



Food and Drug Administration
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August 26, 2016

Yerim Engineering Co., Ltd.
% Priscilla Chung
Regulatory Affairs Consultant
LK Consulting Group USA, Inc.
800 Roosevelt Ste 417
Irvine, California 92620

Re: K161503

Trade/Device Name: Orion
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: May 23, 2016
Received: June 1, 2016

Dear Priscilla Chung:

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,

Christopher J. Ronk -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

Indications for Use

510(k) Number (if known)

K161503

Device Name

ORION

Indications for Use (Describe)

532nm

The ORION is indicated for coagulation and hemostasis of vascular and cutaneous lesions in dermatology including, but not limited to, the following general categories: vascular lesions[angiomas, hemangiomas (port wine), telangiectasia (facial or extremities telangiectasias, venous anomalies, leg veins)]; benign pigmented lesions (nevi, lentigines, chloasma, cafe-au-lait, tattoos (red and green ink); verrucae; skin tags; keratoses; plaques; cutaneous lesion treatment (hemostasis, color lightening, blanching, flattening, reduction of lesion size).

755 nm

The ORION is indicated for stable long-term, or permanent hair reduction which is defined as the long-term, stable reduction in the number of hairs regrowing when measured at 6, 9, and 12 months after the completion of a treatment regime. It is used for all skin types (Fitzpatrick I- VI) including tanned skin. It is also indicated for the treatment of vascular lesions, benign pigmented lesions, and wrinkles.

1064 nm

The ORION is intended for the coagulation and hemostasis of benign vascular lesions such as, but not limited to, port wine stains, hemangiomas, warts, telangiectasia, rosacea, venus lake, leg veins, spider veins and poikiloderma of civatte; and treatment of benign cutaneous lesions such as warts, scars, striae and psoriasis. The laser is also intended for the treatment of benign pigmented lesions such as, but not limited to, lentigos (age spots), solar lentigos (sun spots), cafe au lait macules, seborrheic keratoses, nevi, chloasma, verrucae, skin tags, keratoses, tattoos (significant reduction in the intensity of black and/or blue/black tattoos) and plaques.

The laser is also indicated for the treatment of wrinkles such as, but not limited to, periocular and perioral wrinkles. Additionally, the laser is indicated for the removal of unwanted hair, for the stable long term, or permanent hair reduction which is defined as the long-term, stable reduction in the number of hairs regrowing when measured at 6, 9, and 12 months after the completion of a treatment regime through selective targeting of melanin in hair follicles, and for the treatment of pseudofolliculitis barbae (PFB).

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

(K161503)

This summary of 510(k)-safety and effectiveness information is being submitted in accordance with requirements of 21 CFR Part 807.92.

Date: Aug 19, 2016

1. Applicant / Submitter:

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2. Submission Correspondent:

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3. Device:

Proprietary Name:	ORION
Common Name:	Medical Laser System
Classification Name:	Instrument, Surgical, Powered, Laser
Classification:	Class II, 21 CFR 878.4810
Classification Product Code:	GEX

4. Predicate Device:

- Primary Predicate Device:
Family of Altus Medical Modified Cool Glide Aesthetic Lasers by Altus Medical, Inc. (K014040)
- Reference Predicate Device:
Cynosure Apogee Elite Laser by CYNOSURE, INC. (K034030)
CLARITY LPC Laser System by Lutronic Corporation (K130199)

5. Device Description:

The subject device is composed of the main body and a handpiece which is an irradiation device and as an accessory part, protective goggles for protection of the worker.

It is controlled by a micro processor interfaced to a LCD touch screen control panel. The computer controls start and stop of the treatment. When the key switch of the system is turned clockwise, the main power will be inputted, which will be conveyed to the hand piece through the control board.

Meanwhile, the control board connected to the touch screen is connected to the lamp of the handpiece and controls the same, and controls the whole system through the data connected to the touch screen control panel. When the switch of the hand piece is pressed, the lamp will laser.

6. Indications for Use:

532nm

For coagulation and hemostasis of vascular and cutaneous lesions in dermatology including, but not limited to, the following general categories: vascular lesions[angiomas, hemangiomas (port wine), telangiectasia (facial or extremities telangiectasias, venous anomalies, leg veins)]; benign pigmented lesions (nevi, lentigines, chloasma, cafe-au-lait, tattoos (red and green ink); verrucae; skin tags; keratoses; plaques; cutaneous lesion treatment (hemostasis, color lightening, blanching, flattening, reduction of lesion size).

755 nm

The ORION is indicated for stable long-term, or permanent hair reduction which is defined as the long-term, stable reduction in the number of hairs regrowing when measured at 6, 9, and 12 months after the completion of a treatment regime. It is used for all skin types (Fitzpatrick I- VI) including tanned skin.

It is also indicated for the treatment of vascular lesions, benign pigmented lesions, and wrinkles.

1064 nm

The ORION is intended for the coagulation and hemostasis of benign vascular lesions such as, but not limited to, port wine stains, hemangiomas, warts, telangiectasia, rosacea, venus lake, leg veins, spider veins and poikiloderma of civatte; and treatment of benign cutaneous lesions such as warts, scars, striae and psoriasis. The laser is also intended for the treatment of benign pigmented lesions such as, but not limited to, lentigos (age spots), solar lentigos (sun spots), cafe au lait macules, seborrheic keratoses, nevi, chloasma, verrucae, skin tags, keratoses, tattoos (significant reduction in the intensity of black and/or blue/black tattoos) and plaques.

The laser is also indicated for the treatment of wrinkles such as, but not limited to, periocular and perioral wrinkles.

Additionally, the laser is indicated for the removal of unwanted hair, for the stable long term, or permanent hair reduction which is defined as the long-term, stable reduction in the number of hairs regrowing when measured at 6, 9, and 12 months after the completion of a treatment regime through selective targeting of melanin in hair follicles, and for the treatment of pseudofolliculitis barbae (PFB).

7. Performance Data(Non-Clinical):

The following properties were tested based on the referenced standards. All the test results support substantial equivalence to the predicate devices.

- IEC 60601-1 Medical electrical equipment - part 1: general requirements for basic safety and essential performance
- IEC 60601-1-6 Medical electrical equipment - part 1-6: general requirements for basic safety and essential performance - collateral standard: usability.
- IEC 62366-1 Medical devices - part 1: application of usability engineering to medical devices.
- IEC 60601-2-22 Medical electrical equipment - part 2-22: particular requirements for basic safety and essential performance of surgical, cosmetic, therapeutic and diagnostic laser equipment. (Radiology)
- IEC 60601-1-2 Medical electrical equipment - part 1-2: general requirements for basic safety and essential performance - collateral standard: electromagnetic compatibility - requirements and tests. (General II (ES/EMC))
- IEC 60825-1 Edition 2.0 2007-03, safety of laser products - part 1: equipment classification, and requirements [including: technical corrigendum 1 (2008), interpretation sheet 1 (2007), interpretation sheet 2 (2007)]. (Radiology)

8. Substantial Equivalence

The ORION is substantially equivalent to the Family of Altus Medical Modified Cool Glide Aesthetic Lasers by Altus Medical, Inc. (K014040), Cynosure Apogee Elite Laser by CYNOSURE, INC. (K034030) and CLARITY LPC Laser System by Lutronic Corporation (K130199).

The following comparison table is presented to demonstrate substantial equivalence.

	Subject Device	Primary Predicate Device	Reference Predicate Device	Reference Predicate Device
Device name	ORION	Family of Altus Medical Modified CoolGlide Aesthetic Lasers (Primary Predicate)	Cynosure Apogee Elite Laser (Reference Predicate)	CLARITY LPC Laser System (Reference Predicate)
Manufacturer	YERIM ENGINEERING Co., Ltd.	Altus Medical, Inc.	CYNOSURE, INC.	Lutronic Corporation
510(k) number	K161503	K014040	K034030	K130199
Technology	Long Pulse Nd:YAG	Long Pulse Nd:YAG	Long Pulse Nd:YAG	Long Pulse Nd:YAG
Power (CW Laser)	AC220 - 240 V/16A	110 - 120 VAC/20A 220 - 240 VAC/20A	200/220 VAC/30A	4.0kVA(AC220~230V)
Energy (pulse and	1064nm	100J	100J	100J
	755nm	50J	-	55J

super pulse)	532nm	10J	10J	n/a	n/a
If pulsed, how is this done		Long pulse	Long pulse	Long pulse	Long pulse
Frequency of pulse	1064 nm	1Hz	2Hz	5Hz	Up to 10Hz
	755nm	3Hz	-	3Hz	Up to 10Hz
	532nm	2Hz	2Hz	-	n/a
Pulse train duration	1064 nm	0.1~300ms	0.3 - 300 ms	Adjustable 0.4– 300 msec	0.35 ms - 300 ms
	755nm	0.1~300ms	-	Adjustable 0.5 – 300 msec	0.35 ms - 300 ms
	532nm	0.1~300ms	0.3 - 300 ms	-	-
Spot size at target		2~20mm	10mm	3~24mm	2, 3, 5, 8, 10, 12, 15, 18, 20 mm
Wavelength		1064 nm, 755nm, 532nm	1064 nm, - 532nm	1064 nm, 755nm -	1064 nm, 755nm -
Aiming beam		650nm	650 nm	650nm	650nm
Energy source		Nd:YAG, Alexandrite, KTP	Nd-YAG, KTP	Nd:YAG, Alexandrite	Nd:YAG, Alexandrite
Cooling method		Cold air	Sapphire cooling	Cold air	Cold air
Intended use	532nm	The ORION is indicated for coagulation and hemostasis of vascular and cutaneous lesions in dermatologyincluding, but not limited to, the following general categories: vascular lesions[angiomas, hemangiomas (port wine), telangiectasia (facial or extremities telangiectasias, venous anomalies, leg veins)]; benign pigmented lesions (nevi, lentigines, chloasma,cafk-au-lait, tattoos (red and green ink); verrucae; skin tags; keratoses; plaques; cutaneouslesion treatment (hemostasis, color	For coagulation and hemostasis of vascular and cutaneous lesions in dermatologyincluding, but not limited to, the following general categories: vascular lesions[angiomas, hemangiomas (port wine), telangiectasia (facial or extremities telangiectasias, venous anomalies, leg veins)]; benign pigmented lesions (nevi, lentigines, chloasma,cafk-au-lait, tattoos (red and green ink); verrucae; skin tags; keratoses; plaques; cutaneouslesion treatment (hemostasis, color	-	-

		lightening, blanching, flattening, reduction of lesion size).	flattening, reduction of lesion size).		
	755 nm	<p>The ORION is indicated for stable long-term, or permanent hair reduction. Permanent hair reduction is defined as long-term stable reduction in the number of hair regrowth after a treatment regime. It is used for all skin types (Fitzpatrick I- VI) including tanned skin.</p> <p>It is also indicated for the treatment of vascular lesions, benign pigmented lesions, and wrinkles.</p>	-	<p>The Cynosure Apogee Elite Dermatological Laser is indicated for stable long-term, or permanent hair reduction. Permanent hair reduction is defined as long-term stable reduction in the number of hair regrowth after a treatment regime. It is used for all skin types (Fitzpatrick I- VI) including tanned skin.</p> <p>It is also indicated for the treatment of vascular lesions, benign pigmented lesions, and wrinkles.</p>	<p>The CLARITY LPC Laser System is indicated for temporary hair reduction. Stable long-term or permanent reduction through selective targeting of melanin in hair follicles. Permanent hair reduction is defined as the long-term, stable reduction in the number of hairs regrowing when measured at 6, 9, and 12 months after the completion of a treatment regime. On all skin types (Fitzpatrick 1-VI) including tanned skin. Treatment of benign pigmented lesions. Treatment of wrinkles. The photocoagulation of dermatological vascular lesions (such as port-wine stains, hemangiomas, telangiectasias).</p>
	1064 nm	<p>The ORION is intended for the coagulation and hemostasis of benign vascular lesions such as, but not limited to, port wine stains, hemangiomas, warts, telangiectasia, rosacea, venus</p>	<p><u>Dermatology:</u> The Altus Medical Aesthetic CoolGlide laser systems are intended for thecoagulation and hemostasis of benign vascular lesions such as, but not limited toport wine stains,</p>	<p>The Cynosure Apogee Elite Dermatological laser is intended for the coagulation and hemostasis of benign vascular lesions such as, but not limited to, port wine stains, hemangiomas, warts,</p>	<p>The CLARITY LPC Laser System is indicated for the removal of unwanted hair, for stable long term or permanent hair reduction and for treatment of PFB. Permanent hair reduction is defined as the long-</p>

		<p>lake, leg veins, spider veins and poikiloderma of Civatte; and treatment of benign cutaneous lesions such as warts, scars, striae and psoriasis. The laser is also intended for the treatment of benign pigmented lesions such as, but not limited to, lentigos (age spots), solar lentigos (sun spots), cafe au lait macules, seborrheic keratoses, nevi, chloasma, verrucae, skin tags, keratoses, tattoos (significant reduction in the intensity of black and/or blue/black tattoos) and plaques. The laser is also indicated for the treatment of wrinkles such as, but not limited to, periorcular and perioral wrinkles. Additionally, the laser is indicated for the removal of unwanted hair, for the stable long term, or permanent, hair reduction through selective targeting of melanin in hair follicles, and for the treatment of pseudofolliculitis barbae (PFB).</p>	<p>hemangiomas, warts, telangiectasia, rosacea, Venus lake, leg veins and spider veins. The lasers are also intended for the treatment of benign pigmented lesions such as, but not limited to, lentigos (age spots), solar lentigos (sun spots), cafe au lait macules, seborrheic keratoses, nevi, chloasma, verrucae, skin tags, keratoses, tattoos (significant reduction in the intensity of black and/or blue/black tattoos) and plaques. Additionally, the lasers are indicated for pigmented lesions to reduce lesion size, for patients with lesions that would potentially benefit from aggressive treatment, and for patients with lesions that have not responded to other laser treatments.</p> <p>The CoolGlide lasers are also indicated for the removal of unwanted hair, for the stable long term, or permanent, hair reduction through selective targeting</p>	<p>telangiectasia, rosacea, Venus lake, leg veins, spider veins and poikiloderma of Civatte; and treatment of benign cutaneous lesions such as warts, scars, striae and psoriasis. The laser is also intended for the treatment of benign pigmented lesions such as, but not limited to, lentigos (age spots), solar lentigos (sun spots), cafe au lait macules, seborrheic keratoses, nevi, chloasma, verrucae, skin tags, keratoses, tattoos (significant reduction in the intensity of black and/or blue/black tattoos) and plaques. The laser is also indicated for the treatment of wrinkles such as, but not limited to, periorcular and perioral wrinkles. Additionally, the laser is indicated for the removal of unwanted hair, for the stable long term, or permanent, hair reduction through selective targeting of melanin in hair follicles, and for the treatment of pseudofolliculitis barbae (PFB).</p>	<p>term, stable reduction in the number of hairs regrowing when measured at 6, 9, and 12 months after the completion of a treatment regime. The lasers are indicated on all skin types Fitzpatrick I-VI including tanned skin. Photocoagulation and hemostasis of pigmented and vascular lesions such as but not limited to port wine stains, hemangioma, warts, telangiectasia, rosacea, Venus lake, leg veins and spider veins. Coagulation and hemostasis of soft tissue. Benign pigmented lesions such as, but not limited to, lentigos (age spots), solar lentigos (sun spots), cafe au lait macules, seborrheic keratoses, nevi, chloasma, verrucae, skin tags, keratoses, tattoos (significant reduction in the intensity of black and/or blue-black tattoos) and plaques. The laser is indicated for pigmented lesions to reduce lesion size, for patients with lesions that</p>
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			<p>of melanin in hair follicles, and for the treatment for pseudofolliculitis barbae (PFB). The lasers are also indicated for the reduction of red pigmentation in hypertrophic and keloid scars where vascularity is an integral part of the scar. The CoolGlide lasers are indicated for use on all skin types (Fitzpatrick I-VI), including tanned skin. The intended use of the integral cooling system in the Altus handpiece is to provide cooling of the skin prior to laser treatment, for the reduction of pain during laser treatment, to allow for the use of higher fluences for laser treatments such as hair removal and vascular lesions, and to reduce the potential side effects of laser treatments.</p> <p><u>Surgical Applications:</u> The lasers are indicated for the incision/excision and cutting, ablation, coagulation/hemostasis of soft tissue in the performance of surgical applications in endoscopy/laprosopy,</p>		<p>would potentially benefit from aggressive treatment, and for patients with lesions that have not responded to other laser treatments. The laser is also indicated for the reduction of red pigmentation in hypertrophic and keloid scars where vascularity is an integral part of the scar. Treatment of wrinkles.</p>
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			gastroenterology, general surgery, head andneck/otorhinola ryngology (ENT), neurosurgery, oculoplastics, orthopedics, plastic surgery, pulmonary/thoracic surgery, gynecology (e.g. menorrhagia) andurology.		
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In reference to the Federal Food, Drug and Cosmetic Act, 21 CFR Part 807 and the information provided on the device comparison table and performance test results, the Yerim engineering Co., Ltd. believes that the ORION is substantially equivalent to the predicate device, Family of Altus Medical Modified CoolGlide Aesthetic Lasers (K014040, Altus Medical, Inc.), Cynosure Apogee Elite Laser (K034030, Cynosure, Inc.) and CLARITY LPC Laser System (K130199, Lutronic Corporation). ORION has the same intended use, performance specifications, and similar operational characteristics as the predicate devices. Performance data supports that the device is substantially as safe and effective as the predicate devices for its intended use. Therefore, ORION may be found substantially equivalent to its predicate devices.

9. Conclusion:

Based on the testing results, YERIM ENGINEERING Co., Ltd. concludes that the ORION is substantially equivalent to the predicate device.