October 12, 2022

Alma Lasers Inc.
% Kathy Maynor
Regulatory consultant
Kathy Maynor consulting
26 Rebecca Ct
Homosassa, Florida 34446

Re: K222064
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
Dated: March 1, 2022
Received: July 13, 2022

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
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)*
K222064

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.

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary K222064

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: 352-586-3113 Facsimile: 646-805-1305
Summary Preparation Date	July 11, 2022

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 (SU)	§ 21 CFR 890.550

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

Type	**510(k) #**	**Trade Name**	**Product Code**
Primary	K172193	Soprano Ice Platinum	GEX

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)
- Trio applicator with 1064 nm, 810 nm and 755 nm wavelengths applied simultaneously

- 810 nm applicator
- 755 nm applicator
- Small NIR applicator
- Footswitch and other laser safety accessories

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

Indications for Use

Trio SHR Mode intended use and indications for use:

The Soprano Trio diode laser module with SHR mode 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.

Trio HR Mode intended use and indications for use:
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

The 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)

The 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 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)]

The subject Soprano Titanium system shares with its predicate Soprano Ice Platinum system (K172193) the same underlying technology and presents very similar technological characteristics. Both systems use laser energy, delivered to the skin surface, via applicators.

Specifically, the subject Soprano Titanium is substantially equivalent to the cleared Soprano Ice Platinum system with respect to the hardware and software elements of the system, the principles of operation and the product design. Both the subject Soprano Titanium and the predicate Soprano Ice Platinum have the same main functional components consisting of a system console with a user interface, laser and NIR modules, internal electronics and laser and NIR applicators.

As noted previously, the Soprano Titanium system is a subset of the cleared predicate Soprano Ice Platinum system in that it does not support the 1064nm and 810nm 1.2 cm^2 applicators. The Soprano Titanium system does use the same 755nm, 810nm and NIR small applicator as the predicate Soprano Ice Platinum system.

The Soprano Trio applicator (initially cleared in K172193 as part of the Soprano Ice Platinum system) has a change in spot size from 1cm^2 to 4 cm^2 . The Soprano Trio applicator was previously cleared for benign vascular and vascular dependent lesions removal (K172193). This 510(k) includes a summary of a human clinical study performed to add a hair removal indication to the SHR mode of the Trio applicator. The human clinical study included the 4 cm^2 spot size, and it was performed in accordance with the well-established FDA methodology for conducting and accepting hair removal clinical studies. Additionally, the protocol was reviewed by the FDA in Q181225 prior to its use. The addition of this indication for use does not affect safety or efficacy.

The HR mode of the Trio applicator is indicated for benign vascular and vascular dependent lesions just as the predicate Trio applicator in K172193.

There are a few very minor changes to the 755nm applicator (deletion of laser blanch mode) and 810nm 2 cm^2 applicator (deletion of laser blanch mode, deletion of the 1.2 cm2 spot size) and no change to the small NIR applicator. These changes do not affect safety and efficacy.

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

IEC 60601-1-2 Medical Electrical Equipment 1-2 General Requirements for basic safety and essential performance
IEC 60601-1-2 Medical electrical equipment – Part 1-2 General

requirements for safety and essential performance – Collateral standard: Electromagnetic compatibility

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

ISO10993-1: Biological evaluation of medical devices Part 1: Evaluation and testing within a risk management process

In addition software verification and validation testing was performed and biocompatibility was established.

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

Alma Lasers sponsored a human clinical study for hair removal using the Soprano Titanium applicator (SHR mode) that delivers three wavelengths simultaneously. The US study was conducted at two sites as a multi-center, prospective, open label, single arm study consisting of thirty (30) healthy subjects. Treatment areas included the axilla and bikini line (two treatment areas for each subject).

Following the screening visit, eligible subjects were enrolled into the study. Each subject received 4 hair removal treatments, every 6 weeks. Safety and efficacy was evaluated at the follow-up visit that took place 3 months after the last treatment.

Hairs were physically counted, and three blinded evaluators assessed the results compared to the baseline for each treatment area.

A total of 60 treatment areas were evaluated by 3 evaluators. Statistically significant percent reduction in hair count in all sections from baseline to 3 months was shown with an average reduction of – 42.7%±17.1, range (-77.9-36.5), $p<0.0001$ meeting the primary endpoint of at least thirty percent (30%) reduction in hair count, as assessed by 3 blinded evaluators at 3 months follow up visit compared to baseline.

There weren't any serious adverse events reported in this study.

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

The Soprano Titanium is as safe and effective as the predicate Soprano Ice Platinum. The proposed Soprano Titanium has the same intended use and indications, similar technological characteristics, and same principle of operation as its predicate device. Additionally, a human clinical study supports the new proposed hair removal indication for use. Thus, the Soprano Titanium is substantially equivalent to its predicate.