July 2, 2021

Alma Lasers, Ltd.
Avi Hirshnzon
Evp RAqa
18 Haharash Street, North Industrial Park
Caesarea Ha Zafon, 3079895
Israel

Re: K203441
Trade/Device Name: The Alma Hybrid Laser System
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, ONG
Dated: November 20, 2020
Received: November 23, 2020

Dear Avi Hirshnzon:

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,

Purva Pandya
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)*
K203441

Device Name
The Alma Hybrid Laser System

Indications for Use *(Describe)*

The Alma Hybrid Laser System, Delivery Devices, Applicators and Accessories are intended for use in surgical applications requiring the ablation, vaporization, excision, incision, and coagulation of soft tissue in medical specialties including: aesthetic surgery (dermatology and plastic surgery).

HyLight-CO2
The Alma Hybrid CO2 non-fractional applicator, with wavelength of 10600 nm is cleared for use for the particular indications as follows:

Dermatology & Plastic Surgery
The ablation, vaporization, excision, incision, and coagulation of soft tissue in dermatology and plastic surgery in the performance of:
* laser skin resurfacing
* laser derm-abrasion
* laser burn debridement.

Laser skin resurfacing (ablation and/or vaporization) of soft tissue for the reduction, removal, and/or treatment of: warts, acne scars, nevi epidermal, syringoma. Vaporization/coagulation of warts.

Pixel
The Alma Hybrid Pixel CO2 fractional applicator, with wavelength of 10600 nm is indicated for: The ablation, vaporization, and coagulation of soft tissue in dermatology and plastic surgery in the performance of skin resurfacing.

ProScan
The Alma Hybrid ProScan CO2 fractional applicator, with wavelength of 10600 nm is indicated for:
• Laser skin resurfacing (ablation and/or vaporization) of soft tissue.
The Alma Hybrid ProScan 1570nm fractional applicator, with wavelength of 1570 nm, is indicated for:
• Use in dermatological procedures requiring fractional skin resurfacing and coagulation of soft tissue
The Alma Hybrid ProScan CO2 &1570nm fractional applicator, with wavelengths of 10600 nm & 1570nm is indicated for laser skin resurfacing (ablation and/or vaporization) of soft tissue.

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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K203441 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	18 Haharash Street NORTH INDUSTRIAL PARK CAESAREA , IL 3079895
Contact Person	Kathy Maynor Regulatory Consultant Email : regulatory@almalasers.com Phone: 352-586-3113 (cell) Facsimile: 646-805-1305 Secondary contact: Jessica Rivera-Montejo Assoc. Director of Regulatory Email: regulatory@almalasers.com Phone: 224-377-2019 Facsimile: 646-805-1305
Summary Preparation Date	July 2, 2021

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

Trade or Proprietary Name	The Alma Hybrid Laser System		
Common Device Name(s) and Regulatory Class	**Product Code(s)**	**Classification Panel**	**Regulation**
Electrosurgical cutting and coagulation device and accessories Class II	GEX	General & Plastic Surgery Panel, 79 (SU)	§ 21 CFR 878.4810
Powered Laser Surgical Instrument With Microbeam\Fractional Output	ONG	General & Plastic Surgery Panel, 79 (SU)	§ 21 CFR 878.4810

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

Type	**510(k) #**	**Trade Name**	**Product Code**
Primary	K103501	Alma Lasers Pixel CO2 Laser System	GEX
Reference	K080463	Alma Lasers System	GEX
Secondary	K170060	M22 And ResurFx Systems	GEX

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

The Alma Hybrid Laser System consists of:

- Laser system console (containing the optical bench assembly and laser, the microcontroller control electronics and system software, the high voltage power supply, the laser cooling system, the compressed air-purge system, and the service panel)
- LCD control panel with touch-screen technology: the LCD display provides information on the status and settings of the The Alma Hybrid Laser System with touch-screen technology provided to input commands into the system.
- Two wavelengths – CO2 and 1570 nm
- Articulated arm
- Footswitch
- Delivery devices (Pixel applicators, Hylight applicators, Proscan applicator)

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

The Alma Hybrid Laser System, Delivery Devices, Applicators and Accessories are intended for use in surgical applications requiring the ablation, vaporization, excision, incision, and coagulation of soft tissue in medical specialties including: aesthetic surgery (dermatology and plastic surgery).

HyLight-CO2
The Alma Hybrid CO2 non-fractional applicator, with wavelength of 10600 nm is cleared for use for the particular indications as follows:

Dermatology & Plastic Surgery
The ablation, vaporization, excision, incision, and coagulation of soft tissue in dermatology and plastic surgery in the performance of:
* laser skin resurfacing
* laser derm-abrasion
* laser burn debridement.

Laser skin resurfacing (ablation and/or vaporization) of soft tissue for the reduction, removal, and/or treatment of: warts, acne scars, nevi epidermal, syringoma. Vaporization/coagulation of warts.

Pixel
The Alma Hybrid Pixel CO2 fractional applicator, with wavelength of 10600 nm is indicated for:
The ablation, vaporization, and coagulation of soft tissue in dermatology and plastic surgery in the performance of skin resurfacing.

ProScan
The Alma Hybrid ProScan CO2 fractional applicator, with wavelength of 10600 nm is indicated for:
•Laser skin resurfacing (ablation and/or vaporization) of soft tissue
The Alma Hybrid ProScan 1570nm fractional applicator, with wavelength of 1570 nm, is indicated for:
• Use in dermatological procedures requiring fractional skin resurfacing and coagulation of soft tissue
The Alma Hybrid ProScan CO2 &1570nm fractional applicator, with wavelengths of 10600 nm & 1570nm is indicated for laser skin resurfacing (ablation and/or vaporization) of soft tissue.

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

Device / Feature	Alma Pixel CO2 (**K103501) Primary Predicate**	Hybrid System (K203441) (Subject Device)
Hylight CO2		
Wavelength	10600 nm	Same
Pilot beam	650 nm, 3mW	Same
Spot size (mm)	0.15 dia at 50 mm working distance; 0.2 mm dia. At 100 mm working distance	0.15 – 3.0 at 50 mm working distance 0.25- 3.1 (Dia.) at 200 mm working distance
Repetition Rate	1-5 Hz	Same
Pulse Duration	1-1000 ms	Same
Repeat Delay	0.01 – 1sec	Same
Min output energy	5 mJ	Same
Output Power	30W, 70W	Same
Fluence	Max 1746 J/mm^2 for 30W system Max 3530 J/mm^2 for the 70W system	Same
CO2 Pixel (7x7 pattern; 9x9 pattern)		
Spot Size	0.125 to 0.20 mm dia. pixels in a 10 x10 mm^2 area (49 pixels) @ 50 mm distance – 0.125 to 0.20 mm dia. pixels in a 11 x 11 mm^2 area (81 pixels) @ 100 mm distance	Same
Repetition Rate	1-5 Hz	0.5-2Hz
Pulse Duration	100-300 ms for pulsed	1- 405 ms
Energy	5mJ/Pixel – 150 mJ/Pixel	Same
CO2 ProScan		
Scanner	Dual axis scanner	Same
Spot size (mm)	0.35 mm@ 100 mm distance	Same
Output energy	Up to 1000 mJ	120 (30W model)/240 mJ (70W model)
Beam density	~5% - 95% untreated tissue between spots	~63% - 97% untreated tissue between spots

Device / Feature	**Lumenis ReSurfx K170060 – Secondary Predicate**	Hybrid System (K203441) (Subject Device)
ProScan 1570		
Wavelength	1565 nm	1570 nm
Pilot beam	650 nm, <5mW	650 nm, 3mW
Scanner	Dual axis scanner	Same
Tip	cooled	Same
Scan size (mm)	5-18 mm	Up to 30 mm diameter
Output energy	10 mJ per beam – 70 mJ per beam	24mJ-144 mJ/pixel
Beam density	Up to 500 microbeams/cm2	Up to 390 pixels/cm^2

The technical characteristics for the Hybrid Laser System are substantially equivalent to the predicate devices. The Alma Hybrid 10600nm non-fractional module, with

wavelength of 10600 nm have differences in spot size, pulse duration and output energy, but the fluence is within the range of the predicate devices.

The Alma Hybrid Pixel CO2 fractional applicator, with wavelength of 10600 nm have differences in pulse duration, but the max energy output is within the range of the predicate device.

The Alma Hybrid ProScan fractional applicator, with wavelengths of 10600 nm and/or 1570nm wavelengths offers two main treatment modes Monochromatic or Sequential Radiation. the Alma Hybrid ProScan fractional applicator, with wavelengths of 10600 nm, and/or 1570nm Treatment Modes include three fractional patterns – grid, hygrid and grid sequential– with either single or dual wavelengths. The fractional grid patterns are substantially equivalent to their predicate devices with differences in spot size, beam density and pulse duration. Alma did perform histology testing to justify the technical differences.

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 – 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, requirements and user's guide
ISO 10993-1 Biological evaluation of medical devices -- Part 1
ISO 17665-1 Sterilization of health care products – moist heat
IEC 62304 Medical Device Software
ISO 14971 Risk Analysis

In addition, software verification and performance validation testing were performed.

Alma also performed histology testing on porcine animals for the ProScan Applicator. Testing was performed safely on the test animals, and the histology results complied with the FDA requirements at 0, 3, 7 and 14 days. Three [3] Domestic female (Mixed Landrace & Large White) crossbred swine were used in this study. During the in-life stage, vital signs, ECG and % saturation were monitored, clinical observations and body weights were monitored and recorded. Re-epithelialization was observed three days after radiation in all specimens. No adverse events or unexpected complications have been detected in the swines. On the last day of trial, biopsies were taken from the center of each radiated point by punch biopsy and were sent to H&E. At the end of the procedure at first, third, and seventh days, the animal was awakened and transferred to the recovery room. Euthanizing of the pigs were done at the end of the study on day 14.

In all instances, the Alma Hybrid Laser System, Delivery Devices and Accessories

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 and the predicate, no human clinical studies were deemed needed to support this submission.

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

The Alma Hybrid Laser System is as safe and effective as the predicate devices. The proposed Alma Hybrid Laser System has the same intended use and indications, similar technological characteristics, and the same principles of operation as its predicate devices. Thus, the Alma Hybrid Laser System is substantially equivalent to its predicate