June 5, 2026

Alma Lasers, Inc
Jessica Rivera-Montejo
Director - Regulatory Affairs and Quality Assurance
485 Half Day Rd
#100
Buffalo Grove, Illinois 60089

Re: K251684
Trade/Device Name: Alma TED+ System
Regulation Number: 21 CFR 890.5500
Regulation Name: Infrared Lamp
Regulatory Class: Class II
Product Code: OAP, OUG
Dated: May 5, 2025
Received: June 2, 2025

Dear Jessica Rivera-Montejo:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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: 2026.06.05 17:10:23 -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)*
K251684

Device Name
Alma TED+ System

Indications for Use *(Describe)*
Alma TED+ System is indicated to treat Androgenetic Alopecia and promote hair growth infemales who have Ludwig (Savin) I-4, II-1, II-2, or frontal patterns of hair loss and in males who have Norwood Hamilton Classifications of IIa to V and who both have Fitzpatrick SkinTypers I-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.

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.

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510(k) SUMMARY – K251684
Alma TED+ System

Submitter's Name, Address, Telephone Number, and Contact Person

Alma Lasers Inc.
485 Half Day Rd. Ste. 100
Buffalo Grove, IL 60089

Contact Person: Jessica Rivera-Montejo, Director Regulatory and Quality
Email: Regulatory@almalasers.com

Date Prepared: June 5, 2026

Name of Device

Trade Name: Alma TED+ System

Classification Name: Laser Instrument, Surgical, Powered

Classification Regulation: 21 CFR 890.5500

Product Code: OAP, OUG

Predicate Device / Reference Device(s)

Predicate: Laser Therapy Hair Growth Comb, Model: Lasercomb-001 & Lasercomb-002 (K230134) (Product Code(s): OAP, ISA

Reference: The Alma Soprano Titanium, K230371 (Product Code(s): OUG)

Device Description

The Alma TED+ System is a Class II Medical Device that utilizes 650nm laser light to promote hair growth. The Alma TED+ has an applicator called the IMPACT 650 that utilizes the activation of the applicator performed by pressing the air footswitch or hand switch. Audible and visual indicators are designed to provide safe and effective operation for patients and operator by time counting, signals, and error messages when necessary.

Alma TED+ is a low-level laser therapy device that emits laser light designed to promote hair growth in women and men. The applicator contains 7 laser diodes, and the applicator provides distributed laser light while the tip guides the user to maintain a distance to the scalp.

Alma TED+ is based on the principle of low-level laser therapy laser diodes and a detachable guiding tip, for the user to maintain a distance to the scalp. Output parameters and other system features are controlled from the touch-screen control panel on the Alma TED+ console, which provides an interface to the system's micro-controller through an LCD touchscreen.

The activation of the applicator is performed by pressing the air footswitch or hand switch. Audible and visual indicators are designed to provide safe and effective operation for patients and operators by time counting, signals, and error messages when necessary. Air-

cooling fans cool the applicator and the console elements. The system is grounded through the grounding conductor in the standard power cable and an internal grounding pin.

In addition, this submission will add the Smart Clinic Software. This software was previously cleared in the Alma Titanium K230371.

The system consists of the following major components:

- Alma TED+ System
- Footswitch
- Delivery device handpiece:
  - IMPACT 650 Applicator

Intended Use / Indications for Use

Alma TED+ System is indicated to treat Androgenetic Alopecia and promote hair growth in females who have Ludwig (Savin) I-4, II-1, II-2, or frontal patterns of hair loss and in males who have Norwood Hamilton Classifications of IIa to V and who both have Fitzpatrick Skin Typers I-IV.

Comparison of Technological Characteristics

Parameter	Proposed Device	Predicate Device K230134	Comparison to Predicates
Wavelength	650nm±10nm	650nm±10nm	Same
Type of laser	Visible red light-emitting diodes	Visible red light-emitting diodes	Same
Amount of laser diodes	7	7	Same
Energy per laser diode	5 mW (per each laser diode)	4.56 mW, 4.63 mW, 4.66 mW, 4.78 mW, 4.86 mW, 4.89 mW＜5mW	Similar
Treatment Time [min]	15	15	Same
Class	3R	3R	Same
Treatment Frequency	3 times per week, spaced out every other day, as little as 16 weeks	3 times per week, spaced out every other day, as little as 16 weeks	Same

510(k) SUMMARY – K251684
Alma TED+ System

The Alma TED+ is nearly identical to the predicate device Laser Therapy Hair Growth Comb K230134. Sharing the same wavelength and the type of visible red light-emitting diodes with 7 laser diodes each. The treatment frequency for the subject Alma TED+ is identical to the predicate's 3 times per week, spaced out every other day, as little as 16 weeks. The only slight difference is the energy per laser diode, it is similar and within predicate range of equal to 5 mW per each laser diode or less.

The Alma TED+ will share the same SmartClinic software that was previously cleared in Alma's Soprano Titanium. This MDDS software collects information from the system regarding usage and error messages and sends that information to a cloud that resides on Amazon Web Services. The laser system owner can monitor one or several lasers for performance. The Smart clinic MDDS software does not control or affect the system software.

The SmartClinic was previously cleared in the Alma Titanium (K230371). There have been no changes to the previously cleared SmartClinic. It is identical to the software that was cleared in K230371.

Performance Data

Performance testing was performed for the new IMPACT 650 Applicator with TED detachable tip. The primary difference between the subject device and the predicate device is the TED detachable tip. The company assessed the performance of the IMPACT 650 Applicator through testing the output power. The testing demonstrated that the applicator power output is substantially equivalent between the IMPACT 650 Applicator and the Laser Therapy Hair Growth Comb.

The following additional testing was performed to support substantial equivalence:

- IEC 60601-1:2020 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
- IEC 60825-1:2014 Safety of laser products - Part 1: Equipment classification and requirements
- IEC 60601-1-2:2014:2020 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances -

Requirements and tests

- ISO 15223-1:2021 Medical devices — Symbols to be used with information to be supplied by the manufacturer. Part 1: General requirements
- ISO 20417:2021 Medical devices — Information to be supplied by the manufacturer
- IEC 62304:2015 Medical Device Software: Software Life Cycle Process

- ISO 10993-1:2018 Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process
- ISO 14971:2019 Medical devices – Application of risk management to medical devices
- IEC 62366-1:2020 Medical Devices: Part 1: Application of Usability Engineering to Medical Devices
- IEC 60601-1-6:2020 Medical Electrical Equipment - Part 1-6: General Requirements for Basic Safety and Essential Performance - Collateral Standard: Usability
- ISO 13485:2016 Medical devices - Quality management systems - Requirements for regulatory purposes

In all instances, the Alma TED+ System and the IMPACT 650 Applicator functioned as intended and the results met the pre-defined acceptance criteria.

Conclusion

The Alma TED+ System has the same intended use and indications for use as the predicate device (Laser Therapy Hair Growth Comb, Model: Lasercomb-001 & Lasercomb-002, K230134).

The primary technological difference between the subject device and the predicate device is the TED detachable tip, which has similar technological characteristics and principles of operation as the predicate device's Laser Therapy Hair Growth Comb. The difference in the tip being detachable does not raise different questions of safety or effectiveness because they do not change the overall intended therapeutic use of the laser system, or affect the fundamental scientific technology used to achieve the device's intended use. Furthermore, performance testing of the technological differences showed that the new IMPACT 650 Applicator is as safe and effective as the predicate device's Laser Therapy Hair Growth Comb.

Therefore, the Alma TED+ System is substantially equivalent.