DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

May 31, 2017

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

Re: K170626
Trade/Device Name: Modified Alma Lasers Soprano XL Family Of Multi-application & Multi-technology Platform, Soprano Yag Hand Piece
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: February 27, 2017
Received: March 2, 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Jennifer R. Stevenson -S

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)*
K170626

Device Name
Modified Alma Lasers Soprano XL™ Family of Multi-Application and Multi-Technology Platforms [Soprano^{XL}, Soprano^{XLi}, and Soprano^{ICE}] with 1064nm Diode Laser Module.

Indications for Use *(Describe)*

Intended Use
The additional Soprano 1064nm Diode Laser Module is intended for use in dermatologic and general surgical procedures.

Indications for Use

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.

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	Rekha Anand Senior Regulatory Affairs Associate Email : regulatory@almalasers.com Phone: 224-377- 2019 or 2150 Facsimile: 646-805-1305
Summary Preparation Date	February 27, 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 [Soprano^{XL}, Soprano^{XLi}, and Soprano^{ICE}] with 1064nm Diode Laser Module, Soprano YAG hand piece		
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**	**Product Code**
Primary	K153671, K132185	Family of Coolglide Aesthetic Lasers	GEX
Reference	K140009	Modified Alma Lasers Soprano XL™ Family of Multi-Application and Multi-Technology Platforms [Soprano ^{XL}, Soprano ^{XLi}, and Soprano ^{ICE}]	GEX,ILY

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

The subject device, Alma Lasers Soprano 1064nm Diode Laser Module is an additional hand piece intended to be used with previously cleared Soprano ICE platform. 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, footswitch, 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; the footswitch and pre-existing modules are also unmodified from those cleared in K140009.

The module's operation involves emission of laser (diode) energy through the handpiece to the patient's skin. The materials that could contact the patient during device use are sapphire, aluminum, and plastic; these would all have limited-duration surface contact with intact skin. 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 1064nm module is intended for use in dermatologic and general surgical procedures.

Indications for Use

The indications for use for the 1064nm Diode Laser Module include:

- 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 in HR and SHR Modes
- Treatment of Pseudo folliculitis Barbae (PFB)
- Use on all skin types (Fitzpatrick I-VI), including tanned skin.

There is no change in intended use and indications for use for the existing Diode 810nm, 755nm 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 810nm and 755nm 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 a new diode 1064 module and only new indication being added through the subject device is treatment of PFB. This additional indication does not impact the device's overall intended therapeutic/surgical use, because it is a surface dermatological procedure like those previously cleared. The new indication also does not affect

the safety and effectiveness of the device when used as labeled, because the primary predicate is already cleared for treating PFB, and the subject device mechanism of action for this indication is the same as for the diode laser modules previously cleared in the primary predicate. The Soprano 1064nm diode laser module also has fewer indications for use as compared to the primary predicate at 1064nm, but this omission does not impact the subject module's safety or effectiveness since all of its proposed indications are encompassed by the predicate.

The technological principles underlying the subject device and its prior legally marketed iteration (the Soprano^{ICE} platform cleared in K140009) are the same. Operation of the new 1064nm diode laser module involves 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. The non-laser functions of the Soprano and CoolGlide devices are not implicated in this submission, which focuses only on the proposed new 1064nm diode laser module for the Soprano^{ICE} platform.

The only technological difference in the subject device as compared to the prior iteration of the Soprano^{ICE} platform (K140009) is addition of a new wavelength (1064nm) to its diode laser functionality. This difference does not raise new questions of safety or effectiveness, because the new module functions in exactly the same way as the laser modules previously cleared, and the primary predicate's clearance includes use of laser energy at 1064nm for the same indications as are proposed for the Soprano 1064nm Diode Laser Module.

A table comparing the key features of the subject and reference/primary predicate devices is provided on the following page.

Characteristic[1]	Proposed Soprano 1064nm Diode Laser Module		Reference Predicate Soprano ICE (K140009)			Predicate Family of Coolglide Aesthetic Lasers (K153671), (K132185)
Wavelength [nm]	1064		810, 755			1064
Laser Media	Solid State		Solid State			Solid State
Mode	HR	SHR	HR	SHR	LB	
Spot Size	10mm * 10mm (1cm^2) Optional tapered tip 6mm (0.28 cm$^{2)}$,		<u>810nm:</u> 12*10mm (1.2cm^2), 20 *10 mm(2cm^2) Optional tapered tip 6mm (0.28cm^2), 12 <u>755nm:</u> 15*10mm (1.5cm^2)			*<u>K153671 Clearance letter:</u>* 3mm(0.07cm^2), 4mm(0.12cm^2), 5mm(0.2cm^2), 6mm(0.28cm^2), 7mm(0.38cm^2), 8mm(0.5cm^2), 9mm(0.64cm^2), 10mm(0.8cm^2), 11mm(0.95cm^2), 12mm(1.13cm^2), 13mm(1.32cm^2), 14mm(1.54cm^2), 15mm(1.7cm^2), 16mm(2cm^2), 17mm(2.27cm^2), 18mm(2.54cm^2) *<u>K132185 clearance letter:</u>* 3mm(0.07cm^2),5mm(0.2cm^2)8mm(0.5cm^2).10mm(0.8cm^2),12mm(1.13cm^2)
Pulse Width [msec]	3.3-280		3.3-200			K153671: Not available, K132185: 01.-300
Pulse Repetition Rate [Hz]	0.5-3	5-10	0.5-3	5-10	2	≤ 10 Hz and single shot
Energy Density (Fluence) [J/cm^2]	2-120	2 to 20	2-120	2-20	810nm-`up to 40 755nm-up to 25	K153671: Not Available, K132185: Up to 300
User Interface	LCD Color Touchscreen		LCD Color Touchscreen			Push Button Control or LCD Color Touchscreen
Delivery Devices (How supplied)	Non-Sterile, reusable, cleanable		Non-Sterile, reusable, cleanable			Non-Sterile, reusable, cleanable
Compatible Laser System	Family of Soprano^{XL}, Soprano^{XLi}, and Soprano^{ICE} (cleared K 14009)		Family of Soprano^{XL}, Soprano^{XLi}, and Soprano^{ICE} (cleared K 14009)			Coolglide System
Indications for use	• Permanent reduction [2] in hair regrowth in HR and SHR Mode • Treatment of Pseudo folliculitis Barbae (PFB) • Use on all skin types (Fitzpatrick I-VI), including tanned skin		• Permanent reduction in hair regrowth in HR and SHR Mode • Treatment of vascular and pigmented lesions in LB Mode • Use on all skin types (Fitzpatrick I-VI), including tanned skin			• Permanent reduction in hair regrowth • Treatment of Pseudo folliculitis Barbae (PFB • Treatment of vascular and pigmented lesions[3] • Treatment of wrinkles, such as, but not limited to periocular and perioral wrinkles. • Treatment of mild to moderate inflammatory acne vulgaris • Use on all skin types (Fitzpatrick I-VI), including tanned skin

[1] Only the specifications/parameters relevant to this submission (corresponding to the 1064nm wavelength) are provided in this table.

[2] Permanent reduction in hair regrowth is defined as a long-term, stable reduction in the number of hairs re-growing when measured at 6,9 and 12 month after the completion of a treatment regimen

[3] Benign vascular lesions, such as, but not limited to, port wine stains, hemangiomas, warts, telangiectasis, rosacea, venus lake, leg veins, spider veins, and poikiloderma of civatte; and treatment of benign cutaneous lesions such as, but not limited to warts, scars, striae, and psoriasis. Benign pigmented lesions such as, but not limited to lentigos, solar lentigos, café au lait macules, seborrheic keratosis, nevi, chloasma, verrucae, skin tags, keratosis, tattoos and plaques.

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

IEC 60601-1 Medical Electrical Equipment-Part 1: General Requirements for basic safety and essential performance Ed 3.1
IEC 60601-1-2 Medical Electrical Equipment 1-2 General Requirements for basic safety and essential performance Ed 4.0
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 Ed 3.1
IEC 60601-1-6 Medical Electrical Equipment Part 1-6: General requirements for safety Ed. 3.1
IEC 60825-1 Safety of laser products-Part 1: Equipment Classification and requirements Ed 2.0

In addition software verification and validation testing was performed and biocompatibility was established.
In all instances, the Soprano 1064nm 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, reference, and primary predicate devices, no animal or clinical studies were deemed needed to support this submission.

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

The Soprano 1064nm Diode Laser Module is as safe and effective as the Cutera Family of CoolGlide Aesthetic Lasers (K132185, K153671) ("primary predicate device") and the Alma Lasers Soprano XL™ Family of Multi-Application Platforms [Soprano^{XL}, Soprano^{XLi}, and Soprano^{ICE}] (K140009) ("reference device"). The proposed 1064nm module has the same intended use and similar indications, technological characteristics, and principles of operation as its predicate and reference devices. The minor differences in indications do not alter the intended therapeutic/surgical use of the device and do not affect its safety and effectiveness when used as labeled. In addition, the minor technological differences between the Soprano 1064nm Diode Laser Module and its predicate/reference devices raise no new issues of safety or effectiveness. Thus, the Soprano 1064nm Diode Laser Module is substantially equivalent.