DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
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June 23, 2017

Lutronic Corporation
Jhung Vojir
VP, Quality and Regulatory Affairs
6 Neshaminy Interplex, Suite 100
Trevose, Pennsylvania 19053

Re: K171009
Trade/Device Name: LASEMD 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: April 3, 2017
Received: April 4, 2017

Dear Jhung Vojir:

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,

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)*
K171009

Device Name
LASEMD Laser System

Indications for Use *(Describe)*
The LASEMD Laser System is indicated for use in dermatological procedures requiring the coagulation of soft tissue, treatment of actinic keratosis, and treatment of benign pigmented lesions such as, but not limited to lentigos (age spots), solar lentigos (sun spots) and ephelides (freckles).

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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6. 510(k) SUMMARY OR STATEMENT

The Company’s 510(k) Summary for the LASEMD Laser System is as follows:

510(k) Summary
Lutronic Corporation LASEMD Laser System

This 510(k) Summary is being submitted in accordance with 21 CFR § 807.92.

1. General Information

Applicant:	Lutronic Corporation 219 Sowon-ro Haengsin-dong, Deogyang-gu Goyang-si, Gyeonggi-do 410-220 Republic of Korea Tel: (82) 31-908-3440 FAX: (82) 31-907-3440
Contact Person:	Jhung Won Vojir, Ph.D. VP of Quality and Regulatory Affairs Lutronic Corporation 6 Neshaminy Interplex, Suite 100 Trevose, PA 19053 Tel: 215-205-2219 FAX: 609-488-6958 Email: jvojir@lutronic.com
Summary Preparation Date:	June 20, 2017

2. Names

Trade Name:	LASEMD Laser System
Common Name:	Laser Surgical Instrument
Classification Name:	Powered Laser Surgical Instrument Product Code: GEX 21 CFR § 878.4810 Panel: General & Plastic Surgery

3. Predicate Device

The Fraxel DUAL Laser System is a surgical instrument for performing dermatological procedures in the treatment of actinic keratosis and treatment of pigmented lesions.

510(K) Number	K130193
Company Name	Solta Medical, Inc.
Device Name	Fraxel DUAL 1550/1929 Laser System
Classification Regulation	21 CFR § 878.4810
Classification Name	Powered Laser Surgical Instrument
Product Code	GEX
Device Panel	General & Plastic Surgery

4. Device Description

The LASEMD Laser System is a thulium laser, producing a pulsed beam of coherent near-infrared light (1927 nm) upon activation by a footswitch. The beam is then directed to the treatment zone by means of an optical fiber coupled to a handpiece. An integrated LED touch screen gives the user control over the necessary laser system parameters. The LASEMD Laser System is equipped with a 658 nm aiming beam.

5. Indications for Use

The LASEMD Laser System is indicated for use in dermatological procedures requiring the coagulation of soft tissue, treatment of actinic keratosis, and treatment of benign pigmented lesions such as, but not limited to lentigos (age spots), solar lentigos (sun spots) and ephelides (freckles).

6. Substantial Equivalence

The LASEMD Laser System is substantially equivalent to the legally marketed Solta Medical Fraxel DUAL Laser System that is the subject of 510(k) K130193.

Manufacturer	**Lutronic Corporation**	**Solta Medical, Inc.**
Device	LASEMD Laser System	Fraxel DUAL 1550/1927 Laser System
510(k) Number	K171009	K130193
Indications for Use	The LASEMD Laser System is indicated for use in dermatological procedures requiring the coagulation of soft tissue, treatment of actinic keratosis, and treatment of benign pigmented lesions such as, but not limited to lentigos (age spots), solar lentigos (sun spots) and ephelides (freckles).	1927nm: The Fraxel 1927 nm laser is indicated for use in dermatological procedures requiring the coagulation of soft tissue, treatment of actinic keratosis, and treatment of pigmented lesions such as, but not limited to lentigos (age spots), solar lentigos (sun spots) and ephelides (freckles).

Classification	GEX, 21 CFR § 878.4810	GEX, 21 CFR § 878.4810
Laser Type	Thulium laser	Thulium laser
Laser Wavelength	1927 nm	1927 nm
Aiming Beam	658 nm ≤ 5 mW	658 nm ≤ 5 mW
Beam Delivery	Fiber and Handpiece	Fiber and Handpiece
Emission Control	Footswitch	Footswitch
Display Screen	Yes	Yes
Power	5 W	12 W (1927 nm)
Max Pulse Energy	20 mJ	20 mJ (1927 nm)
Max Pulse Width	20 ms	10 ms
Pulse Repetition Rate	43.5 – 307.7 Hz	0 – 3 kHz
Tip Size	4 mm x 10 mm	Small tip: 7 mm Large tip: 15 mm
Dimensions of Laser Console	413 mm (W) x 324 mm (L) x 255.5 mm (D)	489 mm (W) x 451 mm (L) x 444.5 mm (D)
Spot Size	100 µm, 200 µm	200 µm
Weight of Laser System	33.1 kg	68.0 kg
Electrical Rating	AC 100-240V, 50/60 Hz, Power Consumption	AC 100-240V, 50/60 Hz, Power Consumption

7. Performance Data

The Company's Performance Data for the LASEMD Laser System is as follows:

Bench Testing

The LASEMD Laser System complies with all applicable standards, including ISO 13485:2003, ISO 60601-1 for electrical safety and IEC 60601-1-2 for electromagnetic compatibility.

Animal Testing

Histology confirms that the treatment skin effect of the LASEMD Laser System is the same as the predicate Fraxel DUAL 1927 nm Laser System when used at the same energy settings.

Clinical Testing

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

8. Conclusion

The LASEMD Laser System and the legally marketed Fraxel DUAL Laser System cleared under 510(k) number K130193, have the same intended use and Indications for Use statement. While the technological characteristics differ between the two systems, the differences have been established to be minor. Performance testing data established that the LASEMD Laser System is as safe and effective as the legally marked predicate

device and that the LASEMD Laser System does not raise any different questions of safety and effectiveness than the predicate. On this basis and in accordance with 21 CFR § 807.100(b), the LASEMD Laser System is substantially equivalent to the Fraxel DUAL Laser System and can be legally marketed in the U.S.