



Food and Drug Administration
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Silver Spring, MD 20993-0002

August 17, 2016

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

Re: K160075
Trade/Device Name: Accent XL
Regulation Number: 21 CFR 890.5300
Regulation Name: Ultrasonic diathermy
Regulatory Class: Class II
Product Code: IMI, GEI; ISA; NUV
Dated: July 15, 2016
Received: July 20, 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,

Michael J. Hoffmann -A

for Carlos L. Peña, PhD, MS
Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K160075

Device Name

Accent XL

Indications for Use (Describe)

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

The Alma Lasers Family of Accent RF Systems [Accent, Accent XL, Accent Elite] is indicated for the non-invasive treatment of wrinkles and rhytids using a combined treatment with Unipolar and Bipolar hand pieces.

The massage component of the Alma Lasers Accent Uniform Hand piece is intended for use with the Modified Alma Lasers Family of Accent RF Systems [Accent, Accent XL, Accent Elite] to provide:

-Temporary reduction in the appearance of cellulite.

Simultaneous application of the RF energy and mechanical manipulation of the skin is intended for use with the Modified Alma Lasers Family of Accent RF Systems [Accent, Accent XL, Accent Elite] to provide:

-Temporary reduction in the appearance of cellulite.

The Unipolar and Bipolar hand pieces, when used as a combined treatment, are indicated for the non-invasive treatment of wrinkles and rhytids.

The Pixel RF Tips (stationary and rolling), when used with the unipolar hand piece, are indicated for dermatological procedures requiring ablation and resurfacing of the skin.

Ultrasound Module provides ultrasonic diathermy intended for:

- Relief of pain
- Muscle spasms
- Joint contractures
- NOT for the treatment of malignancies

The hand pieces above are intended to be used with the console cleared in K101147 Alma Lasers Family of Accent RF Systems [Accent, Accent XL, Accent Elite].

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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K160075
510(k) Summary

I. General Information

510(k) Holder: Alma Lasers Inc.
485 Half Day Rd. Suite 100
Buffalo Grove, IL 60089

Contact Person: Kathy Maynor
Regulatory Consultant
352-586-3113

Summary Preparation Date: August 16, 2016

II. Names

Trade Name: Accent XL

Classification Names: Diathermy, Ultrasonic, For Use in Applying Deep
Therapeutic Heat
Electrosurgical Cutting Devices and Accessories
Therapeutic Massager

Product Codes: IMI (Primary) – Diathermy, Ultrasonic, For Use in
Applying Deep Therapeutic Heat
GEI- Electrosurgical, Cutting & Coagulation &
Accessories
ISA - Massager, Therapeutic, Electric
NUV - Massager, Vacuum, Light Induced Heating

Classification Panels: Physical Medicine for ultrasound hand piece
General and Plastic Surgery for other hand pieces

Regulations: 21 CFR Part 890.5300 Ultrasonic Diathermy
21 CFR Part 878.4400 Electrosurgical Cutting Devices
21 CFR 890.5660 Therapeutic Massager
21 CFR 878.4810 Laser Surgical Instrument For Use In
General and Plastic Surgery and in Dermatology

Common Name: Ultrasound, Surgical Devices, Radiofrequency

III. Predicate Devices

K091615	General Project MC1 (primary)
K952536	Zimmer Sono 5 (reference)
K121150	Alma Lasers Family of Pixel RF Tips
K101147	Modified Alma Lasers Family of Accent Radiofrequency (RF) System
K082622	Alma Lasers Accent B-Shape Massager Hand piece/Module

IV. Product Description

The Alma Lasers Accent XL is a console with three previously cleared RF hand pieces and one ultrasound hand piece that is the subject of this submission. The previously cleared hand pieces have not changed from what was cleared in their associated 510(k) submissions. The new ultrasound hand piece is a therapeutic ultrasound hand piece with a frequency of 1 MHz using a 1.2 cm² transducer. The touch screen on the console shows the treatments that have been chosen and when the output is active.

V. Indications for Use

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

The Alma Lasers Family of Accent RF Systems [Accent, Accent XL, Accent Elite] is indicated for the non-invasive treatment of wrinkles and rhytids using a combined treatment with Unipolar and Bipolar hand pieces.

The massage component of the Alma Lasers Accent Uniform Hand piece is intended for use with the Modified Alma Lasers Family of Accent RF Systems [Accent, Accent XL, Accent Elite] to provide:

- Temporary reduction in the appearance of cellulite.

Simultaneous application of the RF energy and mechanical manipulation of the skin is intended for use with the Modified Alma Lasers Family of Accent RF Systems [Accent, Accent XL, Accent Elite] to provide:

- Temporary reduction in the appearance of cellulite.

The Unipolar and Bipolar hand pieces, when used as a combined treatment, are indicated for the non-invasive treatment of wrinkles and rhytids.

The Pixel RF Tips (stationary and rolling), when used with the unipolar hand piece, are indicated for dermatological procedures requiring ablation and resurfacing of the skin.

Ultrasound Module provides ultrasonic diathermy intended for:

- Relief of pain

- Muscle spasms
- Joint contractures
- NOT for the treatment of malignancies

The hand pieces above are intended to be used with the console cleared in K101147 Alma Lasers Family of Accent RF Systems [Accent, Accent XL, Accent Elite].

VI. Summary of Technical Characteristics

Ultrasound

Parameter	K160075 Accent XL with the Alma Ultra handpiece	K091615 MC1 General Project	K952536 Zimmer Sono 5
Product Code & Regulation No.	IMI 21 CFR 890.5300	IMI 21 CFR 890.5300	IMI 21 CFR 890.5300
Cooling	Thermoelectric	Unk,	Unk.
Ultrasounds Frequency	1MHz (± 20%)	1MHz (± 20%)	0.8MHz
Pulse Modulation Frequency	Continuous	Pulsed 20-60kHz	Continuous
Effective Radiating Area (ERA)	1.2 cm ²	4.9cm ²	5.0cm ²
BNR (Maximum Beam Non-uniformity Ratio)	6:1	4:1	6:1
Ultrasonic Intensity	3W/cm ²	3W/cm ²	3W/cm ²
Max treatment time	30 minutes	30 minutes	30 minutes
User Interface	LCD touch screen	LCD touch screen	Unk.
Electrical Requirements	100-240VAC, 50-60 Hz, 6.3 A,	100-240VAC 50-60 Hz	Unk.
Indications for Use	Ultrasonic Diathermy: 1. Relief of pain; 2. Muscle spasms; 3. Joint contractures; 4. NOT for the treatment of malignancies.	Ultrasonic Diathermy: 1. Relief of pain; 2. Muscle spasms; 3. Joint contractures; 4. NOT for the treatment of malignancies.	Not available in FDA website database

RF and Massage

<p>Device Name</p> <p>Characteristics</p>	<p>K160075</p> <p>Accent XL with the Alma Ultra Hand piece</p>	<p>K121150</p> <p>Alma Lasers, Ltd.</p> <p>Family of Accent RF Pixel Tips with Pixel^{RF} Module/ Hand piece</p>	<p>K101147</p> <p>Alma Lasers Family of Accent RF Systems [Accent, Accent XL, Accent Elite] (w/ UniPolar & BiPolar Hand pieces)</p>
Product Code	General & Plastic Surgery	General & Plastic Surgery	General & Plastic Surgery
Regulation	<ul style="list-style-type: none"> • GEI, OUH, NUV, ISA – 21 CFR 878.4400 	<ul style="list-style-type: none"> • GEI, OUH – 21 CFR 878.4400 	<ul style="list-style-type: none"> • NUV, GEI, ISA - 21 CFR 878.4810
Intended Use	Intended for use in dermatologic and general surgical procedures	Intended for use in dermatologic and general surgical procedures	Intended for use in dermatologic and general surgical procedures
Indications for Use	<p>The Unipolar and Bipolar hand pieces, when used as a combined treatment, are indicated for the non-invasive treatment of wrinkles and rhytids.</p> <p>The Pixel RF Tips (stationary and rolling), when used with the unipolar hand piece, are indicated for dermatological procedures requiring ablation and resurfacing of the skin.</p>	<p>The Alma Lasers family of Accent RF Systems (Accent, Accent XL, Accent Elite) with Unipolar and Bipolar Hand pieces are intended for use in dermatologic and general surgical procedures.</p> <p>The Unipolar and Bipolar hand pieces, when used as a combined treatment, are indicated for the non-invasive treatment of wrinkles and rhytids.</p> <p>The Pixel RF Tips (stationary and rolling), when used with the unipolar hand piece, are indicated for dermatological procedures requiring ablation and resurfacing of the skin.</p>	Indicated for: The non-invasive treatment of wrinkles and rhytids using a combined treatment with Unipolar and Bipolar hand pieces
RF Power (or Energy)	<ul style="list-style-type: none"> • UniPolar & UniLarge Up to 200 W (1.51 W/mm²) • BiPolar & BiPolarS Up to 420 W (1.51 W/mm²) 	<ul style="list-style-type: none"> • UniPolar Up to 200 W (2.08 W/mm²) 	<ul style="list-style-type: none"> • UniPolar & UniLarge Up to 200 W (1.51 W/mm²) • BiPolar & BiPolarS Up to 420 W (1.51 W/mm²)
Peak Output	300W	300W	300W
RF Frequency	40.68 MHz ± 20 kHz	40.680MHz	40.680MHz

<div style="text-align: center;">Device Name</div> <div style="text-align: center;">Characteristics</div>	<div style="text-align: center;">K160075</div> <div style="text-align: center;">Accent XL with the Alma Ultra Hand piece</div>	<div style="text-align: center;">K121150</div> <div style="text-align: center;">Alma Lasers, Ltd.</div> <div style="text-align: center;">Family of Accent RF Pixel Tips with Pixel^{RF} Module/ Hand piece</div>	<div style="text-align: center;">K101147</div> <div style="text-align: center;">Alma Lasers Family of Accent RF Systems [Accent, Accent XL, Accent Elite] (w/ UniPolar & BiPolar Hand pieces)</div>
Pulse modulation frequency	RF Pixel: 65KHz UniPolar & BiPolar Hand pieces: 15KHz	RF Pixel: 65KHz	UniPolar & BiPolar Hand pieces: 15KHz
Pulse modulation control	PWM	PWM	PWM
Standing Wave Ratio	1:2	1:2	1:2
RF massage ring rotation speed	150 turns/min (tpm)	Not applicable	150 turns/min (tpm)
Handpiece-Patient contact interface area	<ul style="list-style-type: none"> ● UniPolar & UniLarge 13 to 19 mm dia. ● BiPolarS & BiPolar 8.95 to 13 mm dia. ● Stationary Pixel^{RF} Tips (Unipolar) 12 mm dia. ● Roller Pixel^{RF} Tips (Unipolar) 10 x 22.7 mm circumference 'roller' 	<ul style="list-style-type: none"> ● Stationary Pixel^{RF} Tips (Unipolar) 12 mm dia. ● Roller Pixel^{RF} Tips (Unipolar) 10 x 22.7 mm circumference 'roller' 	<ul style="list-style-type: none"> ● UniPolar & UniLarge 13 to 19 mm dia. ● BiPolarS & BiPolar 8.95 to 13 mm dia.
Tip Matrix	Stationary Pixel^{RF} Tips <ul style="list-style-type: none"> ● ~ 110 Pixel points (1.0 pixels/mm²) Roller Pixel^{RF} Tips <ul style="list-style-type: none"> ● ~132 Pixel points per cm (1.3 pixels/mm²) 	Stationary Pixel^{RF} Tips <ul style="list-style-type: none"> ● ~ 110 Pixel points (1.0 pixels/mm²) Roller Pixel^{RF} Tips <ul style="list-style-type: none"> ● ~132 Pixel points per cm (1.3 pixels/mm²) 	Not applicable
Tip Matrix type	Electrodes	Electrodes	Not applicable
Cooling	Thermo-electric cooling	Not applicable	Thermo-electric cooling

<div style="text-align: center;">Device Name</div> <div style="text-align: center;">Characteristics</div>	<div style="text-align: center;">K160075</div> <div style="text-align: center;">Accent XL with the Alma Ultra Hand piece</div>	<div style="text-align: center;">K121150</div> <div style="text-align: center;">Alma Lasers, Ltd.</div> <div style="text-align: center;">Family of Accent RF Pixel Tips with Pixel^{RF} Module/ Hand piece</div>	<div style="text-align: center;">K101147</div> <div style="text-align: center;">Alma Lasers Family of Accent RF Systems [Accent, Accent XL, Accent Elite] (w/ UniPolar & BiPolar Hand pieces)</div>
Handpiece Size/Weight Dimensions	<u>Size:</u> <ul style="list-style-type: none"> ● UniPolar - 169 x 205 mm ● BiPolar - 167 x 203 mm ● Pixel^{RF} Hand piece - 160 x 155 mm <u>Weight:</u>	<u>Size:</u> Pixel ^{RF} Hand piece - 160 x 155 mm <u>Weight:</u>	<u>Size:</u> <ul style="list-style-type: none"> ● UniPolar - 169 x 205 mm ● BiPolar - 167 x 203 mm <u>Weight:</u>
Patient Contact Materials	Hand pieces: <ul style="list-style-type: none"> ● Anodized aluminum and Delrin plastic Tip: <ul style="list-style-type: none"> ● Stationary Pixel^{RF} Tips – Aluminum ● Roller Pixel^{RF} Tips – Aluminum, Sapphire 	<ul style="list-style-type: none"> ● Stationary Pixel^{RF} Tips – Aluminum ● Roller Pixel^{RF} Tips – Aluminum, Sapphire 	Hand pieces: <ul style="list-style-type: none"> ● Anodized aluminum and Delrin plastic
How provided	Disposable and Reusable Stationary & Roller Pixel^{RF} Tips: Reusable, cleanable, serializable Tips and disposable tips also available	Disposable and Reusable Stationary & Roller Pixel^{RF} Tips: <ul style="list-style-type: none"> ● Reusable, cleanable, serializable Tips and disposable tips also available 	Not applicable

VII. Substantial Equivalence Information and Performance Testing

The review of the indications for use and technical characteristics provided above, demonstrates that the Accent XL with the Alma Ultra hand piece, is substantially equivalent to the predicate devices.

Testing was performed in accordance with the following IEC tests:

IEC 60601-1:05+CORR.1(2006)+CORR.2(2007)+A1:12 The general standard IEC 60601-1 – Medical Equipment / medical electrical equipment - Part 1: General requirements for basic safety and essential performance - gives general requirements of the series of standards. The standard contains requirements concerning basic safety and essential performance that are generally applicable to medical electrical equipment.

IEC 60601-1-2:2007 (edition 3.0): Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility - Requirements and tests.

IEC 60601-2-2:2009: Medical electrical equipment – Part 2-2: Particular requirements for the basic safety and essential performance of high frequency surgical equipment and high frequency surgical accessories

IEC 60601-2-5:2009: Medical electrical equipment - Part 2-5: Particular requirements for the basic safety and essential performance of ultrasonic physiotherapy equipment.

Biocompatibility testing was performed in accordance with the following standards and the patient contacting material for the ultrasound hand piece has been previously cleared in K042000 and K141237:

ISO 10993-5:1999 Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity

ISO 10993-10:1999 Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization

Performance Bench Testing

Additionally, temperature testing was conducted to ensure that (1) the ultrasound device must raise the skin temperature to 40-45°C in less than 15 minutes, (2) the ultrasound device must be capable of maintaining the skin temperature at 40-45°C for a minimum of 10 minutes and (3) the ultrasound device can treat for 30 minutes with no adverse effects.

VIII. Conclusion

The Accent XL with the Alma Ultra hand piece has the same intended use as the predicate devices with similar indications for use. It presents similar technological

characteristics as the predicate device including design features, ultrasonic intensity, ultrasound frequency etc.

Although there are some differences between the Accent XL with the Alma Ultrasound hand piece, and its predicate devices in terms of Effective Radiating Area (ERA), BNR (Maximum Beam Non-uniformity Ratio) etc., the differences do not present any new concerns of safety and effectiveness, since the Accent XL with the Alma Ultra hand piece parameters are within the range used by the predicate devices for treatment of temporary relief of pain, muscle spasms and joint contractures.

The Accent XL with the Alma Ultra hand piece and its predicate devices operate with the same mechanism of action, based on converting electromagnetic energy in ultrasonic oscillations and delivering ultrasonic waves to the treated area.

The RF hand pieces and the massager hand piece that can also be attached to the Accent XL console were previously cleared via K121150 and K101147.

Therefore, the Accent XL with the Alma Ultra hand piece has the same intended use, technological characteristics, and principles of operation as the predicate devices. Thus, the Accent XL with the Alma Ultra hand piece is substantially equivalent to the predicate device.