July 14, 2022

Alma Lasers, Ltd.
% Connie Hoy
Consultant
Hoy & Associates Regulatory Consulting
1830 Bonnie Way
Sacramento, California 95825

Re: K212073
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: June 10, 2022
Received: June 13, 2022

Dear Connie Hoy:

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
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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

# Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
*See PRA Statement below.*

510(k) Number *(if known)*
K212073

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 rm 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)

**CONTINUE ON A SEPARATE PAGE IF NEEDED.**

This section applies only to requirements of the Paperwork Reduction Act of 1995.

***DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.***

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
*PRAStaff@fda.hhs.gov*

*"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."*

# 510(k) Summary

This 510(k) Summary is being submitted in accordance with requirements of 21CFR Section 807.92.

The assigned 510(k) Number: K212073

1. Date of Preparation
   07/14/2022

2. Applicant

| | |
|---|---|
| Name: | Alma Lasers, Ltd. |
| Address: | Alma Lasers, Ltd., 18 Haharsah Street, North Industrial Park Caesarea, Israel 3079895. |
| Contact Person: | Avi Farbstein, Chief Technology and Strategy Officer |
| Telephone: | +972-54-3303402 |
| Email: | avi.farbstein@almalasers.co.il |

3. Identification of the Proposed Device

| | |
|---|---|
| Trade/Device Name: | Alma Diode Tabletop Laser |
| Common Name: | Powered Laser Surgical Instrument |
| Classification Name: | Powered Laser Surgical Instrument |
| 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 |

4. Identification of Predicate Device

| | |
|---|---|
| 510(k) Number: | K160952 |
| Product Name: | Alma Diode Tabletop Laser |
| Manufacturer: | Alma Lasers, Ltd. |

5. Device Description
   The Diode Tabletop System is a small, tabletop laser console that can be sold with one of three wavelengths – 1470nm, 980nm or 810nm. It is comprised of 4 major components. The main console unit contains the laser module, controller, cooling and user interface. The Footswitch is used to activate the laser. The diode laser modules are contained in the main console and emit laser energy in the required wavelength. All of the accessories connect via a fiber to the SMA connection port on the laser console. A single use, radial emitting fiber will be provided sterile by an OEM manufacturer. The fiber is sterilized using ETO. It is for prescription use only.

6. 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 rm 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 indcations 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.

7. Substantially Equivalent (SE) Comparison

Comparison of the Indications for Use: Indications for use statement of the subject and predicate devices are identical.

Comparison of Technology:

| **Device & Predicate Device(s):** | K212073<br>Alma Diode Tabletop Laser | K160952<br>Alma Diode Tabletop Laser |
|---|---|---|
| General Device Characteristics | | |
| Product Code<br>Regulation | GEX<br>21 CFR 878.4810 | GEX<br>21 CFR 878.4810 |
| Laser wavelengths | 810 nm<br>980 nm<br>1470 nm | 810 nm<br>980 nm<br>1470 nm |
| Maximum power | 30 W @ 810nm<br>30 W @ 980 nm<br>15 W @ 1470 nm | 30 W @ 810nm<br>30 W @ 980 nm<br>15 W @ 1470 nm |
| Light source | Diode | Diode |
| Operation mode | Continuous wave, single pulse, pulsed | Continuous wave, single pulse, pulsed |
| Pulse duration | 10-990 ms | 10-990 ms |
| Laser delivery | Optical fiber | Optical fiber |
| Bare fiber size (µm) | 200, 300, 320, 400, 600, 800, 1000 | 200, 300, 320, 400, 600, 800, 1000 |
| User interface | LCD touch screen | LCD touch screen |
| Aiming beam | 635 nm | 635 nm |
| Temperature sensing for lipolysis | Yes, via LipoSense cannula | No |

The technological features of the subject device are comparable to the corresponding technological features of the predicate device. Any difference in the technological features do not raise different questions of safety and effectiveness.

The modified Alma Diode Tabletop laser, subject of this submission, is a modification of the previously cleared device. The modification is to add a temperature sensing thermistor to the cannula to be use during laser lipolysis procedures. The temperature sensor will detect the tissue temperature in near real time and notify the user via an audible beep if the preset temperature has been exceeded. Performance testing was conducted to demonstrate the time required for the temperature sensor to register the tissue temperature and notify the user. Additional performance testing was conducted in an ex vivo porcine model to demonstrate the accuracy of the temperature detection and the relationship between the tissue temperature located at the thermistor as opposed to the temperature a specified distance from the thermistor. Based on the overall performance characteristics, Alma Lasers Ltd believe that there is no significant difference in the subject device and the predicate device.

8. Non-Clinical Testing

Non clinical tests were conducted to verify that the proposed device met all design specifications and was Substantially Equivalent (SE) to the predicate device. The following tests were conducted:

- IEC 60601-1:2005/A1:2012 Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance;
- IEC 60601-1-2:2014 Test for Medical Equipment for General Requirements for basic safety

and essential performance: electromagnetic compatibility;

- IEC 60601-2-22:2012, 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: 2014, Safety of laser products - Part 1: Equipment classification and requirements;
- ISO 17665-1:2006/(R)2013 Sterilization of health care products – Moist Heat – Part 1: Requirements for the development, validation, and routine control of a sterilization process for medical devices;
- Biocompatibility evaluation per ISO 10993 and FDA guidance;
- Software Validation & Verification Test;
- Bench Testing to verify the performance.

9. Clinical Testing

No clinical study is included in this submission.

10. Conclusion

Based on the comparison and analysis above, the proposed subject device is determined to be Substantially Equivalent (SE) to the predicate device.