January 9, 2018

Alma Lasers Inc.
c/o Rekha Anand
Senior Regulatory Affairs Associate
485 Half Day Road Suite # 100
Buffalo Grove, Illinois 60089

Re: K172193
Trade/Device Name: Modified Alma Lasers Soprano XL™ Family ofMulti-Application & Multi-Technology Platforms [SopranoXL, SopranoXLi, SopranoICE and Soprano ICE Platinum] with Duo and Trio Diode Laser Modules., Soprano Duo and Trio Diode Laser Modules
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: December 12, 2017
Received: December 13, 2017

Dear Rekha Anand:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Jennifer R. Stevenson -S3

For Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K 172193

Device Name
Modified Alma Lasers Soprano XL™ Family of Multi-Application and Multi-Technology Platforms [SopranoXL, SopranoXLi, Soprano ICE and Soprano ICE Platinum] with Trio Diode Laser Module

Indications for Use *(Describe)*

Intended Use

The device is intended for use in dermatologic and general surgical procedures.

Indications for Use

The Soprano trio Diode Laser Module is intended for use in dermatology procedures requiring coagulation. The indications for use for the Soprano Trio Diode Laser Module include:

- Benign vascular and vascular dependent lesions removal.

The indications for use for the Soprano1064nm 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.
- Treatment of Pseudo folliculitis Barbae (PFB)
- Use on all skin types (Fitzpatrick I-VI), including tanned skin.

The indications for use for the 810nm Modified Diode Laser Module 1.2 cm^2 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.
- The treatment of benign vascular and pigmented lesions.(The Laser Blanch (LB) Mode)
- Use on all skin types (Fitzpatrick I-VI), including tanned skin.(HR, SHR and LB Modes)

Optional Tapered Light Guide: It is intended for the same use as the device.

The indications for use for the 810nm Modified Diode Laser Module 2 cm^2 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 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.
- The treatment of benign vascular and pigmented lesions.(The Laser Blanch Mode)
- Use on all skin types (Fitzpatrick I-VI), including tanned skin.(HR, SHR and Laser Blanch Modes)

NIR Modules
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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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	Rekha Anand Senior Regulatory Affairs Associate Email : regulatory@almalasers.com Phone: 224-377- 2019 or 2150 Facsimile: 646-805-1305
Summary Preparation Date	Dec 12, 2017

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

Trade or Proprietary Name	Modified Alma Lasers Soprano XL™ Family of Multi-Application and Multi-Technology Platforms [SopranoXL, SopranoXLi, Soprano^{ICE} and Soprano ^{ICE} Platinum] with Trio Module		
Common Device Name(s) and Regulatory Class	**Product Code(s)**	**Classification Panel**	**Regulation**
Laser Powered Surgical Instruments (& Accessories) Class II	GEX	General & Plastic Surgery Panel, 79 (SU)	§ 878.4810, Laser surgical instrument for use in general and plastic surgery and dermatology
	Surgical Powered Lasers and Delivery Devices/Hand piece Accessories		
Lamp, Infrared, Therapeutic Heating Class II	ILY	General & Plastic Surgery Panel, 79 (SU)	§ 890.5500-Lamp, Infrared, Therapeutic Heating
	Lamp, Infrared		

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

Type	**510(k) #**	**Trade Name**
Primary	K140009, K170626	Modified Alma Lasers Soprano XL™ Family of Multi-Application and Multi-Technology Platforms [Soprano ^{XL}, Soprano ^{XLi}, and Soprano ^{ICE}]
Reference	K050779	Cynosure Cynergy Multiplex Laser

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

The subject device, Alma Lasers Soprano Trio Diode Laser Module is an additional hand piece intended to be used with previously cleared Soprano platforms. Consistent with the previous clearance the system is intended to be used in user facilities such as hospitals, physicians' offices and medical spas, and its major components are still the main console unit, foot switch, and individual modules. No change has been made to the main console unit except for incorporation of the software needed to run the new module and adding a new device name (Soprano Ice Platinum) to the Soprano family name for marketing purposes. The footswitch and pre-existing modules are also unmodified from those cleared in K140009 and K170626.

The module's operation involves emission of laser (diode) energy through the hand piece to the patient's skin. The materials that could contact the patient during device use are as cleared in the predicate. The device is re-usable and non-sterile; instructions for cleaning its components between uses are provided in the labeling.

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

Intended Use

The Soprano Trio module is intended for use in dermatology procedures requiring coagulation.

Indications for Use

The indications for use for the Soprano Trio Diode Laser Module include:

- Benign vascular lesions and vascular dependent lesions removal

There is no change in intended use and indications for use for the existing Diode 810nm, 755nm, 1064nm and NIR hand pieces.

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

There is no change in intended use or indications for use for the existing 755nm, 810nm and 1064nm diode laser hand pieces or the near-infrared light (NIR) hand pieces of the cleared Soprano ICE platform. Thus, there is only an addition of one new diode module, the Trio Module, composed of 755nm, 810m, and 1064nm wavelengths with similar intended and indications for use.

The technological principles underlying the subject device and its prior legally marketed iteration (the Soprano ICE platform cleared in K140009, K170626) are the same. Operation of the new diode laser module involves activation of foot switch and delivery of diode

laser energy through the tip built into the corresponding handpiece, just as use of the device with the previously cleared laser modules involves delivery of laser energy through the different-sized tips of the selected handpiece, or through the tapered light guide tip for treating smaller areas. The NIR modules have not been modified since their clearance in K140009; they emit pulsed-light energy in the infrared spectrum to provide topical heating for the purpose of elevating tissue temperature for temporary relief of minor muscle and joint pain, temporary increase in local circulation, and muscle relaxation.

Energy source type and parameters are the same as in prior iteration of the device. The only technological difference in the subject device as compared to the prior iteration of the Soprano platform (K140009, K170626) is combining three (Trio Module) wavelengths into a single hand piece being simultaneously fired.

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

IEC 60601-1 Medical Electrical Equipment-Part 1: General Requirements for safety
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 60825-1Safety of laser products-Part 1: Equipment Classification, requirements and user's guide

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

In addition animal histology testing was performed to ascertain that there were no new safety or effectiveness issues raised by this modification. The animal histology compared the histology of the individual wavelengths compared to the histology of the combined wavelengths over a range of energies from lowest to highest. Testing showed no significant differences between the individual tissue effects and the combined wavelength tissue effects.

In all instances, the Soprano Trio Diode Laser Module functioned as intended and the results observed were as expected.

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

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

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

The Soprano Trio Diode Laser Module is as safe and effective as the primary predicate Alma Lasers Soprano XL^{TM} Family of Multi-Application Platforms [Soprano^{XL}, Soprano^{XLi}, and Soprano^{ICE}] (K140009, K170626) and reference predicate Cynosure Cynergy Multiplex laser (K050779) The proposed Trio diode laser module has similar intended use and indications, similar technological characteristics, and same principle of operation as its predicate device. Combining different wavelengths in one module does not alter the intended use of the device and does not affect its safety and effectiveness when used as labeled. Thus, the Soprano Trio Diode Laser Module is substantially equivalent.