February 8, 2024

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

Re: K233024
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, OUG
Dated: September 22, 2023
Received: September 22, 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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Tanisha L. Hithe -S
2024.02.08 13:44:30 -05'00'

Tanisha Hithe
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)*
K233024

Device Name
Alma Harmony

Indications for Use *(Describe)*

Intended Use:
The Alma Harmony is 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).

Clear Skin Pro 1540nm Applicator:
The ClearSkin Pro 1540nm is indicated for : Use in dermatological procedures requiring fractional skin resurfacing and coagulation of soft tissue.

SupErb 2940nm Applicator:
The 2940 nm Er:YAG Laser Module handpiece with standard and scanner accessory tips (with and without contact-cooling) is indicated for use in soft tissue (skin, cutaneous tissue, subcutaneous tissue, striated and smooth tissue, muscle, cartilage meniscus, mucous membrane, lymph vessels and nodes, organs, and glands.

Dermatology and Plastic Surgery: Skin resurfacing, Treatment of wrinkles, Epidermal nevi, Telangiectasia, Spider veins, Actinic chelitis, Keloids, Verrucae, Skin tags, Anal tags, keratoses, Scar revision (including acne scars), Debulking benign tumors, Debulking cysts, Superficial skin lesions, Diagnostic biopsies, Decubitus ulcers.

General Surgery: Surgical incision/excision, vaporization, ablation, and coagulation of soft tissue where skin incision, tissue dissection, excision of external tumors and lesions, complete or partial resection of internal organs, tumors and lesions, tissue ablation, and/or vessel coagulation may be indicated.

Genitourinary: Treatment of: Lesions of the external genitalia, urethra and anus, penis, scrotum, and urethra (includes condyloma acuminate, giant perineal condyloma, and verrucous carcinoma), vulvar, lesions, polyps, and familiar polyps of the colon.

Gynecology: Treatment of: Cervical intraepithelial neoplasia (CIN), herpes simplex, endometrial adhesions, cysts, and condyloma.

Oral/Maxiofacial: Treatment of: Benign oral tumors, oral and glossal lesions, and gingivectomy.

Otorhrynolaringology / Head and Neck (ENT): Treatment of: Ear, nose and throat lesions, polyps, cysts, hyperkeratosis, Excision of carcinogenic tissue and oral leukoplakia.

Ophthalmology : Treatment of: Soft tissue surrounding the eye and orbit.

Podiatry: Treatment of: Warts, plantar verrucae, large mosaic verrucae, Matrixectomy.

Clear Lift Pro Q-Switched Cr: Nd: YAG 1064 / 532 nm Applicator
1064nm mode is indicated for the removal or lightening of unwanted facial or body hair, for skin resurfacing (ablation of epidermal skin layers) in dermatology and aesthetic surgery, benign pigmented lesions (dermal melanocytosis) and tattoo removal for dark and blue inks.

532 nm mode is indicated for tattoo removal including red, blue and light blue and green inks, for the treatment of benign vascular lesions including telangiectasias, spider angiomas, cherry angiomas, spider nevi and the treatment of benign pigmented lesions including Café-au-lait birthmarks, solar lentigines, Becker's nevi, freckles nevus spilus and nevus of ota. 532nm mode is also indicated for incision, excision, ablation and vaporization of soft tissue in general dermatology.

ClearVas Nd:YAG 1064nm
For the coagulation and hemostasis of benign vascular lesions such as, but not limited to, port wine stains, hemangiomas, warts, telangiectasia, rosacea, venus lake, leg veins, and spider veins.

Treatment of wrinkles.

Removal of unwanted hair and for the treatment of pseudofolliculitis barbae (PFB).

The ClearVas Nd:YAG 1064nm is indicated for use on all skin types (Fitzpatrick I-VI), including tanned skin.

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 of the 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 Alma Harmony K233024

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 4, 2024

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

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	§ 21 CFR 878.4810
Lamp, Infrared Therapeutic Class II	ILY	General & Plastic Surgery Panel 79	§ 21 CFR 890.5500
Powered Light Based Non-Laser Surgical Instrument with thermal effect	ONF	General & Plastic Surgery Panel 79	§ 21 CFR 878.4810
Medical Device Data System	OUG	General Hospital, Panel 80	§ 21 CFR 880.6310

III. Predicate Device table by Applicator

Applicator	Predicate K Number	Predicate Name	Reference K Number	Reference Name
Iris SHR	K230308	Alma Harmony	N/A	N/A
ClearSkin Pro 1540nm	K203441	Hybrid ProScan 1570	N/A	N/A
SupErb 2940nm	K072564	Er:YAG Laser	N/A	N/A

Applicator	Predicate K Number	Predicate Name	Reference K Number	Reference Name
		Module		
ClearLift Pro Q-Switch (1064nm and 532nm)	K170850	Alma Q	N/A	N/A
ClearVas Nd:YAG 1064nm	K170850	Alma Q	K231054	Wontech
Previously cleared applicators			N/A	N/A
Iris VL/PL	K230308	Alma Harmony		
Iris Dye VL / SVL	K230308	Alma Harmony		
Iris Acne	K230308	Alma Harmony		
Iris NIR	K230308	Alma Harmony		
Iris Diode Laser	K230308	Alma Harmony		

In addition, this submission will add the Smart Clinic Software. This software was previously cleared in the Alma Titanium K230371.

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

Intended Use:

The Alma Harmony is 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).

Indications for use:

ClearSkin Pro 1540nm applicator

The ClearSkin Pro 1540 nm is indicated for: Use in dermatological procedures requiring fractional skin resurfacing and coagulation of soft tissue.

SupErb 2940 nm Applicator

The 2940 nm Er:YAG Laser Module handpiece with standard and scanner accessory tips (with and without contact-cooling) is indicated for use in soft tissue (skin, cutaneous tissue, subcutaneous tissue, striated and smooth tissue, muscle, cartilage meniscus, mucous membrane, lymph vessels and nodes, organs, and glands.

Dermatology and Plastic Surgery: Skin resurfacing, Treatment of wrinkles, Epidermal nevi, Telangiectasia, Spider veins, Actinic chelitis, Keloids, Verrucae, Skin tags, Anal tags, keratoses, Scar revision (including acne scars), Debulking benign tumors, Debulking cysts, Superficial skin lesions, Diagnostic biopsies, Decubitus ulcers.

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Genitourinary: Treatment of: Lesions of the external genitalia, urethra and anus, penis, scrotum, and urethra (includes condyloma acuminate, giant perineal condyloma, and verrucous carcinoma), vulvar. lesions, polyps, and familiar polyps of the colon.

Gynecology: Treatment of: Cervical intraepithelial neoplasia (CIN), herpes simplex, endometrial adhesions, cysts, and condyloma.

Oral/Maxiofacial: Treatment of: Benign oral tumors, oral and glossal lesions, and gingivectomy.

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Ophthalmology: Treatment of: Soft tissue surrounding the eye and orbit.

Podiatry: Treatment of: Warts, plantar verrucae, large mosaic verrucae, Matrixectomy.

Clear Lift Pro Q-Switched Cr: Nd: YAG 1064 / 532 nm Applicator

1064nm mode is indicated for the removal or lightening of unwanted facial or body hair, for skin resurfacing (ablation of epidermal skin layers) in dermatology and aesthetic surgery, benign pigmented lesions (dermal melanocytosis) and tattoo removal for dark and blue inks.

532 nm mode is indicated for tattoo removal including red, blue and light blue and green inks, for the treatment of benign vascular lesion s including telangiectasias, spider angiomas, cherry angiomas, spider nevi and the treatment of benign pigmented lesions including Café-au-lait birthmarks, solar lentigines, Becker's nevi, freckles nevus spilus and nevus of ota. 532nm mode is also indicated for incision, excision, ablation and vaporization of soft tissue in general dermatology.

ClearVas Nd: YAG 1064 nm Applicator

For the coagulation and hemostasis of benign vascular lesions such as, but not limited to, port wine stains, hemangiomas, warts, telangiectasia, rosacea, venus lake, leg veins, and spider veins.

Treatment of wrinkles.

Removal of unwanted hair and for the treatment of pseudofolliculitis barbae (PFB).

The ClearVas ND:YAG 1064nm is indicated for use on all skin types (Fitzpatrick IVI), including tanned skin.

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 of the legs and face, pigmented lesions (e.g. cafe-au-lait stains, lentigo), hemangiomas, port wine stains, rosacea.

V. 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 10 applicators that are attached to the console, which can be selected for use in treatment through the user interface.

In addition, this submission will add the Smart Clinic Software that was previously cleared in the Soprano Titanium (K210371).

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

The subject Harmony system shares with the predicate devices the same underlying technology and presents nearly identical technological characteristics. Both systems use laser, IPL and Near InfraRed (NIR) energy delivered to the skin surface via 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.

Comparison of the ClearSkin Pro 1540nm and the Hybrid ProScan

Device Trade Name	Subject Device	Predicate Device	Comparison
ClearSkin Pro	Harmony ClearSkin Pro	Hybrid ProScan/HyLight – K203441	
Wavelength (nm)	1540 nm	1570 nm	The subject device's wavelength is similar to the predicate and is supported by the histology study.
Energy range per pulse per microbeam (mJ/Pixel)			
7x7	6-82 mJ/Pixel	1-144 mJ/Pixel	It is within the predicate range, and it is supported in the histology study.
Microbeam diameter (Pixel) include pic [mm]			
7X7	1.27mm	1mm	The proposed device's spot size does not raise new concerns for safety and effectiveness, and it is supported in the histology study.
Spacing between the micro beam centers [mm]			
7X7	1.33mm	1.8mm	It is supported in the histology study and does not raise new concerns for safety and effectiveness.
Pulse Width (milliseconds)	3	0.4-30	It is within the predicate range, and it is supported in the histology study.
Pulse Repetition Rate (Hz)	1-3	1-5	The PR range is within the range of the predicate device.
Cooling	Yes	Yes	Same

Comparison of the SupErb 2940nm to the Er:YAG Laser Module

Device Trade Name	Subject Device	Predicate Device	Comparison
SupErb	Harmony SupErb	Er:YAG Laser Module K072564	
Wavelength (nm)	2940 nm	2940 nm	Same
Energy range per pulse per microbeam (mJ/Pixel)			
7x7	4-73 mJ/Pixel	4-51 mJ/Pixel	The proposed device's energy range does not raise new concerns for safety and effectiveness, and it is supported in the histology study.
7 X 1	29-100 mJ/Pixel	4-51 mJ/Pixel (7x7)	This tip(7x1) is the same as the 7x7 technology. Same tip with one row. The proposed device's energy range does not raise new concerns for safety and effectiveness.. It is supported in the histology study
Microbeam diameter (Pixel) include pic [mm]			
7X7	0.7mm	0.7mm	Same
7 X 1	0.7mm	0.7mm	Same
Spacing between the micro beam centers [mm]			
7X7	1.3mm	1.1mm	Does not raise new concerns for safety and effectiveness.
7 X 1	1.2mm	1.3mm	Does not raise new concerns for safety and effectiveness.
Focus beam diameter (non-Fractional)	1mm – 6mm	1mm – 6mm	Same
Energy range per pulse per Spot Size [mJ/pulse] for the non-Fractional Focus Beam			
1mm	200-1400	100-1400	Within the range of the predicate device.
2mm	200-1400	N/A	The corresponding lower fluence for the 2mm spot size does not raise new concerns regarding safety and effectiveness when compared to the 1mm spot size.
3mm	200-1400	N/A	The corresponding lower fluence for the 3mm spot size does not

Device Trade Name	Subject Device	Predicate Device	Comparison
SupErb	Harmony SupErb	Er:YAG Laser Module K072564	
			raise new concerns regarding safety and effectiveness.
4mm	200-1400	100-1400	Within the range of the predicate device.
5mm	200-1400	N/A	The corresponding lower fluence for the 5mm spot size does not raise new concerns regarding safety and effectiveness.
6mm	200-1400	N/A	The corresponding lower fluence for the 6mm spot size does not raise new concerns regarding safety and effectiveness.
8mm	100-250	N/A	The corresponding lower fluence for the 8mm spot size does not raise new concerns regarding safety and effectiveness.
Pulse Width (ms)	0.25-1.5	1-2	The proposed device's PW does not raise new concerns for safety and effectiveness
Pulse Repetition Rate (Hz)	1mm-6mm: 2-6 8mm: 20 @ 0.18ms	2,5	Higher rep rate for subject device is in-motion at a lower fluence. The proposed device's RR does not raise new concerns for safety and effectiveness.
Cooling	Yes	Yes	Same

Comparison of the ClearLift Pro(532nm) to the Alma Q (532nm)

Device Trade Name	Subject Device	Predicate Device	Comparison
ClearLift Pro	Harmony ClearLift Pro	Alma Q K170850	
Wavelength (nm)	532 nm	532 nm	Same
Spot Size	2mm-10mm	2mm-8mm	The lower fluence for the 9mm and 10mm spot sizes does not raise new concerns regarding safety and effectiveness.
Energy range per pulse per Spot Size [mJ/pulse]			
2mm	400	50-450	

Device Trade Name	Subject Device	Predicate Device	Comparison
ClearLift Pro	Harmony ClearLift Pro	Alma Q K170850	
3mm	400	50-450	Within predicate range.
4mm	400	50-450	
5mm	400	50-450	
6mm	400	50-450	
7mm	400	50-450	
8mm	400	350-700	
9mm	400	N/A	Compared to the 2mm-8mm spot sizes, the corresponding lower fluence does not raise new concerns for safety and effectiveness.
10mm	400	N/A	Compared to the 2mm-8mm spot sizes, the corresponding lower fluence does not raise new concerns for safety and effectiveness
Focus beam diameter	2mm – 10mm	2mm – 8mm	Compared to the 2mm-8mm spot sizes, the corresponding lower fluence does not raise new concerns for safety and effectiveness
Pulse Width (nsec)	10nsec	7nsec	Device PW does not raise new concerns for safety and effectiveness.
Pulse Repetition Rate (Hz)	1-6	1, 2, 5, 10	It is within the predicate range.
Cooling	Yes	Yes	Same

Comparison of the ClearLift Pro (1064nm)

Device Trade Name	Subject Device	Predicate Device	Comparison
ClearLift Pro (1064nm)	Harmony ClearLift Pro	Alma Q K170850	
Wavelength (nm)	1064 nm	1064 nm	Same
Spot Size (mm)	2-10mm	1-8mm	The lower fluence for the 9mm and 10mm spot sizes does not raise new concerns regarding safety and effectiveness
Energy range per pulse per Spot Size [mJ/pulse]			
2mm	400-1600	200-2000	Within predicate range.

Device Trade Name	Subject Device	Predicate Device	Comparison
ClearLift Pro (1064nm)	Harmony ClearLift Pro	Alma Q K170850	
3mm	400-1600	200-2000	
4mm	400-1600	200-2000	
5mm	400-1600	200-2000	
6mm	400-1600	200-2000	
7mm	400-1600	200-2000	
8mm	400-1600	200-2000	
9mm	400-1600	N/A	The lower fluence for the 9mm and 10mm spot sizes does not raise new concerns regarding safety and effectiveness.
10mm	400-1600	N/A	
Focus beam diameter (mm)	2mm – 10mm	2mm – 8mm	The lower fluence for the 9mm and 10mm spot sizes does not raise new concerns regarding safety and effectiveness
Pulse Width (milliseconds)	10nsec	7nsec	The device's PW does not raise new concerns for safety and effectiveness.
Pulse Repetition Rate (Hz)	1-6	1, 2, 5, 10	Within the predicate range.
Cooling	Yes	Yes	Same

Comparison of the ClearVas to the Alma Q K170850

	Subject Device	Predicate Device	Reference Device	Comparison
ClearVas	**Harmony ClearVas**	Alma Q K170850	**Wontech K231054**	
Wavelength (nm)	1064 nm	1064 nm	1064 nm	Same
Spot Size	2mm-8mm	3mm-8mm	2-12mm	Within reference predicate range.
Fluence range per pulse per Spot Size [J/cm^2]				
2mm	200-500	N/A	2-300	Does not raise new concerns for safety and effectiveness
3mm	200-400	80-500	2-300	Within predicate range.
4mm	50-170	N/A	2-300	Within reference predicate range.
5mm	50-170	30-180	2-300	Within predicate range.
6mm	50-170	N/A	2-300	Within reference predicate range.
7mm	N/A	14-92	2-300	Subject device does not offer 7mm spot size.
8mm	2-7	7-58	4-7	Within reference predicate range,

	Subject Device	Predicate Device	Reference Device	Comparison
ClearVas	**Harmony ClearVas**	Alma Q K170850	**Wontech K231054**	
				when use In-Motion.
Focus beam Diameter (mm)	2mm – 8mm	3mm – 8mm	2mm-12mm	Within reference predicate range.
Pulse Width (milliseconds)	0.7-45ms	0.5 – 60ms	Max. 60 ms	Within range of the predicate.
Pulse Repetition Rate (Hz)	1,10	1,2,3,5	Max. 10 Hz	Within reference predicate range.
Cooling	Yes	Yes	Yes	Same

Comparison of the Iris SHR to the previously cleared Iris SHR

Device Trade Name	Subject Device	Predicate Device	Comparison
Iris SHR	Harmony Iris SHR 650-950nm	Iris SHR 650-950nm K230308	
Wavelength	650-950 nm (HR/SHR)	650-950 nm (HR/SHR)	Same
Energy Density (Fluence) J/cm^2	SHR: 3-7 HR: 5-20	SHR: 3-7 HR: 5-20	Same
Spot Size	6.4 cm2	3 cm2	The increased spot size does not raise new concerns for safety and effectiveness.
Pulse Width (ms)	30,40,50 msec: HR (Stationary) 8 msec: SHR (In-Motion)	30,40,50 msec: HR (Stationary) 8 msec: SHR (In-Motion)	Same
Rep Rate (Hz)	0.5 and 3	0.5 and 3	Same
Mode	Stationary and In Motion	Stationary and In Motion	Same
Cooling	Yes	Yes	Same

Comparison of the Iris VL / PL to the previously cleared VL / PL

Device Trade Name	Current Iris VL / PL –540 nm -950 nm	Previously cleared VL / PL – 540 nm -950 nm	Comparison
Iris VL / PL	Harmony Iris VL / PL	K230308	
Wavelength	540-950nm	540-950nm	Same
Energy Density (Fluence) J/cm^2	5-30	5-30	Same
Spot Size	3 cm2	3 cm2	Same
Pulse Width	10,12,15 mSec	10,12,15 mSec	Same
Rep Rate	0.67 Hz	0.67 Hz	Same
Mode	Stationary	Stationary	Same
Cooling	Yes	Yes	Same

Comparison of the Iris Dye VL/SVL to the previously cleared Iris Dye VL / SVL

Device Trade Name	Current Iris Dye VL / Dye SVL 500 nm -600 nm	Previously Cleared Iris Dye VL / Dye SVL 500 nm -600 nm	Comparison
Iris Dye VL / Dye SVL	Harmony Iris Dye VL/SVL	K230308	
Wavelength	500-600nm	500-600nm	Same
Energy Density (Fluence) J/cm^2	Dye VL : 5-15 Dye SVL: 1-4	Dye VL : 5-15 Dye SVL: 1-4	Same
Spot Size	3 cm2	3 cm2	Same
Pulse Width (ms)	10,12,15	10,12,15	Same
Rep Rate (Hz)	VL – 0.5 SVL – 3	VL – 0.5 SVL – 3	Same
Mode	Stationary	Stationary	Same
Cooling	Yes	Yes	Same

Comparison of the Iris HR Mode to the previously cleared Iris HR Mode

Device Trade Name	Current Iris HR Mode 650-950 nm	Previously Cleared HR 650-950 nm	Comparison
Iris HR Mode 650-950 nm	Harmony Iris HR	K230308	
Wavelength	650-950 nm (HR)	650-950 nm (HR)	Same
Energy Density (Fluence) J/cm^2	HR: 5-20	HR: 5-20	Same
Spot Size	6.4 cm2	6.4 cm2	Same
Pulse Width (ms)	30,40,50 msec)	30,40,50 msec)	Same
Rep Rate (Hz)	0.5	0.5	Same
Mode	Stationary	Stationary	Same
Cooling	Yes	Yes	Same

Comparison of the Iris Acne to the previously cleared Iris Acne

Device Trade Name	Current Iris Acne 420-950nm	Previously Cleared Acne 420-950nm	Comparison
Iris Acne 420-950nm	Harmony Iris Diode	K230308	
Wavelength	420-950nm	420-950nm	Same
Energy Density (Fluence) J/cm^2	5-25	5-25	Same
Spot Size	6.4 cm2	6.4 cm2	Same
Pulse Width (ms)	30-50msec	30-50msec	Same
Rep Rate (Hz)	1	1	Same
Mode	Stationary	Stationary	Same
Cooling	Yes	Yes	Same

Comparison of the Iris NIR to the Previously Cleared Iris NIR

Device Trade Name	Current Iris NIR 1300nm	Previously Cleared NIR 1300nm	Comparison
Iris NIR	Harmony Iris NIR	K230308	
Wavelength	1300nm	1300nm	Same
Energy Density	15w-25w	Up to 25W	Same
Spot Size	6.4 cm2	6.4 cm2	Same
Pulse Width	CW	CW	Same
Mode	CW Stamping	CW Stamping	Same
Cooling	Yes	Yes	Same

Comparison of the Iris Diode Laser to the Previously Cleared Iris Diode Laser

Device Trade Name	**Current Iris Diode -520nm**	**Previously Cleared Iris Diode -520nm**	**Comparison**
Iris Diode - 532	Harmony Iris Diode	K230308	
Wavelength	520nm	520nm	Same
Energy Density (Fluence) J/cm2	16-40 J/cm2	16-40 J/cm2	Same
Spot Size	0.5-2mm	0.5-2mm	Same
Pulse Width	1-100ms	1-100ms	Same
Rep Rate	1-10hz	1-10hz	Same
Mode	Stamping and Motion	Stamping and Motion	Same
Cooling	No	No	Same

Discussion and summary of technological characteristics:

Based on the summary of technological characteristics of the Alma Harmony in comparison to the predicates, the proposed modifications do not raise new types of considerations for safety and effectiveness compared to the predicate devices as seen in the tables above.

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.

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

Software verification and validation testing was conducted, and documentation provided as recommended by the FDA's "Guidance for the Content of Premarket Submissions Contained in Medical Devices.

Chronic animal studies were performed for the ClearSkin Pro 1540nm applicator. Histology was collected at immediate post 1,3, 7, 14, -day post, and 21-day post treatment on 3 porcine and showed healing at the 21-day point and the SupErb 2940 nm Applicator Histology was collected at immediate post, 1,3, 7-day post, and14-day post treatment on 3 porcine and showed healing at the 3-day point.

Based on the above performance as documented in this application, the subject device was found to have a safety and effectiveness profile that is similar to the predicate devices. Safety is supported by performance testing as well as the animal study.

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 device that is the subject of this 510k pre-market notification is the same or similar in design, intended use, principles of operation, and technological characteristics, compared to the predicate devices. Differences in the subject devices output parameters do not raise new types of questions with regards to safety and effectiveness, and performance testing and histology data provided in this 510k support that the device can be used safely and effectively for the proposed indications for use. The Alma Harmony device that is the subject of this 510K is considered to be substantially equivalent to the predicate devices.