MAR - 8 2012 K113810

Section 5 – 510(k) Summary

I. General Information

Submitter: Alma Lasers, Inc.
485 Half Day Rd. Suite No. 100
Buffalo Grove, IL 68900, USA

Contact Person: Tatiana Epstein
VP Regulatory Affairs
224-377-2011

Summary Preparation Date: December 21, 2011

II. Names

Device Name(s): Modified Alma Lasers Harmony 1064nm (Nd:YAG) Modules

Classification Information:
- Classification Name(s): Surgical Powered Laser Instrument (and accessories)
- Product Code(s): GEX
- Regulation(s): US Title 21 Part 878.4810

III. Predicate Devices
- Cutera GenesisPlus Laser System, manufactured by Cutera, Inc. (K103626)
- PinPointe™ FootLaser™, manufactured by PinPointe USA, Inc. (K093547).
- PinPointe™ FootLaser™ (Model 6W, 30W, 100W), manufactured by Incisive, Inc. (K093545)
- Q-Clear™ Nd:YAG Laser, manufactured by Light Age, Inc. (K110370)
- Alma Lasers Harmony XL™ Muli-Application Platform, manufactured by Alma Lasers (K072564)

IV. Product Description

The Modified Alma Lasers Harmony 1064nm (Nd:YAG) Modules for use in podiatry and for the temporary increase in clear nail in patients with onychomycosis is a laser handpiece that contains the optical bench that emits the high power Nd:YAG laser beam. The Modified Alma Lasers Harmony 1064nm (Nd:YAG) Modules are designed to be used with the Harmony XL™ Muli-Application Platform [Accent, Accent XL, Accent Beauty] for the delivery of long-pulse or Q-switched laser energy. The patient contact portion of the Modified Alma Lasers Harmony 1064nm (Nd:YAG) Modules is a removable, cleanable, sterilizable stand-off tip.

The Modified Alma Lasers Harmony 1064nm (Nd:YAG) Modules are comprised of the following main components:
- Handpiece Housing
  - Incorporates the optical head (laser)
  - Handpiece trigger.

- Standoff-Tip (cleanable/ sterilizable)
- Laser emission indicator – illuminates prior to- and during laser energy emission

- Umbilical cable – houses the wiring to the Harmony XL™ Muli-Application Platform
- Module (handpiece) connector – connects the handpiece umbilical cable to its port on the Harmony XL™ Muli-Application Platform.

V. Intended Use & Indications for Use

Intended Use

The Modified Alma Lasers Harmony 1064nm (Nd:YAG) Modules are intended to be used with the Harmony XL™ Muli-Application Platform for use in aesthetic, cosmetic, and surgical applications requiring the ablation, vaporization, excision, incision, and photothermolysis (photocoagulation or coagulation) of soft tissue in the medical specialties of dermatology, general and plastic surgery, endoscopic/laparoscopic general surgery, gastroenterology, gynecology, otorhinolaryngology (ENT), neurosurgery, oculoplastics, oral surgery, ophthalmology (skin around the eyes), orthopedics, podiatry, pulmonary/thoracic surgery, and urology for surgical and aesthetic applications.

Indications for Use

The Modified Alma Lasers Harmony 1064nm (Nd:YAG) Module handpieces (Long Pulsed and Q-Switched with and without contact-cooling) used with the Harmony XL™ Muli-Application Platform are indicated for use in:

Podiatry

Podiatry (ablation, vaporization, incision, excision, and coagulation of soft tissue) including:

- Matrixectomy
- Periungual and subungual warts
- Plantar warts
- Radical nail excision
- Neuromas

The Modified Alma Lasers Harmony 1064nm (Nd:YAG) Modules (Long Pulsed and Q-Switched) are intended for use with the Harmony XL™ Multi-Application Platform for use for the temporary increase of clear nail in patients with onychomycosis (e.g., dermatophytes *Trichophyton rubrum* and *T mentagrophytes*, and/or yeasts *Candida albicans, etc.)*.

The 1064 nm Nd:YAG Laser Module handpieces (Long Pulsed and Q-Switched with and without contact-cooling) are indicated for treatment and clearance of.

- Benign vascular lesions such as, but not limited to treatment of:
  - Port wine stains
  - Hemangiomas
  - Warts
  - Superficial and deep telangiectasias (venulectasias)
  - Reticular veins (0.1-4.0 mm dia.) of the leg
  - Rosacea
  - Venus lake
  - Leg veins

- Spider veins
- Poikiloderma of Civatte
- Angiomas

- Benign cutaneous lesions, such as, but not limited to:
  - Warts
  - Scars
  - Striae
  - Psoriasis

- Benign pigmented lesions such as, but not limited to:
  - Lentigos (age spots)
  - Solar lentigos (sun spots)
  - Cafe-au-lait macules
  - Seborrheic keratoses
  - Nevi and nevus of Ota
  - Chloasma
  - Verrucae
  - Skin tags
  - Keratoses
  - The removal of black, blue or green tattoos (significant reduction in the intensity of black and /or blue/black tattoos).
  - Plaques

- Pigmented lesions to reduce lesion size, for patients with lesions that would potentially benefit from aggressive treatment, and for patients with lesions that have not responded to other laser treatments.
- The non-ablative treatment of facial wrinkles, such as, but not limited to:
  - Periocular wrinkles
  - Perioral wrinkles
- Laser skin resurfacing procedures for the treatment of:
  - Acne scars
  - Wrinkles
- Reduction of red pigmentation in hypertrophic and keloid scars where vascularity is an integral part of the scar.
- Indicated for use on all skin types (Fitzpatrick I-VI), including tanned skin.

The 1064 nm Nd:YAG lasers (Long Pulsed only, with and without contact-cooling) is indicated for:

- Removal of unwanted hair, for stable long-term, or permanent, hair reduction through selective targeting of melanin in hair follicles.
- Removal or lightening of unwanted hair (with and without adjuvant preparation)
- Treatment of pseudofolliculitis barbae (PFB)

VI. Summary of Technological Characteristics

The technological characteristics of the Modified Alma Lasers Harmony 1064nm (Nd:YAG) Modules are substantially equivalent to those of the predicate devices.

Long Pulsed Module

Characteristic	K11 Modified Alma Lasers Harmony 1064nm (Nd:YAG) Module (Long Pulsed) Alma Lasers, Inc.		K103626 Cutera GenesisPlus Laser System Cutera, Inc.	K093547 & K093545 PinPointe™ FootLaser™ (Model 6W, 30W, 100W) PinPointe USA & Incisive, Inc.	K072564 Alma Lasers Harmony XL™ Muli-Application Platform Alma Lasers, Ltd.		
Product Code Regulation	General & Plastic Surgery GEX, 21 CFR 878. 4810		General & Plastic Surgery GEX, 21 CFR 878. 4810				
Treatment λ	1064 nm (Nd:YAG)		1064 nm (Nd:YAG)	1064 nm (Nd:YAG)	1064 nm (Nd:YAG)		
Spot Size	1 mm dia.	1.5 mm dia.	1 mm dia.	1-1.5 mm dia.	2 mm dia.	6 mm dia.	10 mm dia.
Pulse Energy	20-3500 mJ	20-3500 mJ	20-3500 mJ	20-3500 mJ	400-1,200 mJ		
Pulse Duration	0.1 - 3.0 ms	0.1 - 3.0	0.1 - 3.0 ms	0.1 - 3.0 ms	8-15 ms	40-60 ms	15 ms
Laser Power	≤ 100 W		≤ 100 W	≤ 100 W	0.4 - 1.2W	0.4 - 1.2W	0.4 - 1.2W
Energy Density	25.5 J/cm^2	25.5 J/cm^2	25.5 J/cm^2 (1 mm dia. spot)	25.5 J/cm^2 (1 mm dia. spot)	30-450 J/cm^2	30-150 J/cm^2	30-150 J/cm^2
Repetition Rate	5 -100 Hz	5 -100 Hz	5 -100 Hz	5 -100 Hz	1 Hz	1 Hz	1 Hz
Patient Contact Materials	Stand-off tip		Unknown	Unknown	Stand-off tip		
How provided	**Reusable:** Non-sterile, reusable, cleanable, sterilizable tip		Unknown	**Reusable:** Non-sterile, reusable, cleanable, sterilizable tip	**Reusable:** Non-sterile, reusable, cleanable, sterilizable tip		
Electrical Reqs	220-240 VAC, 50/60Hz		Unknown	120 V~, 60 Hz	220-240 VAC, 50/60Hz		
System Dimensions (W x D x H)	15.7 x 21.7 x 48.5 inches		Unknown	32 x13 x 14 inches	15.7 x 21.7 x 48.5 inches		
System Weight	133 lbs		Unknown	38 lbs	133 lbs		

Q-Switched Module

Characteristic	K11 Modified Alma Lasers Harmony 1064nm (Nd:YAG) Module (Q-Switched) Alma Lasers, Inc.	K110370 Q-Clear™ Nd:YAG Laser Light Age, Inc.	K072564 Alma Lasers Harmony XL™ Muli-Application Platform Alma Lasers, Ltd.
Product Code Regulation	General & Plastic Surgery GEX, 21 CFR 878. 4810	General & Plastic Surgery GEX, 21 CFR 878. 4810	General & Plastic Surgery GEX, 21 CFR 878. 4810
Treatment λ	1064 nm (Nd:YAG) - Q-Switched	1064 nm (Nd:YAG) - Q-Switched	1064 nm (Nd:YAG) - Q-Switched
Spot Size	2.5 mm & 3.5 mm dia. (1, 2, 3, 4, 5, 6 mm dia. for other applications)	2.5 mm & 3.5 mm dia. 2.5 mm, 3.5 mm, 5 mm; (optional 6 mm) dia. for other applications)	1, 2, 3, 4, 5, 6 mm dia.
Pulse Energy	400 mJ (for onychomycosis) (system range 400-1,200 mJ/pulse)	400 mJ (for onychomycosis)* *Level 1 = 350 mJ/pulse Level 2 = 500 mJ/pulse Level 3 = 600 mJ/pulse Level 4 = 700 mJ/pulse	400-1,200 mJ/pulse
Pulse Duration	3 - 10 nsec (system up to 20 nsec)	3 - 10 nsec	20 nsec
Laser Power	Up to 6 W	Up to 6 W	0.4 - 6 W
Energy Density	7.5 J/cm^2 (3.5 mm dia. spot) (system range 7.5 - 450 J/cm^2)	7.5 J/cm^2 (3.5 mm dia. spot)	Up to 152 J/ cm^2
Repetition Rate	3 - 5 Hz (for onychomycosis) (system range 1 - 5 Hz)	3 - 5 Hz (range 1 - 5 Hz)	1, 2, 5 Hz
Patient Contact Materials	Stand-off tip	Unknown	Stand-off tip
How provided	**Reusable:** Non-sterile, reusable, cleanable, sterilizable tip	Reusable: Non-sterile, reusable, cleanable, sterilizable tip	**Reusable:** Non-sterile, reusable, cleanable, sterilizable tip
Electrical Reqs	220-240 VAC, 50/60Hz	120 V~, 60 Hz	220-240 VAC, 50/60Hz
System Dimensions (W x D x H)	15.7 x 21.7 x 48.5 inches	32 x13 x 14 inches	15.7 x 21.7 x 48.5 inches
System Weight	133 lbs	38 lbs	133 lbs

VII. Rationale for Substantial Equivalence

The Modified Alma Lasers Harmony 1064nm (Nd:YAG) Modules (used with the Harmony XL™ Muli-Application Platform) share the same indications for use, device operation, overall technical and functional capabilities, and therefore are substantially equivalent to the predicate devices.

VIII. Safety and Effectiveness Information

The review of the indications for use and technical characteristics demonstrates that the Modified Alma Lasers Harmony 1064nm (Nd:YAG) Modules (used with the Harmony XL™ Muli-Application Platform) are substantially equivalent to the predicate devices for their intended uses.

IX. Conclusion

The Modified Alma Lasers Harmony 1064nm (Nd:YAG) Modules (used with the Harmony XL™ Muli-Application Platform) were found to be substantially equivalent to the predicate devices for their intended uses.

The Modified Alma Lasers Harmony 1064nm (Nd:YAG) Modules (used with the Harmony XL™ Muli-Application Platform)share the same indications for use, similar design features, and functional features with, and thus are substantially equivalent to, the predicate devices for their intended uses.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

May 13, 2013

Alma Lasers, Inc.
% Ms. Anne Worden
Regulatory Consultant
485 Half Day Road, Suite 100
Buffalo Grove, Illinois 68900

Re: K113810
Trade/Device Name: Modified Alma Lasers Harmony 1064nm (Nd:YAG) 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: PDZ, GEX
Dated: December 21, 2011
Received: December 23, 2011

Dear Ms. Worden:

This letter corrects our substantially equivalent letter of March 08, 2012.

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 Small Manufacturers, International and Consumer Assistance 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" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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 yours,
FOR

Peter D. Rumm -S

Mark N. Melkerson
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K11 3816

Device Name: Modified Alma Lasers Harmony 1064nm (Nd:YAG) Modules

Indications for Use:

Intended Use

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Indications for Use

The Modified Alma Lasers Harmony 1064nm (Nd:YAG) Module handpieces (Long Pulsed and Q-Switched with and without contact-cooling) used with the Harmony XL™ Muli-Application Platform are indicated for use in:

Podiatry

Podiatry (ablation, vaporization, incision, excision, and coagulation of soft tissue) including:

- Matrixectomy
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- Plantar warts
- Radical nail excision
- Neuromas

The Modified Alma Lasers Harmony 1064nm (Nd:YAG) Modules (Long Pulsed and Q-Switched) are intended for use with the Harmony XL™ Multi-Application Platform for use for the temporary increase of clear nail in patients with onychomycosis (e.g., dermatophytes *Trichophyton rubrum* and *T. mentagrophytes*, and/or yeasts *Candida albicans, etc.).*

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Prescription Use ✓ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic, and Restorative Devices

510(k) Number K113810

Indications for Use Statement

510(k) Number (if known): K11 3810

Device Name: Modified Alma Lasers Harmony 1064nm (Nd:YAG) Modules

Indications for Use - Continued from previous page

The 1064 nm Nd:YAG Laser Module handpieces (Long Pulsed and Q-Switched with and without contact-cooling) are indicated for treatment and clearance of.

- Benign vascular lesions such as, but not limited to treatment of:
  - Port wine stains
  - Hemangiomas
  - Warts
  - Superficial and deep telangiectasias (venulectasias)
  - Reticular veins (0.1-4.0 mm dia.) of the leg
  - Rosacea
  - Venus lake
  - Leg veins
  - Spider veins
  - Poikiloderma of Civatte
  - Angiomas

- Benign cutaneous lesions, such as, but not limited to:
  - Warts
  - Scars
  - Striae
  - Psoriasis

- Benign pigmented lesions such as, but not limited to:
  - Lentigos (age spots)
  - Solar lentigos (sun spots)
  - Cafe-au-lait macules
  - Seborrheic keratoses
  - Nevi and nevus of Ota

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Prescription Use ✓ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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Division of Surgical, Orthopedic, and Restorative Devices

510(k) Number K113810

Indications for Use Statement

510(k) Number (if known): K113810

Device Name: Modified Alma Lasers Harmony 1064nm (Nd:YAG) Modules

Indications for Use - Continued from previous page

- Benign pigmented lesions - continued:
  - Chloasma
  - Verrucae
  - Skin tags
  - Keratoses
  - The removal of black, blue or green tattoos (significant reduction in the intensity of black and /or blue/black tattoos).
  - Plaques
- Pigmented lesions to reduce lesion size, for patients with lesions that would potentially benefit from aggressive treatment, and for patients with lesions that have not responded to other laser treatments.
- The non-ablative treatment of facial wrinkles, such as, but not limited to:
  - Periocular wrinkles
  - Perioral wrinkles
- Laser skin resurfacing procedures for the treatment of:
  - Acne scars
  - Wrinkles
- Reduction of red pigmentation in hypertrophic and keloid scars where vascularity is an integral part of the scar.
- Indicated for use on all skin types (Fitzpatrick I-VI), including tanned skin.

The 1064 nm Nd:YAG lasers (Long Pulsed only, with and without contact-cooling) is indicated for:

- Removal of unwanted hair, for stable long-term, or permanent, hair reduction through selective targeting of melanin in hair follicles.
- Removal or lightening of unwanted hair (with and without adjuvant preparation)
- Treatment of pseudofolliculitis barbae (PFB)

Prescription Use ✓ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K113810