October 27, 2021

Alma Lasers Inc.
% Kathy Maynor
Consultant
Kathy Maynor Consulting
26 Rebecca Ct
Homosassa, Florida 34446

Re: K201520
Trade/Device Name: The Alma Opus System, Colibri Applicator and Tips
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting and Coagulation Device and Accessories
Regulatory Class: Class II
Product Code: GEI
Dated: October 1, 2021
Received: October 1, 2021

Dear Kathy 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. 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,

Long Chen, Ph.D.
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)*
K201520

Device Name
The Alma Opus System, Colibri Applicator and Tips

Indications for Use *(Describe)*
The Alma Lasers Family of Accent RF Systems [Accent, Accent XL, Accent Elite, and Opus] is intended for use in dermatologic and general surgical procedures.

The Opus Plasma Applicator and Tips -
The Opus Plasma Tips (Focus and Glide), when used with the unipolar applicator, are indicated for dermatological procedures requiring ablation and resurfacing of the skin.

The Opus Colibri Applicator and Tips
The Opus Colibri Tips, when used with the unipolar Opus Colibri applicator, are indicated for dermatological procedures requiring resurfacing of the skin.

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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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 (Primary) Regulatory consultant Email: regulatory@almalasers.com Phone: 352-586-3113 Facsimile: 646-805-1305 Jessica Rivera-Montejo (Secondary) Director of Regulatory and Quality Email: regulatory@almalasers.com Phone: 224-377-2019
Summary Preparation Date	Oct. 27, 2021

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

Trade or Proprietary Name	The Alma Opus System, Colibri Applicator and Tips		
Common Device Name(s) and Regulatory Class	**Product Code(s)**	**Classification Panel**	**Regulation**
Electrosurgical cutting and coagulation device and accessories Class II	GEI	General & Plastic Surgery Panel, 79 (SU)	§ 878.4400, Electrosurgical, Cutting & Coagulation & Accessories

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

Type	**510(k) #**	**Trade Name**	**Product Code**
Primary	K121150	Family of Accent Pixel RF Tips	GEI

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

The new Colibri handpiece with two tips incorporates the unipolar RF-based technology and delivers radiofrequency energy via the designed tips that creates

micro-plasma causing controlled ablation micro-perforations and a thermal injury zone in the skin, surrounding the perforations.

The new Colibri RF fractional tips are made of the same material as the existing cleared RF tips. The purpose of the Colibri tips is to treat very small areas of skin.

V. Intended use of device and Indications for Use [21 CFR 807.92(a) (5)]

Indications for Use

The Alma Lasers Family of Accent RF Systems [Accent, Accent XL, Accent Elite, and Opus] is intended for use in dermatologic and general surgical procedures.

The Opus Plasma Applicator and Tips -

The Opus Plasma Tips (Focus and Glide), when used with the unipolar applicator, are indicated for dermatological procedures requiring ablation and resurfacing of the skin.

The Opus Colibri Applicator and Tips

The Opus Colibri Tips, when used with the unipolar Opus Colibri applicator, are indicated for dermatological procedures requiring resurfacing of the skin.

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

The technological principles underlying the subject device and its prior legally marketed predicate (K121150) are the same. The intended use remains the same.

Operation of the modified hand piece involves the delivery of RF energy through micro ablative tips. Energy source type and parameters are the within the range already cleared in prior iteration of the device. The only technological differences in the subject device are:

- The Colibri has a single point delivery electrode
- The Colibri tip is supplied as a non-sterile, single-use device
- The Colibri handpiece does not accept the currently cleared RF pixel tips. Those tips are on the currently cleared unipolar handpiece.

These differences do not raise new questions of safety or effectiveness, as the operation of the device and technological parameters are substantially equivalent to the predicate.

VII. Performance Testing [21 CFR 807.92(b)(1)]

IEC 60601-1-2 Medical Electrical Equipment 1-2 General Requirements for basic safety and essential performance, Electromagnetic Compatibility
IEC 60601-2-2 Medical Electrical Equipment – Part 2-2: Particular Requirements For The Basic Safety and Essential Performance Of High Frequency Surgery Equipment and High Frequency Surgical Accessories
IEC 60601-1 Medical Electrical Equipment - General Requirements for basic safety and essential performance

In addition, software verification and validation testing were performed.

Non-Clinical Performance Testing

Alma also performed histology testing on porcine animals for The Alma Opus System Colibri Applicators and tips. Testing was performed safely on the test animals, and the histology results complied with the FDA requirements at 0, 3, 7 and 14 days. Three [3] Domestic female (Mixed Landrace & Large White) crossbred swine were used in this study. During the in-life stage, vital signs, ECG and % saturation were monitored, clinical observations and body weights were monitored and recorded. Re-epithelialization was observed three days after radiation in all specimens. No adverse events or unexpected complications have been detected in the swine. On the last day of trial, biopsies were taken from the center of each radiated point by punch biopsy and were sent to H&E. At the end of the procedure at first, third, and seventh days, the animal was awakened and transferred to the recovery room. Euthanizing of the pigs were done at the end of the study on day 14.

To summarize, according to this preclinical investigation the Opus Colibri RF technology does not pose any unexpected risks. The damage was found to be very superficial and limited. The Alma Opus System Delivery Devices (Colibri Applicator Tips) and Accessories 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 the predicate, no clinical studies were deemed needed to support this submission.

IX. Conclusions Safety and Effectiveness SE [21 CFR 807.92(b) (3)]

The Alma Opus System, Colibri Applicator and Tips is as safe and effective as the predicate K121150. The proposed system has the similar indications, similar technological characteristics, and same principle of operation as its predicate device. The addition of the Alma Opus System, Colibri Applicator and Tips does not alter the intended therapeutic use and does not affect safety and effectiveness when used as labeled. Thus, the Alma Opus system, Colibri Applicator and Tips is substantially equivalent to its predicate.