DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
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June 15, 2017

Alma Lasers LTD
Rekha Anand
Regulatory Associate
Halamish St Pob 3021 Industrial Park
Caesarea, 3088900 Il

Re: K170850
Trade/Device Name: Alma Q
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
Dated: March 21, 2017
Received: March 22, 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 -S3

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)*

K170850

Device Name

Alma Q Laser

Indications for Use *(Describe)*

The Alma Q laser is intended for use in aesthetic 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.

a) LP1064nm

1. 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.
2. The Alma Q laser system is also indicated for the treatment of wrinkles.
3. The Alma Q is also indicated for the removal of unwanted hair and for the treatment of pseudofolliculitis barbae (PFB).
4. The Alma Q laser system is indicated for use on all skin types (Fitzpatrick IVI), including tanned skin.
5. The intended use of the integral cooling system in the Alma Q laser handpiece is to provide cooling of the skin prior to laser treatment, for the reduction of pain during laser treatment, to allow for the use of higher fluences for laser treatments such as hair removal and vascular lesions, and to reduce the potential side effects of laser treatments.

b) QS 532nm

1. Tattoo removal
   -Red inks
   -Blue and light blue inks
   -Green inks
2. Treatment of benign vascular lesions
   -Telangiectasias
   -Spider angiomas
   -Cherry angiomas
   -Spider nevi
3. Treatment of benign pigmented lesions
   -Cafe-au-lait birthmarks solar lentigines
   -Solar lentigines
   -Becker's nevi
   -Freckles
   -Nevus spilus
   -Nevus of ota
4. Incision, excision, ablation, and vaporization of soft tissue in general dermatology

c) QS 1064nm

The Alma Q laser treatment system is intended for use:

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 dermal pigmented lesions (dermal melanocytosis); and

For tattoo removal (dark and blue inks).

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	Kathy Maynor Regulatory Consultant Email : kathy.maynor@almalasers.com Phone: 352-586-3113
Summary Preparation Date	March 21, 2017

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

Trade or Proprietary Name	Alma Q Laser		
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		

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

510(k) #	Trade Name	Product Code
K040384	Mydon/Quantel Derma	GEX
K032667	Naturalase/Focus Medical	GEX
K992597	Naturalase/Focus Medical	GEX

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

The subject device, Alma Q Laser incorporates a flash lamp pumped Nd:Yag laser. The radiation emitted by this device has the ideal 1064nm wavelength. It also incorporates a built-in frequency conversion technology to obtain the 532nm (green) wavelength. The laser system is operated with an articulated arm system for transmitting the laser radiation with different size tips. Alma Q can operate in Q-switching mode and produce 1064nm wavelength beam. This

beam can also be efficiently converted into 532nm wavelength beam using a KTP crystal. This laser can also operate in long-pulsed mode at 1064nm wavelength. The system is intended to be used in user facilities such as hospitals, physicians' offices and medical spas.

The material that could contact the patient during device use is aluminum with 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)]

The Alma Q laser is intended for use in aesthetic 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.

The indications for use for the Alma Q laser share the same or similar indications for use as the predicate devices in that:

LP1064nm

1. 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.
2. The Alma Q laser system is also indicated for the treatment of wrinkles.
3. The Alma Q is also indicated for the removal of unwanted hair and for the treatment of pseudofolliculitis barbae (PFB).
4. The Alma Q laser system is indicated for use on all skin types (Fitzpatrick IVI), including tanned skin.
5. The intended use of the integral cooling system in the Alma Q laser handpiece is to provide cooling of the skin prior to laser treatment, for the reduction of pain during laser treatment, to allow for the use of higher fluences for laser treatments such as hair removal and vascular lesions, and to reduce the potential side effects of laser treatments.

QS 532nm

1. Tattoo removal
   -Red inks
   -Blue and light blue inks
   -Green inks

2. Treatment of benign vascular lesions
   -Telangiectasias
   -Spider angiomas
   -Cherry angiomas
   -Spider nevi

3. Treatment of benign pigmented lesions
   -Cafe-au-lait birthmarks
   -Solar lentigines
   -Becker's nevi
   -Freckles

-Nevus spilus
-Nevus of ota

4. Incision, excision, ablation, and vaporization of soft tissue in general dermatology

QS 1064nm

The Alma Q laser treatment system is intended for use:

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 dermal pigmented lesions (dermal melanocytosis); and

For tattoo removal (dark and blue inks).

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

The technological principles underlying the subject and the predicate devices are the same. A table comparing the key features of the subject and predicate devices is provided on the following page.

Alma Q LP 1064nm Substantial Equivalence Table

Characteristic	**Alma Q**	**Mydon (K040384)**
Wavelength	1064nm	1064nm
Output energy	40J	40J
Fluence	10-450J/cm2 3.0mm spot = 30-300J/cm2 5mm spot = up to 240 J/cm2 7mm spot = 15-100 J/cm2 8mm collimated = up to 58J/cm2	10-450J/cm2 1.5mm spot = 160-450 J/cm2 3.0mm spot = 30-300J/cm2 5mm spot = up to 240 J/cm2 7mm spot = 15-100 J/cm2 10mm spot = 15-50 J/cm2
Pulse duration	0.5 – 60ms	0.5 to 90 ms
Repetition rate	1,2,3, 5 for LP	Single shot to 10Hz
Delivery system	Removable tips	Permanently attached handpiece with inserts
Spot size	3,5,7,8mm	1.5-10mm
Aiming beam	red	red
Footswitch	Yes	Yes
Console dimensions	176 cm x 29 cm x 86 cm (top height of articulated arm) (66.3" x 11.42" x 34")	Not known
Weight	75 kg. / 165.4 lbs.	Not known
Indications for Use	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. 2. The Alma Q laser system is also indicated for the treatment of wrinkles. 3. The Alma Q is also indicated for the removal of unwanted hair and for the treatment of pseudofolliculitis barbae (PFB). 4. The Alma Q laser system is indicated for use on all skin types (Fitzpatrick IVI), including tanned skin. 5. The intended use of the integral cooling system in the Alma Q laser handpiece is to provide cooling of the skin prior to laser treatment, for the reduction of pain during laser treatment, to allow for the use of higher fluences for laser treatments such as hair removal and benign vascular lesions, and to reduce the potential side effects of laser treatments.	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. 2. The MYDON C laser system is also indicated for the treatment of wrinkles. 3. The MYDON C is also indicated for the removal of unwanted hair and for the treatment of pseudofolliculitis barbae (PFB). 4. The MYDON C laser system is indicated for use on all skin types (Fitzpatrick IVI), including tanned skin. 5. The intended use of the integral cooling system in the MYDON C laser handpiece is to provide cooling of the skin prior to laser treatment, for the reduction of pain during laser treatment, to allow for the use of higher fluences for laser treatments such as hair removal and vascular lesions, and to reduce the potential side effects of laser treatments.

Alma Q QS 1064nm Substantial Equivalence Table

Characteristic	Alma Q	Naturalase K992597
Laser wavelength	QS 1064nm	QS 1064nm
Pulse width	7ns	(6-8ns)
Light source	Solid state	Solid state
Repetition (Hz)	1,2,5,10 Hz	1,2,5,10 Hz
Max Output energy	1800mJ	1800mJ
Fluence	2mm – 57.32 J/cm2 3mm – 25.5 J/cm2 4mm - 14.3 J/cm2 5mm – 9.17 J/cm2 6mm - 6.4 J/cm2 7mm - 4.7 J/cm2 8mm - 3.6 J/cm2	2mm – 57.32 J/cm2 3mm – 25.5 J/cm2 4mm –14.3 J/cm2 5mm – 9.17 J/cm2 6mm – 6.4 J/cm2 7mm –4.7 J/cm2 8mm – 3.6 J/cm2 9mm – NA 10mm - NA
Spot Size	3-7mm 8mm collimated	3 – 10mm
Operation mode	Single shot, continuous	Single shot
Aiming beam	Red. Variable intensity	red
Footswitch	Yes	Yes

Characteristic	Alma Q	Naturalase K992597
Console dimensions	176 cm x 29 cm x 86 cm (top height of articulated arm) (66.3" x 11.42" x 34")	124cm x 43cm x 66cm (50" x 17" x 27")
Weight	75 kg. / 165.4 lbs	125Kg./275lbs.
Articulated arm	Yes	Yes
Electrical requirements	230 VAC, 13A, 50/60 Hz, single phase	AC 230 V, 50/60 Hz
Indications for Use	The Alma Q laser treatment system is intended for use: For the removal or lightening of unwanted facial or body hair. For skin resurfacing (ablation of epidermal skin layers) in dermatology and aesthetic surgery, Dermal benign pigmented lesions (dermal melanocytosis); and For tattoo removal (dark and blue inks).	The Lorad LT-100 laser treatment system is intended for use: Alone or in conjunction with an adjuvant lotion for the removal or lightening of unwanted facial or body hair. One or two treatments may be required for lightening or removing unwanted hair without the adjuvant lotion; In combination with the adjuvant lotion for skin resurfacing (ablation of epidermal skin layers) in dermatology and aesthetic surgery, Dermal pigmented lesions (dermal melanocytosis); and For tattoo removal (dark and blue inks). The adjuvant lotion is a suspension of carbon powder in a base of Light Mineral Oil, NF

Alma Q QS532 Substantial Equivalence Table

Characteristic	Alma Q - Proposed	Naturalase K032667
Laser wavelength	QS 532	532nm
Pulse width	7ns	(6-8ns)
Light source	Solid state	Solid state
Repetition (Hz)	1,2,5,10 Hz	1,2,5,10 Hz
Max Output energy	Single-Pulse: 50-450mJ Double-Pulse: 350-700mJ	900 mJ
Fluence	2mm - 22.3 J/cm2 3mm - 9.9 J/cm2 4mm - 5.6 J/cm2 5mm – 3.7J/cm2 6mm - 2.5 J/cm2 7mm - 1.8 J/cm2 8mm - 1.4 J/cm2	2mm – 28.66 J/cm2 3mm – 12.74 J/cm2 4mm – 7.17 J/cm2 5mm – 4.59 J/cm2 6mm – 3.18 J/cm2 7mm – 2.34 J/cm2 8mm – 1.79 J/cm2 9mm - NA
Spot Size	2-7mm 8mm collimated	2mm-9mm
Operation mode	Single shot, double shot	Single shot
Aiming beam	Red, variable intensity	red
Footswitch	Yes	Yes
Articulated arm	Yes	Yes
Electrical requirements	230 VAC, 13A, 50/60 Hz, single phase	220v, single phase, 8 amp
Console dimensions	176 cm x 29 cm x 86 cm (top height of articulated arm) (66.3" x 11.42" x 34")	124cm x 43cm x 66cm (50" x 17" x 27")
Weight	75 kg. / 165.4 lbs.	125Kg/275 lbs.

Indications for Use	Tattoo removal Red inks Blue and light blue inks Green inks Treatment of Benign Vascular Lesions Port wine birthmark Telangiectasias Spider angiomas Cherry angiomas Spider nevi Treatment of Benign Pigmented Lesions - Cafe-au-lait birthmarks Solar lentigines Solar lentigines Becker's nevi Freckles Nevus spilus Nevus of ota Incision, excision, ablation, and vaporization of soft tissue in general dermatology	Tattoo removal Red inks (532 nm Hand Piece Adapter) Blue and light blue inks (Yellow Dye Pack) Green inks (Red Dye Pack) Treatment of Vascular Lesions - 532 nm Hand Piece Accessory Port wine birthmark Telangiectasias Spider angiomas Cherry angiomas Spider nevi Treatment of Pigmented Lesions - 532 nm Hand Piece Accessory Cafe-au-lait birthmarks Solar lentigines Solar lentigines Becker's nevi Freckles Nevus spilus Nevus of ota Incision, excision, ablation, and vaporization of soft tissue in general dermatology.

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
IEC 60601-1-6 Medical electrical equipment - Part 1-6: General requirements forbasic safety and essential performance - Collateral standard: Usability
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
IEC 62304 Medical device software - Software life cycle processes

In addition software verification and validation testing was performed and biocompatibility was established.

In all instances, the Alma Q Laser 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 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 Alma Q Laser is as safe and effective as the predicate devices Mydon and Naturalase (K040384, and K992597/K032667 respectively). The proposed subject device has the same intended use and similar indications, technological characteristics, and principles of operation as its predicate devices. The minor differences in indications do not alter the intended use of the device and do not affect its safety and effectiveness when used as labeled. In addition, the minor technological differences between the subject and its predicate devices raise no new issues of safety or effectiveness. Thus, the Alma Q Laser is substantially equivalent.