February 22, 2023

Alma Lasers Inc.
℅ Kathy Maynor
Regulatory Consultant
Kathy Maynor consulting
26 Rebecca Ct
Homosassa, Florida 34446

Re: K230371
Trade/Device Name: The Alma Soprano Titanium
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, ILY, OUG
Dated: February 10, 2023
Received: February 13, 2023

Dear Kathy Maynor:

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

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K230371

Device Name
Soprano Titanium

Indications for Use *(Describe)*

The Soprano Titanium diode laser module is intended for use in dermatology procedures requiring coagulation. The indications for use for the Soprano Trio diode laser module include:

The Super Hair Removal (SHR) Mode is intended for temporary hair reduction.

The Soprano Trio diode laser module HR mode is intended for use in dermatology procedures requiring coagulation. The indications for use for the Soprano Trio diode laser HR module include: Benign vascular and vascular dependent lesions.

810nm Applicator
Soprano Titanium 810 nm applicator intended use and indications for use:
The indications for use for the 810nm Modified Diode Laser Module 2 cm2 include:

• The Hair Removal (HR) and Super Hair Removal (SHR) Mode are intended for permanent reduction in hair regrowth defined as a long term, stable reduction in the number of hairs re-growing when measured at 6,9 and 12 months after the completion of a treatment regimen.

Use on all skin types (Fitzpatrick I-VI), including tanned skin.(HR, and SHR Modes)

755nm applicator
Soprano Titanium 755 nm applicator intended use and indications for use:
The indications for use for the 755nm Diode Laser Module include:
• The Hair Removal (HR) and Super Hair Removal (SHR) Mode are intended for permanent reduction in hair regrowth defined as a long term, stable reduction in the number of hairs re-growing when measured at 6,9 and 12 months after the completion of a treatment regimen.
• Use on all skin types (Fitzpatrick I-VI), including tanned skin.(HR, SHR Modes)

NIR Applicator
NIR Applicator intended use and indications for use
The Alma Lasers NIR Modules intended use is to emit energy in the near infrared (NIR) spectrum to provide topical heating.

The indications for use for NIR Modules are:
• Elevating the tissue temperature for the temporary relief of minor muscle pain and joint pain and stiffness,
• The temporary relief of minor joint pain associated with arthritis,
• The temporary increase in local circulation where applied, and
• The relaxation of muscles; may also help muscle spasms, minor sprains and strains, and minor muscular back pain.

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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Section 8 510(k) Summary

A summary of 510(k) safety and effectiveness information in accordance with the requirements of 21 CFR 807.92

I. Submitter Information [21 CFR 807.92(a) (1)]

Owner Name	Alma Lasers Inc.
Address	485 Half Day Rd. Suite 100 Buffalo Grove, IL 60089
Contact Person	Kathy Maynor Regulatory Consultant Email : regulatory@almalasers.com Phone: 224-377- 2019 or 2150 Facsimile: 646-805-1305
Summary Preparation Date	February 10, 2023

II. Name of device [21 CFR 807.92 (a) (2)]

Trade or Proprietary Name	Soprano Titanium		
Common Device Name(s) and Regulatory Class	**Product Code(s)**	**Classification Panel**	**Regulation**
Powered Laser Surgical Instrument Class II	GEX	General & Plastic Surgery Panel, 79 (SU)	§ 21 CFR 878.4810
Lamp, Infrared Therapeutic Heating Class II	ILY	General & Plastic Surgery Panel 79	§ 21 CFR 890.550
Medical Device Data System	OUG	General Hospital Panel 80	§ 21 CFR 880.6310

III. Predicate Devices [21 CFR 807.92(a) (3)]

Type	510(k) #	Trade Name	Product Code
Primary	K222064	Alma Lasers Soprano Titanium	GEX, ILY

IV. Device Description [21 CFR 807.92(a) (4)]

The Alma Lasers Soprano Titanium Laser System consists of:

- System console (contains the laser diodes, the system software, power supply and various other electronic and mechanical parts)
- Operator control panel with touch screen technology (GUI)
- 810 nm applicator
- 755 nm applicator
- Small NIR applicator
- Trio 4 cm^2 applicator
- Trio 2 cm^2applicator

V. Intended use of device and Indications for Use [21 CFR 807.92(a) (5)]

The Soprano Titanium diode laser module is intended for use in dermatology procedures requiring coagulation. The indications for use for the Soprano Trio diode laser module include:

The Super Hair Removal (SHR) Mode is intended for temporary hair reduction.

The Soprano Trio diode laser module HR mode is intended for use in dermatology procedures requiring coagulation. The indications for use for the Soprano Trio diode laser HR module include: Benign vascular and vascular dependent lesions.

810nm Applicator

Soprano Titanium 810 nm applicator intended use and indications for use:

The indications for use for the 810nm Modified Diode Laser Module 2 cm2 include:

The Hair Removal (HR) and Super Hair Removal (SHR) Mode are intended for permanent reduction in hair regrowth defined as a long term, stable reduction in the number of hairs re-growing when measured at 6,9 and 12 months after the completion of a treatment regimen.

Use on all skin types (Fitzpatrick I-VI), including tanned skin.(HR, and SHR Modes)

755nm applicator
Soprano Titanium 755 nm applicator intended use and indications for use:
The indications for use for the 755nm Diode Laser Module include:
•The Hair Removal (HR) and Super Hair Removal (SHR) Mode are intended for permanent reduction in hair regrowth defined as a long term, stable reduction in the number of hairs re-growing when measured at 6,9 and 12 months after the completion of a treatment regimen.
• Use on all skin types (Fitzpatrick I-VI), including tanned skin.(HR, SHR Modes)

NIR Applicator
NIR Applicator intended use and indications for use
The Alma Lasers NIR Modules intended use is to emit energy in the near infrared (NIR) spectrum to provide topical heating.

The indications for use for NIR Modules are:
• Elevating the tissue temperature for the temporary relief of minor muscle pain and joint pain and stiffness,
• The temporary relief of minor joint pain associated with arthritis,
• The temporary increase in local circulation where applied, and
• The relaxation of muscles; may also help muscle spasms, minor sprains and strains, and minor muscular back pain.

VI. Summary of technological characteristics of the device compared to the predicate[21 CFR 807.92(a)(6)]

This submission introduced two product changes – the addition of a Trio 2 cm^2 handpiece (with optional tapered light guide) and the incorporation of software module Smart Clinic, an MDDS software system.

The Trio 4 cm^2 handpiece was cleared in K222064. The addition of a Trio 2 cm^2 handpiece (with optional tapered light guide) does not raise any new questions on safety or efficacy because the fluence remains the same, and it is the fluence that determines the therapeutic effect on the skin. The indications for use for the new Trio 2 cm^2 handpiece is exactly the same as the currently cleared Trio 4 cm^2 handpiece.

The new Smart Clinic software is classified as MDDS (medical device data system) software by FDA guidance document *Medical Device Data Systems, Medical Image Storage Devices and Medical Image Communications Devices* dated September 2022. MDDS software does not require a submission, but since it is part of the system software, it was included in the software verification and validation activities.

VII. Performance Testing [21 CFR 807.92(b)(1)]

ANSI/AAMA ES 60601-1 Medical Electrical Equipment – Part 1: General Requirements for safety and essential performance
IEC 60601-1-2 Medical Electrical Equipment 1-2 General Requirements for basic safety and essential performance
IEC 60601-2-22 – Medical Electrical Equipment – Part 2-22 – Particular Requirements for basic safety and essential performance of surgical, cosmetic, therapeutic and diagnostic laser equipment
IEC 60825-1, Safety of laser products - Part 1: Equipment classification, and requirements

IEC 60601-2-57 – Medical Electrical Equipment – Part 2-57: Particular Requirements for the Basic Safety and Essential Performance of Non-Laser Light Source Equipment Intended for Therapeutic, Diagnostic, Monitoring and Cosmetic/Aesthetic Use

In addition, software verification and validation testing was performed to the requirements of IEC 62304 and biocompatibility conformance to FDA standards was established.

VIII. Clinical Data [21 CFR 807.92(b) (2)]

Based on the similarities in the safety and effectiveness profiles of the subject and the predicate, no clinical studies were deemed needed to support this submission.

IX. Conclusions Safety and Effectiveness SE [21 CFR 807.92(b) (3)]

The Alma Lasers Soprano Titanium laser system is as safe and effective as the predicate K222064. The proposed Alma Lasers Soprano Titanium laser system has the same intended use and indications, similar technological characteristics, and same principle of operation as its predicate device. Thus, the Alma Lasers Soprano Titanium laser system is substantially equivalent to its predicate.