Lutronic Corporation
James Childs
Clinical Science Director
Lutronic Center, 219, Sowon-ro
Deogyang-gu, Goyang-si, 410-220
Republic of Korea

June 14, 2019

Re: K183566
Trade/Device Name: CLARITY II Laser System
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 8, 2019
Received: May 13, 2019

Dear James Childs:

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,

Neil R.P. Ogden, MS
Acting Assistant Director, Light Based Devices Team
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K183566

Device Name

Clarity II Laser System

Indications for Use *(Describe)*

755 nm

The CLARITY II 755 nm Laser System is indicated for temporary hair reduction and 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.
The 755 nm laser is also indicated for treatment of benign pigmented lesions, vascular lesions and wrinkles.

1064 nm

The CLARITY II 1064 nm Laser System is indicated for stable long term or permanent hair reduction and for treatment of PFB (Pseudofolliculitis Barbae) on all skin types, Fitzpatrick I – VI, including tanned skin.
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.
The 1064 nm laser is also indicated for coagulation and hemostasis of soft tissue, for hemostasis of vascular lesions such as but not limited to port wine stains, hemangiomna, warts, telangiectasia, rosacea, venus lake, leg veins and spider veins.
The 1064 nm laser system is also indicated for the treatment of benign pigmented lesions such as, but not limited to, lentigos (age spots), solar lentigos (sun spots), café au lait macules, seborrheic keratoses, nevi, chloasma, verrucae, skin tags, keratoses, (significant reduction in the intensity of black and/or blue- black tattoos) and plaques.
The 1064 nm Laser is also indicated for the treatment of wrinkles such as, but not limited to, periocular and perioral wrinkles.

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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"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."

6. 510(k) Summary

The Company's 510(k) Summary for the CLARITY II Laser System is as follows:

510(k) Summary for the Lutronic Corporation CLARITY II Laser System

This 510(k) Summary is being submitted in accordance with the requirements of the SMDA 1990 and 21 CFR 807.92.

1. General Information

Applicant:

Lutronic Corporation
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Haengsin-dong, Deogyang-gu.
Goyang-si, Gyeonggi-do, 410-722

Republic of Korea
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Contact Person:

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Lutronic Global
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Billerica, MA 01821
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Summary/Preparation Date: December 20, 2018

2. Names

Trade Name: CLARITY II Laser System

Common Name: Dermatology Laser

Classification Name: Laser instrument, Surgical powered

Product Code: GEX
Panel: General and Plastic Surgery

3. Predicate Devices

The CLARITY II Laser System is substantially equivalent to the CLARITY LPC Laser System (K130199) and the Elite + Laser (K141425).

4. Device Description

The CLARITY II Laser System contains two separate resonators, an Alexandrite resonator and an Nd:YAG (Neodymium-doped Yttrium Aluminum Garnet) resonator which generates pulsed laser energy at the nominal wavelength 755 nm and 1064 nm,

respectively. The outputs of each laser generator and the aiming beam are optically combined on the laser rail so that their beam paths are identical as they exit the laser system. This allows the use of a single delivery system for either the 755 nm or 1064 nm wavelength. It is a medical device, designed for specific clinical applications, emitting laser energy via a handpiece and controlled by the user with a handpiece finger switch or optional footswitch. The CLARITY II Laser System consists of a system main body with an LCD touch screen, optical fiber with an AC or ICD handpiece.

The control panel is equipped with an LCD touch screen so that users may easily adjust parameters for optimal settings.

The CLARITY II Laser System is a medical device, designed for specific clinical applications, emitting laser energy at 755 nm and 1064 nm via a handpiece attached to an optical fiber. The pulsed beam is directed to the treatment zone through a lens-coupled optical fiber attached to a handpiece. When the beam contacts human tissue, the energy of the beam is absorbed by the tissue, resulting in very rapid highly localized temperature increase in the target.

The CLARITY II Laser System is composed of three main components, including the system main body, optical fiber (with optional AC handpiece or ICD handpiece), and the footswitch. The system main body is composed of the system control module, power supply, laser module, control panel (LCD touch screen), emergency stop button, and key switch. Laser radiation will be emitted from the handpiece through the optical fiber when the footswitch or finger switch is pressed. Safety goggles are provided with the system (optical density of 7 or higher at 1064 nm and 755 nm) for ancillary personnel. The casters and handle on the main body allows for transportation of the laser system within the treatment room. The laser console measures 563.6 mm (W) x 952.3 mm (L) x 998.5 mm (H).

The laser delivery system begins at the laser aperture, which is the fiber socket, at the upper front of the device. At this point, the invisible and infrared laser beam (755 nm or 1064 nm) and the visible 515-535 nm aiming beam are fed into and pass through the optical fiber and exit at the handpiece aperture.

Cartridges are available for the AC handpiece and ICD handpiece. The system is fitted with a window to protect the lens inside the cartridges from foreign material. The cartridge irradiation diameters available within the system are 2, 3, 5, 8, 10, 12, 15, 16, 18, 20, 22, 24mm. Users can use a cartridge fitted with an intelligent tracking tip (roller), O-type tip, C-type tip, or I-type tip.
The AC handpiece can be used with the CryoMini air cooling system that was cleared April 2008 (K080735).

5. Indications for Use

755 nm

The CLARITY II 755 nm Laser System is indicated for temporary hair reduction and 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. The 755 nm laser is also indicated for treatment of benign pigmented lesions, vascular lesions and wrinkles.

1064 nm

The CLARITY II 1064 nm Laser System is indicated for stable long term or permanent hair reduction and for treatment of PFB (Pseudofolliculitis Barbae) on all skin types, Fitzpatrick I –VI, including tanned skin. 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. The 1064 nm laser is also indicated for coagulation and hemostasis of soft tissue, for hemostasis of vascular lesions such as but not limited to port wine stains, hemangiomna, warts, telangiectasia, rosacea, venus lake, leg veins and spider veins. The 1064 nm laser system is also indicated for the treatment of benign pigmented lesions such as, but not limited to, lentigos (age spots), solar lentigos (sun spots), café au lait macules, seborrheic keratoses, nevi, chloasma, verrucae, skin tags, keratoses, (significant reduction in the intensity of black and/or blue- black tattoos) and plaques. The 1064 nm Laser is also indicated for the treatment of wrinkles such as, but not limited to, periocular and perioral wrinkles.

6. Substantial Equivalence

The CLARITY II Laser System is substantially equivalent to the CLARITY LPC Laser System (K130199) and the Elite + Laser (K141425). It has the same technological characteristics as the predicate devices. All three devices use two separate laser resonators, an Alexandrite resonator and an Nd:YAG (Neodymium-doped Yttrium Aluminum Garnet) resonator which generates pulsed laser energy at the nominal wavelengths of 755 nm and 1064 nm. They have the same intended uses and similar operating principles. They also have the same spot sizes, pulse widths and fluences. The laser systems differ in the features offered. Unlike its predicated devices, the Subject device includes a skin temperature monitoring feature for informational purposes only. In addition, the Subject device includes an Intelligent Tracking Tip that insures selectable overlap of contiguous pulses during treatment. These features, however, do not affect the safety and effectiveness of the subject device and therefore it is substantially equivalent to the Predicate devices.

7. Performance Data

The Company's performance data for the CLARITY II Laser System is as follows:

Device Name			Clarity II	Clarity LPC	Elite +
Manufacturer			Lutronic Corporation	Lutronic Corporation	Cynosure
510(k) Number			NA	K130199	K141425
	755 nm	Max Fluence (J/cm2)	600	600	60
		Max Energy (J)	60	60	30
		Max Rep Rate (Hz)	10	10	5
		Pulse Duration (ms)	0.1 – 300	0.35 - 300	0.1 - 300
		Spot Sizes (mm)	2,3,5,8,10,12,15,16,18,20,22,24	2,3,5,8,10,12,15,18,20	3,5,7,10,12,15,18,20,22,24
	1064 nm	Max Fluence (J/cm^2)	600	600	300
		Max Energy (J)	100	100	50
		Max Rep Rate (Hz)	10	10	10
		Pulse Duration (ms)	0.1 – 300	0.35 - 300	0.1 - 300
		Spot Sizes (mm)	2,3,5,8,10,12,15,16,18.20,22,24	2,3,5,8,10,12,15,18,20	3,5,7,10,12,15,18,20,22,24
	755/1064 nm	Aiming Beam	Green	Green	Red
		Electrical Requirements (Power consumption)	AC220-230V 50/60 Hz Fuse: 250V/30A, Circuit Breaker: 30A Power Consumption: 6.0 kVa	VAC 220-230, single phase, 30A, 50/60 Hz	VAC 208/240, single phase, 30A, 50/60 Hz
		Size (mm)	563.6 (W) x 952.3 (L) x 998.5 (H) mm	434 (W) x 776.8 (D) x 1148.8 (H)	381 (W) x 635 (D) x 1041.4 (H)
		Weight (kg)	110	110	81.8
		Optical Delivery System	Optical fiber with handpiece	Optical fiber with handpiece	Optical fiber with handpiece
		Cooling System	Chilled Air or ICD	Chilled Air or ICD	Chilled Air

Bench Testing

The CLARITY II Laser System complies with all applicable standards, including ISO 13485:2016, ISO 60601-1 for electrical safety and IEC 60601-1-2 for electromagnetic compatibility.

Clinical Testing

No performance data has been provided since the CLARITY II Laser System is equivalent to the previously cleared predicate devices with no new issues regarding safety and effectiveness.

8. Conclusion

The intended use of the CLARITY II Laser System is virtually identical to the intended use of the predicate devices and the technological characteristics of the CLARITY II Laser System. Any differences between the CLARITY II Laser System and the predicate devices have no

significant influence on safety or effectiveness of the CLARITY II Laser System. Therefore, the CLARITY II Laser System is substantially equivalent to the predicate devices.