March 15, 2018

ELEMENIC Co., Ltd.
% Priscilla Chung
Regulatory Affairs Consultant
LK Consulting Group USA, Inc.
690 Roosevelt
Irvine, California 92620

Re: K180224
Trade/Device Name: ELEMENT-TL
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: January 19, 2018
Received: January 26, 2018

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.

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.

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,

Jennifer R. Stevenson -S3

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 below.

510(k) Number *(if known)*
K180224

Device Name

ELEMENT-TL

Indications for Use *(Describe)*

532nm

The ELEMENT-TL 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, cafk-au-lait, tattoos (red and green ink); verrucae; skin tags; keratoses; plaques; cutaneouslesion treatment (hemostasis, color lightening, blanching, flattening, reduction of lesion size).

755 nm

The ELEMENT-TL 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.

1064nm

The ELEMENT-TL 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.

510(k) Summary

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

Date: March 13, 2018

1. Applicant / Submitter:

ELEMENIC Co., Ltd.
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Bucheon-si, Gyeonggi-do,
14731 Republic of Korea

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Fax : +82-32-613-5009

2. Submission Correspondent:

Priscilla Chung
LK Consulting Group USA, Inc.
690 Roosevelt
Irvine CA 92620
Phone: 714-202-5789 Fax: 714-409-3357
Email: juhee.c@lkconsultinggroup.com

3. Device:

Proprietary Name:	ELEMENT-TL
Common Name:	Medical Laser System
Classification Name:	Laser surgical instrument for use in general and plastic surgery and in dermatology
Classification:	Class II, 21 CFR 878.4810
Classification Product Code:	GEX

4. Predicate Device:

ORION by YERIM ENGINEERING Co., Ltd. (K161503)

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.
This equipment 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
The ELEMENT-TL 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, cafk-au-lait, tattoos (red and green ink); verrucae; skin tags; keratoses; plaques; cutaneouslesion treatment (hemostasis, color lightening, blanching, flattening, reduction of lesion size).

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The ELEMENT-TL 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.

1064nm
The ELEMENT-TL 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 ELEMENIC-TL is substantially equivalent to the ORION by YERIM ENGINEERING Co., Ltd. (K161503).
The following comparison table is presented to demonstrate substantial equivalence.

		Subject Device	Primary Predicate Device
Device name		ELEMENT-TL	ORION
Manufacturer		ELEMENIC Co., Ltd.	YERIM ENGINEERING Co., Ltd.
510(k) number		K180224	K161503
Technology		Long Pulse Nd:YAG	Long Pulse Nd:YAG
Power (CW Laser)		AC220 - 240 V/16A	AC220 - 240 V/16A
Energy (pulse and super pulse)	1064nm	100J	100J
	755nm	50J	50J
	532nm	10J	10J
If pulsed, how is this done		Long pulse	Long pulse
Frequency of pulse	1064 nm	1Hz	1Hz
	755nm	3Hz	3Hz

	532nm	2Hz	2Hz
Pulse train duration	1064 nm	0.1~300ms	0.1~300ms
	755nm	0.1~300ms	0.1~300ms
	532nm	0.1~300ms	0.1~300ms
Spot size at target		2~20mm	2~20mm
Wavelength		1064 nm, 755nm, 532nm	1064 nm, 755nm, 532nm
Aiming beam		650nm	650 nm
Energy source		Nd:YAG, Alexandrite, KTP	Nd:YAG, Alexandrite, KTP
Cooling method		Cold air	Cold air

Indications for Use	<u>532nm</u> The ELEMENT-TL 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, cafk-au-lait, tattoos (red and green ink); verrucae; skin tags; keratoses; plaques; cutaneouslesion treatment (hemostasis, color lightening, blanching, flattening, reduction of lesion size). <u>755 nm</u> The ELEMENT-TL 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	<u>532nm</u> 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, cafk-au-lait, tattoos (red and green ink); verrucae; skin tags; keratoses; plaques; cutaneouslesion treatment (hemostasis, color lightening, blanching, flattening, reduction of lesion size). <u>755 nm</u> 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

	vascular lesions, benign pigmented lesions, and wrinkles. <u>1064nm</u> The ELEMENT-TL 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).	is also indicated for the treatment of vascular lesions, benign pigmented lesions, and wrinkles. <u>1064nm</u> 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).

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 ELEMENIC Co., Ltd.

believes that the ELEMENIC-TL is substantially equivalent to the predicate device, ORION (K161503, YERIM ENGINEERING Co., Ltd.).
ELEMENT-TL has the same intended use, performance specifications, and similar operational characteristics as the predicate devices.
The differences might be in device housing, button locations, and display UI, however, these differences do not raise an issue in safety and performance. And the performance data supports that the device is substantially as safe and effective as the predicate devices for its intended use.
Therefore, ELEMENT-TL may be found substantially equivalent to its predicate devices.

9. Conclusion:

Based on the testing results, ELEMENIC Co., Ltd. concludes that the ELEMENIC-TL is substantially equivalent to the predicate device.