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 5, 2016

Alma Ltd
% Ms. Kathy Maynor
Regulatory Consultant
26 Rebecca Ct
Homosassa, Florida 34446

Re: K160952
Trade/Device Name: Alma Diode Tabletop Laser
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: April 1, 2016
Received: April 5, 2016

Dear Ms. Maynor:

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 yours,

Jennifer R. Stevenson -A

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 on last page.

510(k) Number *(if known)*
K160952

Device Name
Alma Diode Tabletop Laser

Indications for Use *(Describe)*

Intended Use
The Alma Diode Tabletop Laser is intended for use in dermatologic and general surgical procedures.

Indications for Use
The Alma Diode Tabletop Laser includes three possible diode laser modules depending on the customer order.
Diode Laser Modules:

The indications for use for the 810 nm Alma Diode Tabletop Laser include:
- The Alma 810 nm diode tabletop laser is indicated for endoluminal or endovenous laser surgery for saphenous incompetent veins.

The indications for use for the 980 nm Alma Diode Tabletop Laser include:
-The Alma 980 nm diode tabletop laser is indicated for use in endovenous occlusion of the greater saphenous vein in patients with superficial vein reflux. The Alma 980 nm diode tabletop laser is further indicated for laser assisted lipolysis.

The indications for use for the 1470 nm Alma Diode Tabletop Laser include:
-The Alma 1470 nm diode tabletop laser is indicated for use in endovenous occlusion of the greater saphenous vein in patients with superficial vein reflux. The Alma 1470 nm diode tabletop laser is further indicated for laser assisted lipolysis.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Section 8 – 510(k) Summary or 510(k) Statement

I. General Information

Submitter:	Alma Lasers, Ltd, Halamish St. POB 302 Industrial Park Caesarea Israel 38900
Contact Person:	Kathy Maynor Consultant 352-586-3113 (cell)
Summary Preparation Date:	May 4, 2016

II. Names

Device Names:	Alma Diode Tabletop Laser
Primary Classification Names:	Surgical Powered Light Instrument

III. Predicate Devices

K #	Predicate Device
K140005	ALMA DIODE TABLETOP LASER
K133774	DIOTECH CO LTD - ATOVEN

IV. Product Description

The Alma Diode Tabletop Laser is comprised of the following major components:

1. The main console unit
2. Pull-back
3. Footswitch
4. Accessories

V. Indications for Use

Intended Use
The Alma Diode Tabletop Laser is intended for use in dermatologic and general surgical procedures.

Indications for Use
The Alma Diode Tabletop Laser includes three possible diode laser modules depending on the customer order.

Diode Laser Modules:
The indications for use for the 810 nm Alma Diode Tabletop Laser include:
- The Alma 810 nm diode tabletop laser is indicated for endoluminal or endovenous laser surgery for saphenous incompetent veins.

The indications for use for the 980 nm Alma Diode Tabletop Laser include:
-The Alma 980 nm diode tabletop laser is indicated for use in endovenous occlusion of the greater saphenous vein in patients with superficial vein reflux. The Alma 980 nm diode tabletop laser is further indicated for laser assisted lipolysis.

The indications for use for the 147 0nm Alma Diode Tabletop Laser include:
-The Alma 1470 nm diode tabletop laser is indicated for use in endovenous occlusion of the greater saphenous vein in patients with superficial vein reflux. The Alma 1470 nm diode tabletop laser is further indicated for laser assisted lipolysis.

VI. Summary of Technical Characteristics

Table 1: Salient Characteristics of the 1470nm module and the Predicate Devices

Parameter	**K13** Alma diode tabletop laser	**K100558** Quanta Diode Laser Family
Product Code & Regulation No.	GEX 21 CFR 878.4810	GEX 21 CFR 878.4810
Laser Wavelength [nm]	1470	1470
Max power	15W	15W
Light/Laser Source	Diode	Diode
Laser Delivery	Optical Fiber	Optical Fiber
Operation Mode	Continuous wave, single pulse, pulsed	Continuous wave, single pulse, pulsed
Pulse Duration	10-990ms	3ms – 2.5s
Bare fiber size	200, 300, 320, 400, 600, 800, 1000	200, 300, 320, 400, 600, 800, 1000
User Interface	LCD touch screen	LCD touch screen
Aiming beam	635nm	650nm
Electrical Requirements	100-240, V AC 50-60 Hz, 6.3 A,	100-240, V AC 50-60 Hz, 6.3 A, single phase,
Indications for Use	The Alma 1470nm diode tabletop laser is indicated for use in endovenous occlusion of the greater saphenous vein in patients with superficial vein reflux. The Alma 1470nm diode tabletop laser is further indicated for laser assisted lipolysis,	The QUANTA Diode Laser System is intended for delivery of laser light to soft tissue in the contact and non contact mode during surgical procedures including via endoscopes. The QUANTA Diode Laser System is generally indicated for use in endovenous occlusion of the greater saphenous vein in Patients with Superficial Vein Reflux. The QUANTA147O Diode Laser is further indicated for laser assisted lipolysis.

Manufacturer	Alma Lasers LTD	Alma Lasers LTD	DIOTECH CO LTD
Cleared Device	**KXXXXXX**	K140005	K133774
System Platform	Alma Diode Tabletop Laser	Alma Diode Tabletop Laser	ATOVEN
Accessory Description	Alma Lasers Pull-Back Device		Automatic fiber pull-back driver ATOVEN
Wavelength Supported	1470nm	810nm, 980nm, and 1470nm	1470nm
Intended Use / Indications For Use	The Alma Lasers Pull-Back Device is an accessory intended for use in conjunction with the previously cleared Alma Diode Tabletop Laser 1470nm (K140005). The Alma Diode Tabletop Laser 1470 nm (K140005) is intended for use in dermatologic and general surgical procedures: endovenous occlusion of the greater saphenous vein in patients with superficial vein reflux, and for laser assisted lipolysis.	The Alma Diode Tabletop Laser 1470 nm is intended for use in dermatologic and general surgical procedures: endovenous occlusion of the greater saphenous vein in patients with superficial vein reflux, and for laser assisted lipolysis.	ATOVEN is a diode laser system designed to delivery of laser light to soft tissue during general surgery procedures. This device intended for treatment of reflux of the saphenous veins of thigh associated with varicose veins and varicosities.
Pullback Accessory			
Dimensions (cm) (H x W x D)	5x20x8	NA	Unk.
Weight (kg)	~0.5	NA	Unk.
Pullback Speed (mm/sec)	4 Steps: 1, 2, and 4 mm/sec	NA	6 Steps: 0.5, 0.7, 1.0, 1.2, 1.5, and 2.0 mm/sec
Pullback mode	Automatic	NA	Automatic
Acceptable fiber sizes	400µm fiber 600µm fiber	NA	400µm fiber 600µm fiber
Mode of Action	Controls the rate of fiber movement along the vein wall providing consistent exposure and minimizing treatment time.	NA	Controls the rate of fiber movement along the vein wall providing consistent exposure and minimizing treatment time.

VII. Safety and Effectiveness Information

The review of the indications for use and technical characteristics provided demonstrates that the Alma diode tabletop laser is substantially equivalent to the predicate devices. Additional product electrical safety testing and EMC testing was successfully completed in accordance with the following standards:

- 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 Collateral Standard: Electromagnetic disturbances - Requirements and tests

VIII. Design Verification Testing

Design verification testing was performed for the Alma 1470nm diode tabletop laser with the pull-back accessory. The testing consisted of performing mechanical tests to verify the actual pull back speeds matched the requested speeds.

Additionally, the software controlling the Alma 1470nm diode tabletop laser with the pull-back accessory was fully verified and validated in accordance with IEC 62304 and the FDA guidance document entitled "*Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices*".

IX. Conclusion

The Alma diode tabletop laser with the pull-back accessory was found to be substantially equivalent to the predicate device.

The Alma diode tabletop laser with the pull-back accessory shares the same or similar indications for use, similar design features, and functional features with, and thus is substantially equivalent to the predicate device.