March 1, 2023

Alma Lasers, Inc.
Jessica Rivera Montejo
Director Regulatory Affairs and Quality
485 Half Day Road #100
Buffalo Grove, Illinois 60089

Re: K230308
Trade/Device Name: Alma Harmony
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, ONF
Dated: February 2, 2023
Received: February 3, 2023

Dear Jessica Rivera Montejo:

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)*
K230308

Device Name
Alma Harmony

Indications for Use *(Describe)*

Iris VL / PL Applicator:
Intended for use in aesthetic and cosmetic applications requiring selective photothermolysis (photocoagulation or coagulation) and hemostasis of soft tissue in the medical specialties of general and plastic surgery, and dermatology.

The treatment of benign pigmented epidermal lesions including dyschromia, hyperpigmentation, melasma, and ephelides (freckles), lentigines, nevi, melasma, and cafe-au-lait macules.

The treatment of benign cutaneous vascular lesions including port wine stains, hemangiomas, facial, truncal and leg telangiectasias, rosacea, erythema of rosacea, angiomas and spider angiomas, poikiloderma of Civatte, leg veins and venous malformations. Use on all skin types (Fitzpatrick I- VI).

Iris Dye VL / Dye SVL Applicator:
The treatment of benign pigmented lesions including café -au-lait (macules), lentigines (senile and solar), freckles (ephelides), chloasma, nevi, nevus spillus, nevus of Ota, and Becker's Nevi. • The treatment of other pigmented cutaneous lesions including verrucae, skin tags, keratosis, and plaques. • The treatment of benign cutaneous vascular lesions including port wine stains, hemangiomas, facial, truncal and leg telangiectasias, rosacea, erythema of rosacea, angiomas and spider angiomas, poikiloderma of Civatte, leg veins and venous malformations. • Use on skin types (Fitzpatrick I-V).

Iris SHR Applicator:
The Advanced Fluorescence Technology (AFT) 650-950 nm handpiece (with and without contact-cooling) is indicated for: The treatment of tattoos, the treatment of moderate inflammatory acne vulgaris, the treatment of benign pigmented epidermal lesions including dyschromia, hyperpigmentation, melasma, and ephelides (freckles), lentigines, nevi, melasma, and cafe-au-lait, the treatment of cutaneous lesions including warts, scars and striae, the treatment of benign cutaneous vascular lesions including port wine stains, hemangiomas, facial, truncal and leg telangiectasias, rosacea, erythema of rosacea, angiomas and spider angiomas, poikiloderma of Civatte, leg veins and venous malformations.
The removal of unwanted hair and to effect stable long-term or permanent hair reduction.
Use on all skin types (Fitzpatrick I-VI), including tanned skin

Iris Acne Applicator:
Intended for use in aesthetic and cosmetic applications requiring selective photothermolysis (photocoagulation or coagulation) and hemostasis of soft tissue in the medical specialties of general and plastic surgery and dermatology
The Advanced Fluorescence Technology (AFT) 420-950 nm Acne Module Applicator (with and without contact-cooling) is indicated for:

The treatment of moderate inflammatory acne vulgaris.

The treatment of benign pigmented epidermal lesions including dyschromia, hyperpigmentation, melasma, and ephelides (freckles).

The treatment of cutaneous lesions including warts, scars and striae.

The treatment of benign cutaneous vascular lesions including port wine

stains, hemangiomas, facial, truncal and leg telangiectasias, rosacea, erythema of rosacea, angiomas and spider angiomas, poikiloderma of Civatte, leg veins and venous malformations.

Use on all skin types (Fitzpatrick I-VI).

Iris NIR Applicator:
Intended to emit energy in the infra-red spectrum to provide topical heating for the purpose of 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.

Iris Diode Applicator
The Iris diode is intended for use for vascular lesions, spider veins, spider naevi, teleangiectasis, red superficial veins o fthe legs and face, pigmented lesions (e.g. cafe-au-lait stains, lentigo), hemangiomas, port wine stains, rosacea.

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 7 510(k) Summary-K230308

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	Jessica Rivera-Montejo 224-377-2000– phone Jessica.rivera-montejo@almalasers.com
Summary Preparation Date	February 2, 2023

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

Trade or Proprietary Name	Alma Harmony		
Common Device Name(s) and Regulatory Class	**Product Code(s)**	**Classification Panel**	**Regulation**
Laser Surgical Instrument for use in general and plastic surgery and in dermatology Class II	GEX	General & Plastic Surgery Panel, 79 (SU)	§ 21 CFR 878.4810
Lamp, Infrared Therapeutic Class II	ILY	General & Plastic Surgery Panel, 79 (SU)	§ 21 CFR 890.5500
Powered Light Based Non-Laser Surgical Instrument with thermal effect	ONF	General & Plastic Surgery Panel, 79 (SU)	§ 21 CFR 878.4810

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

There are 6 applicators included in this submission. Each applicator has its own indication for use. As a result, there are 5 primary predicate devices. Below is the list predicate devices and which applicator utilizes which predicate device.

Predicate Devices

Subject Applicator	**510(k) #**	**Trade Name**	**Product Code**
Iris NIR	K222064	Soprano Titanium	GEX, ILY
Iris VL / PL Iris SHR Mode	K141237	Alma Harmony Lite	ONF, ILY
Iris Dye VL / SVL	K181298	Harmony XL Multi-Application System	GEX, ONF
Iris Acne Iris HR Mode	K072564	Harmony XL Multi-Application System	GEX
Iris Diode	K053604	Wavelight IDAS	GEX

Reference Devices

Subject Applicator	510K #	Trade Name	Product Code
Iris Dye VL / SVL	K033946	Lovely Family	GEX
Iris SHR	K033946	Lovely Family	GEX

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

The Alma Harmony is a Class II Medical Device that combines multiple technologies into one platform for use in dermatologic, aesthetic procedures and pain management procedures. The system is comprised of a micro-processor-controlled and user-friendly console that houses the power supply, the electronics and the user interface. It has 6 applicators that are attached to the console, which can be selected for use in treatment through the user interface.

There are 6 separate applicators. Each handpiece has its own indication for use.

- Iris VL / PL is an IPL handpiece operating in the wavelength range of 540nm-950nm
- Iris Dye VL and Dye SVL is an IPL handpiece operating in the wavelength range of 500nm-600nm
- Iris SHR is an IPL handpiece that operates in the wavelength range of 650nm-950nm
- Iris Acne is an IPL handpiece operating in the wavelength range of 420nm – 950nm
- Iris NIR is near infrared with a wavelength of 1300nm
- Iris Diode is a 520nm diode laser.

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

Indications for Use

Iris VL / PL Applicator

Intended for use in aesthetic and cosmetic applications requiring selective photothermolysis (photocoagulation or coagulation) and hemostasis of soft tissue in the medical specialties of general and plastic surgery, and dermatology

The treatment of benign pigmented epidermal lesions including dyschromia, hyperpigmentation, melasma, and ephelides (freckles), lentigines, nevi, melasma, and cafe-au-lait macules.

The treatment of benign cutaneous vascular lesions including port wine stains, hemangiomas, facial, truncal and leg telangiectasias, rosacea, erythema of rosacea, angiomas and spider angiomas, poikiloderma of Civatte, leg veins and venous malformations. Use on all skin types (Fitzpatrick I- VI).

Iris Dye VL / Dye SVL Applicator

The treatment of benign pigmented lesions including café -au-lait (macules), lentigines (senile and solar), freckles (ephelides), chloasma, nevi, nevus spillus, nevus of Ota, and Becker's Nevi. • The treatment of other pigmented cutaneous lesions including verrucae, skin tags, keratosis, and plaques. • The treatment of benign cutaneous vascular lesions including port wine stains, hemangiomas, facial, truncal and leg telangiectasias, rosacea, erythema of rosacea, angiomas and spider angiomas, poikiloderma of Civatte, leg veins and venous malformations. • Use on skin types (Fitzpatrick I-V).

Iris SHR Applicator

The Advanced Fluorescence Technology (AFT) 650-950 nm handpiece (with and without contact-cooling) is indicated for: * The treatment of tattoos. * The treatment of moderate inflammatory acne vulgaris. * The treatment of benign pigmented epidermal lesions including dyschromia, hyperpigmentation, melasma, and ephelides (freckles), lentigines, nevi, melasma, and cafe-au-lait. • The treatment of cutaneous lesions including warts, scars and striae. * The treatment of benign cutaneous vascular lesions including port wine stains, hemangiomas, facial, truncal and leg telangiectasias, rosacea, erythema of rosacea, angiomas and spider angiomas, poikiloderma of Civatte, leg veins and venous malformations. The removal of unwanted hair and to effect stable long-term or permanent hair reduction. • Use on all skin types (Fitzpatrick I-VI), including tanned skin

Iris Acne Applicator

Intended for use in aesthetic and cosmetic applications requiring selective photothermolysis (photocoagulation or coagulation) and hemostasis of soft tissue in the medical specialties of general and plastic surgery and dermatology
The Advanced Fluorescence Technology (AFT) 420-950 nm Acne Module Applicator (with and without contact-cooling) is indicated for:

The treatment of moderate inflammatory acne vulgaris.

The treatment of benign pigmented epidermal lesions including dyschromia, hyperpigmentation, melasma, and ephelides (freckles).

The treatment of cutaneous lesions including warts, scars and striae.

The treatment of benign cutaneous vascular lesions including port wine stains, hemangiomas, facial, truncal and leg telangiectasias, rosacea, erythema of rosacea, angiomas and spider angiomas, poikiloderma of Civatte, leg veins and venous malformations.

Use on all skin types (Fitzpatrick I-VI).

Iris NIR Applicator

Intended to emit energy in the infra-red spectrum to provide topical heating for the purpose of 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.

Iris Diode Applicator

The Iris diode is intended for use for vascular lesions, spider veins, spider naevi, telangiectasia, red superficial veins of the legs and face, pigmented lesions (e.g. cafe-au-lait stains, lentigo), hemangiomas, port wine stains, rosacea.

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

The subject Alma Harmony system shares with the predicate devices the same underlying technology and presents nearly identical technological characteristics. Both systems use laser energy delivered to the skin surface via applicators. Both the Alma Harmony and the predicate devices have the same main functional components consisting of a system console with a user interface, laser and NIR modules, internal electronics and IPL, Laser and NIR applicators.

The subject Alma Harmony is substantially equivalent to the previously cleared predicate devices with respect to hardware and software, principle of operation and product design.

There are very minor changes to the applicators that do not affect safety and efficacy.

The Iris VL / PL Applicator has a fluence of 5-30J/cm^2 while the predicate device has a fluence of 10-30J/cm^2. This negligible difference does not raise new concerns for safety or efficacy.

The Iris Dye VL / SVL applicator has a repetition rate of 1/2Hz. The predicate has a repetition rate of 2/3Hz. This negligible difference does not raise new concerns for safety or efficacy.

The Iris HR / SHR applicator has a slightly different fluence. The SHR fluence is 3-7J/cm^2 for the proposed device and the SHR for the predicate is 1-5J/cm^2. The HR predicate fluence is 5-25J/cm^2 and the HR proposed device is 5-20J/cm^2. The negligible difference does not raise new concerns for safety or efficacy.

The Iris Acne applicator has a higher repetition rate of 1Hz. The predicate has a repetition rate of 2/3 Hz. This allows for the treat to be performed faster and does not raise new concerns of safety or efficacy. The energy density falls within the predicate range.

The Iris Diode has a pulse width of 1-100ms which is a subset of the pulsewidth in the predicate device. This does not raise new concerns of safety or efficacy.

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

The following performance data was provided in support of the substantial equivalence determination:

IEC 60601-1 Test for Medical Electrical equipment was performed for General Requirements for basic safety and essential performance.

IEC 60601-1-2 Test for Medical Equipment for General Requirements for basic safety and essential performance: electromagnetic compatibility.

IEC 60601-2-22 Test for Particular requirements for basic safety and essential performance of surgical, cosmetic, therapeutic and diagnostic laser equipment.

IEC 60601-2-57 Particular requirements for basic safety and essential performance of non-laser light source equipment intended for therapeutic, diagnostic, monitoring and cosmetic/aesthetic use.

ISO 10993-1 Biological Evaluation of Medical Devices - Part 1: Evaluation and Testing Within a Risk Management Process.

In addition, software verification and validation testing was performed.

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