June 13, 2018

Alma Lasers Inc.
% Janice Hogan
Regulatory Counsel
Hogan Lovells US LLP
1735 Market Street, 23rd Floor
Philadelphia, Pennsylvania 19103

Re: K181298
Trade/Device Name: Harmony XL Multi-Application Platform
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: ONF
Dated: May 16, 2018
Received: May 16, 2018

Dear Janice Hogan:

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.

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 comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

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)*

K181298

Device Name

Harmony XL™ Multi-Application Platform (with the Dye VL Handpiece)

Indications for Use *(Describe)*

The Dye VL Handpiece (500-600 nm) is indicated for:

- 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).

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.

510(k) SUMMARY – K181298

Alma Lasers, Inc.'s Harmony XL™ Multi-Application Platform

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared

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Date Prepared: June 6, 2018

Name of Device

Harmony XL™ Multi-Application Platform

Common or Usual Name

Intense Pulsed Light Instrument

Classification

21 CFR 878.4810, Class II, product code ONF

Predicate Devices

- Harmony XL™ Multi-Application Platform and Thermoelectric Cooler (K072564) (Primary Predicate)
- Alma Harmony Lite (K141237) (Predicate)

Intended Use / Indications for Use

The Dye VL Handpiece (500-600 nm) is indicated for:

- 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).

Device Description

The Harmony XL™ continues to be comprised of the identical console unit, footswitch, and a variety of handpieces. The main console of the Harmony XL™ continues to consist of the same control panel, system controller, power supply modules, cooling system, switching module, and isolation transformer.

Comparison of Technological Characteristics

The subject change is to add a version of the 515-950 nm SVL515 Module AFT handpiece ("SVL515") provided in the company's cleared Harmony XL™ (K072564) to the Harmony XL™ system. The modified handpiece has a narrowed wavelength range of 500-600 nm as compared to the SVL515 handpiece that has a wavelength of 515-950 nm. In addition, the modified handpiece is named the "Dye VL handpiece." Further, the identification color of the distal end of the handpiece is being changed from turquoise to light green.

With regard to indications for use, the intended use/indications for use of the Dye VL handpiece are the same as the primary and secondary predicate devices. Specifically, the Dye VL handpiece consists of a subset of the indications for use of the 532 nm Long Pulsed and Q-Switched FD Nd: YAG Laser Module Handpiece ("532 nm handpiece") included in the primary predicate. Both the subject handpiece and the 532 nm handpiece are indicated for the treatment of benign pigmented lesions including café-au-lait (macules), lentigines (senile and solar), freckles (ephelides), chloasma, nevi, nevus spillus, nevus of Ota, Becker's Nevi and other pigmented cutaneous lesions including verrucae, skin tags, keratosis, and plaques. Further, the indications for use of both the subject Dye VL handpiece and the SVL515 included in both the primary and secondary predicate device are indicated for 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 and are indicated to be used on skin types Fitzpatrick I-V. Therefore, the indications for use of the subject device are the same as its predicates.

Performance Data

- Software verification and validation was performed, and demonstrates that the software performs as intended.
- Electrical safety (IEC 60601-1) and electromagnetic compatibility (IEC 60601-1-2) was established.
- Biocompatibility of patient-contacting components was established per ISO 10993.

In all instances, the subject device functions as intended and meets all the same acceptance criteria as the predicate devices.

Substantial Equivalence

The Harmony XL™ has the same intended use/indications for use, as well as very similar

technological characteristics, and identical principles of operation as its predicate devices. The minor technological differences between the subject and predicate devices do not raise new questions of safety or effectiveness.

Conclusion

The minor technological differences between the subject and predicate devices do not raise new or different questions of safety or effectiveness. Design verification activities demonstrated that the device performs as intended and thus is substantially equivalent.