Alma Lasers Inc.
Attention: Avi Hirshnzon
18 Haharash Street
North Industrial Park
CAESAREA
Ha Zafon 3079895, ISREAL

February 9, 2023

Re: BK220713 (Formally K171242)
Trade/Device Name: Alma LipoFlow System
Regulation Number: 21 CFR 878.5040
Regulation Name: Suction lipoplasty system
Regulatory Class: Class II
Product Code: QKL

Dear Mr. Hirshnzon:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change related to your previous substantial equivalence (SE) determination letter dated July 14, 2017. Specifically, FDA is updating this SE Letter because FDA has assigned your submission a new submission tracking number and created a new product code to better categorize your device technology.

Please update the registration and listing of the device within the FURLS Device Registration and Listing Module according to http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/RegistrationandListing/ucm053185.htm.

For more information, please refer to the Federal Register Notice *Consolidation of Devices That Process Autologous Human Cells, Tissues, and Cellular and Tissue-Based Products at the Point of Care To Produce a Therapeutic Article* (86 FR 50887, available at https://www.federalregister.gov/documents/2021/09/13/2021-18912/consolidation-of-devices-that-process-autologous-human-cells-tissues-and-cellular-and-tissue-based).

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact the Regulatory Project Manager, Hosna Keyvan by email at hosna.keyvan@fda.hhs.gov.

Sincerely,

Wilson W. Bryan, MD
Director
Office of Tissues and Advanced Therapies
Center for Biologics Evaluation and Research

Enclosure

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

July 14, 2017

Alma Lasers Inc.
% Janice Hogan, J.D.
Regulatory Counsel
Hogan Lovells US LLP
1835 Market Street, 29th Floor
Philadelphia, Pennsylvania 19103

Re: K171242
Trade/Device Name: Alma LipoFlow System
Regulation Number: 21 CFR 878.5040
Regulation Name: Suction Lipoplasty System
Regulatory Class: Class II
Product Code: MUU,
Dated: April 27, 2017
Received: April 27, 2017

Dear Ms. 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.

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,

David Krause -S

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)*

K171242

Device Name

Alma LipoFlow System

Indications for Use *(Describe)*

The Alma LipoFlow System is used in the aspiration, harvesting, filtering and transferring of autologous adipose tissue and infiltration for aesthetic body contouring. If the harvested fat is to be re-implanted, the harvested fat is only to be used without any additional manipulation.

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.

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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

Alma Lasers, Inc.'s Alma LipoFlow System

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

Rekha Anand, Senior Regulatory Affairs Associate
Alma Lasers, Inc.
485 Half Day Rd. Suite #100
Buffalo Grove, Illinois, 60089

Phone: 224-377-2000 (Ext 2019)
Email: Rekha.Anand@almalasers.com

Date Prepared: June 29, 2017

Name of Device

Alma LipoFlow System

Common or Usual Name

Suction Lipoplasty System

Classification

21 C.F.R. 878.5040, Class II, product code MUU

Predicate Devices

MicroAire LipoFilter System (K150779) (primary)
MicroAire LipoTower System (K113128)

Intended Use / Indications for Use

The Alma LipoFlow System is used in the aspiration, harvesting, filtering and transferring of autologous adipose tissue and infiltration for aesthetic body contouring. If the harvested fat is to be re-implanted, the harvested fat is only to be used without any additional manipulation.

Device Description

The Alma LipoFlow System is a wheeled cart (also called as console) that contains a peristaltic irrigation pump and an adjustable vacuum source. The peristaltic pump (120 VAC, 50-60 Hz and 220-230 VAC, 50-60 Hz) is intended for continuous and/or intermittent delivery of tumescent liquid into a patient's body. The vacuum source is a rocking piston oil-less

pump that delivers an adjustable vacuum pressure intended for subsequent aspiration of localized subcutaneous fatty deposit.

The console has a control panel that is the user interface for operating the system. The control panel has a peristaltic knob that allows a flow-rate selection of up to 535ml/min. The control panel also has a vacuum knob that allows the delivery of vacuum pressure of up to 27 in Hg (90 kPa). The device operates using a Peristaltic Pump Mode or a Vacuum Pump Mode. Only one mode can be activated at a time using the footswitch.

The system also includes an AC Power Cord, isolation transformer, wires and connectors. Other third party components of the system include: canister-style filters, tubing, syringe for potential re-injection, infiltration cannulas, aspiration cannulas, HEPA filter, HEPA filter tubing, tumescent tubing, suction canister holder and waste canisters.

The canister filter (fat canister) is a closed loop tissue collection system with a volume capacity of up to 2500 mL. It includes a vacuum port, collection port, tissue port and lid. It is used with the aspiration system to separate and filter adipose tissue for possible re-implantation. The aspiration system provides the vacuum suction source to the canister. As the tissue is harvested from the patient, it enters the canister via the collection port in the canister lid. The physician removes unwanted waste materials from the collection system via the vacuum port by closing the valve. This process leaves the fatty tissue that can be transferred to syringes via the tissue port for autologous fat re-injection.

Technological Characteristics

The Alma LipoFlow System has similar technological characteristics as the predicate devices. The subject device combines the technological characteristics of both predicate devices into one device. Similar to the MicroAire LipoTower System (K113128) predicate device, the proposed device is comprised of the system console that controls the overall performance of the system and provides an adjustable suction vacuum source and an adjustable flow irrigation peristaltic pump for the aspiration of soft tissue. Both the Alma LipoFlow System and the MicroAire LipoTower System (K113128) predicate have cooling fans that cool the system. Both devices also include displays that show vacuum pressure and tool setting for control and status of the system and foot controls for controlling the suction and irrigation pump.

Similar to the MicroAire LipoFilter System (K150779) predicate device, Alma Lasers uses a fat canister containing a vacuum port, collection port, tissue port and lid that is used with the aspiration system to separate and filter the adipose tissue for possible re-implantation via syringe.

Performance Data

The following performance testing was conducted to support the substantial equivalence of the Alma LipoFlow System to its predicate devices. In all instances, the Alma LipoFlow System functioned as intended.

- Software verification and validation was performed, and demonstrated that the software performs as intended.
- Electrical safety (IEC 60601-1) and electromagnetic compatibility (IEC 60601-1-2) testing was conducted and results were passing.
- Biocompatibility of patient-contacting components was established.
- Sterility validation was established for all required components.
- Adipose viability testing demonstrated that fat tissue viability was maintained.
- Bench/laboratory testing was completed to verify the functionality of the device components and combined system.

Substantial Equivalence

The Alma LipoFlow System has the same intended use/indications for use, as well as very similar technological characteristics, and principles of operation as its primary predicate device. The minor technological differences between the Alma LipoFlow System and the predicate devices do not raise different questions of safety or effectiveness. Performance testing of the device has demonstrated that the device performs as intended and thus, is substantially equivalent.

Conclusion

Alma Lasers' Alma LipoFlow System is a Suction Lipoplasty System and has been evaluated in nonclinical testing, including adipose viability testing. Testing demonstrates that the device performs as intended. The Alma LipoFlow System is substantially equivalent to its predicate devices.