adverse events in any subjects.

Isolated occurrences of other device related adverse events were reported (itchiness [n=2], skin sensitivity [n=2], and oiliness [n=1]), all were of “Mild” severity, and no trends were observed in the analyses by subgroup as occurrences tracked the subject’s subgroup category.

Comparison of the Proposed Device and Predicate Device:

Both the AviClear and the predicate device are quasi-CW diode lasers with emission wavelengths in the mid-infrared region, and both provide skin cooling before, during, and after laser energy delivery to protect the epidermis and superficial dermis from thermal injury. The non-clinical performance testing conducted supports that the device can perform its laser output functions safely and effectively. Although the AviClear device uses a different wavelength and may use different output parameters compared to those of the predicate device, the wavelength and output parameter differences did not raise new types of questions with regard to using lasers for the intended use. Performance testing in the form of a clinical study was conducted and results support that the AviClear Laser System can be used to safely and effectively treat mild to severe inflammatory acne vulgaris.

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Technical Specification Comparison

	AviClear Laser System (current submission)	Candela Smoothbeam Laser System (K041242)
Wavelength	1726 nm	1450 nm
Max Fluence	Single pulse mode: 30 J/cm ² Double pulse mode: 20 J/cm ²	25 J/cm ²
Max Pulse Energy	5 J	5 J
Pulse Duration	Up to 50 ms	210 ms total pulse duration divided into four equal sub-pulses of 52.5 ms
Spot Size	3 mm or 10 mm 7-spot hexagonal array	4 mm or 6 mm
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
Delivery System	Optical fiber handpiece	Optical fiber handpiece
Skin Cooling	0°C to 5°C, Sapphire window	Cryogen spray
Aiming Beam	650 nm	Unknown
Handpiece	Non-sterile, reusable, cleanable	Non-sterile, reusable, cleanable
The AviClear Laser System and the predicate device have the same general intended uses in the specialties of dermatology and aesthetic medicine.		

Conclusion:

The AviClear Laser System and the predicate device both use laser technology for treatment of acne. Although the AviClear Laser System uses a different wavelength and may use output parameters that are different than those used by the predicate device, the differences did not raise new fundamental questions with regard to using lasers for the intended use. Performance testing in the form of a clinical study was conducted and results support that the AviClear Laser System can be used to safely and effectively treat mild to severe inflammatory acne vulgaris. The non-clinical performance testing also supports that the device can perform its laser output functions safely and effectively. The AviClear Laser System is considered to be substantially equivalent to the predicate K041242 laser device.