November 12, 2019

Lutronic Global
James Childs
Clinical Science Director
19 Fortune Drive
Billerica, Massachusetts 01821

Re: K192331
Trade/Device Name: LaseMD LEO 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: September 11, 2019
Received: September 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,

Purva Pandya
Acting Assistant Director
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)*
K192331

Device Name
LaseMD LEO Laser System

Indications for Use *(Describe)*
The LaseMD LEO 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 (sunspots) 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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K192331

510(k) Summary for the Lutronic Corporation LASEMD LEO 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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Email: jchilds@lutronic.com

Summary Preparation Date: August 23, 2019

2. Names

Trade Name: LASEMD LEO Laser System

Common Name: Dermatology Laser

Classification Name: Laser instrument, Surgical, Powered

Product Code: GEX
Panel: General and Plastic Surgery

3. Predicate Devices

The LASEMD Laser System and Fraxel DUAL Laser System are surgical instruments for performing dermatological procedures in the treatment of actinic keratosis and treatment of benign pigmented lesions.

510(K) Number	K171009	K130193
Company Name	Lutronic Corporation	Solta Medical, Inc.
Device Name	LASEMD Laser System	Fraxel DUAL 1550/1927 Laser System
Classification Regulation	21 CFR § 878.4810	21 CFR § 878.4810
Classification Name	Powered Laser Surgical Instrument	Powered Laser Surgical Instrument
Product Code	GEX	GEX
Device Panel	General & Plastic Surgery	General & Plastic Surgery

4. Device Description

The LaseMD LEO 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 LCD touch screen gives the user control over the necessary laser system parameters. The LaseMD LEO Laser System is equipped with a 658 nm aiming beam.

5. Indications for Use

The LaseMD LEO 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 (sunspots) and ephelides (freckles).

6. Substantial Equivalence

The LaseMD LEO Laser System offers the user the same wavelength, same pulse energy range, same optical train, similar spot sizes, same spot fluence settings and similar per-pass treatment density range as the legally marketed Solta Medical Fraxel DUAL Laser System that is the subject of 510(k) K130193, and LASEMD Laser System (K171009) legally marketed by Lutronic Corporation. The subject and the predicate devices also all operate in pulsed-power mode. The pulsed power setting is user selectable in Expert Mode between 1 – 20W. The maximum power of 20W with the LaseMD LEO system is greater than the maximum pulsed powers available in the predicate devices and is for user convenience. The peak power densities (W/cm^2) remain substantially below the ablation threshold and the mechanism of action - thermal coagulation -- is identical to that of the predicate devices. Further, an Animal Study report is included in the submission that establishes equivalence between LaseMD LEO in Energy mode (20W) with the Fraxel Dual device (12W) at similar energy settings. In addition, the LaseMD LEO system operating at 5W or

lower power settings is identical in design and performance to the LaseMD system at the same power and energy settings. The C5 tip with 350 um spot size provides fluences within the range of the predicate devices. Further, the shot density of the C5 tip includes 144 mB/cm^2 and 225 mB/cm^2 shot density settings. The shot density of the Predicate device is up to 426 MTZ/cm^2. At 20 mJ beam energy treatment, the maximum average shot area energy density (J/cm^2) for C5 is 0.02 J x 144 mB/cm^2 = 2.88 J/cm^2 and 0.02 J x 225 mB/cm^2 = 4.5 J/cm^2 for the 144 mB/cm^2 and 225 mB/cm^2 shot densities, respectively. The average shot area energy density for the Predicate device at the same beam energy is up to 0.02 J x 426 MTZ/cm^2 = 8.52 J/cm^2. Therefore the C5 tip average shot energy density settings are within those of the Predicate device and do not raise any new concerns about safety. No new concerns about effectiveness arise with the 144 mB/cm^2 and 225 mB/cm^2 shot densities because they are greater than the densities of the cleared Predicate device with 100 mB/cm^2 (comparing the square tip in Stamping mode). Final treatment coverage is also controlled by the number of passes and is the same as those of the predicate devices. Therefore, the technological differences between the subject device and the predicate devices are considered to be minor and no new concerns for safety or effectiveness arise.

Device	LaseMD LEO Laser System	Fraxel DUAL 1550/1927 Laser System	LASEMD Laser System
510(k) Number	To be assigned	K130193	K171009
Indications for Use	The LaseMD LEO 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).	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 benign pigmented lesions such as, but not limited to lentigos (age spots), solar lentigos (sun spots) and ephelides (freckles).	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).
Classification	GEX, 21 CFR § 878.4810	GEX, 21 CFR § 878.4810	GEX, 21 CFR § 878.4810
Laser Type	Thulium laser	Thulium laser	Thulium laser
Laser Wavelength	1927 nm	1927 nm	1927 nm
Aiming Beam	658 nm ≤ 5 mW	658 nm ≤ 5 mW	658 nm ≤ 5 mW
Beam Delivery	Fiber and Handpiece	Fiber and Handpiece	Fiber and Handpiece
Emission Control	Footswitch	Footswitch	Footswitch
Display Screen	Yes	Yes	Yes
Power	20 W	12 W	5 W

Max Pulse Energy	20 mJ	20 mJ	20 mJ
Max Pulse Width	20 ms	10 ms	20 ms
Pulse Repetition Rate	C1 Tip: 43 -323 Hz C5 Tip: 46 – 632 Hz	0 – 3 kHz	43.5 – 307.7 Hz
Laser Beam Spot Size (Spot Fluence Range) [Treatment Method]	200 μm (All C1 Tips) (3 – 60 J/cm^2) [Stamping or Rolling] 350 μm (C5 Tip) (1 – 20 J/cm^2) [Stamping]	200 μm (All Tips) (3 – 60 J/cm^2) [Rolling]	100 μm (Cap 100) (12 – 240 J/cm^2) [Stamping or Rolling] 200 μm (Cap200) (3 – 60 J/cm^2) [Stamping]
Rolling Tx Tips **Function:** **Scan Area/Shot** **Density** **Pulses/Shot** **Shot Energy Range**	**C1 with Rollers** Random: 2.5 mm x 10 mm Density 40 mB/cm^2 (10 Pulses per shot) 10 − 200 mJ Dynamic: 2 mm x 10 mm Density 25 mB/cm^2 (5 Pulses per shot): 5 − 100 mJ CW: 4 mm x 10 mm Density 100 mB/cm^2 (40 Pulses per Shot) 40 - 800 mJ	Small tip: 7 mm (Max at least 426 MTZ/cm^2) Large tip: 15 mm (Max at least 426 MTZ/cm^2)	**Caps 100, 200** Random: 2.5 mm x 10 mm Density 40 mB/cm^2 (10 Pulses per shot) 10 − 200 mJ Dynamic: 2 mm x 10 mm Density 25 mB/cm^2 (5 Pulses per shot): 5 − 100 mJ CW: 4 mm x 10 mm Density 100 mB/cm^2 (40 Pulses per Shot) 40 - 800 mJ
Stamping Tx Tips **Function:** **Shot Area** **Density** **Pulses/Shot** **Shot Energy Range**	**C1 (Square, Comb Tip)** Static: 4 mm x 10 mm Density: 100 mB/cm^2 (40 Pulses per Shot) 40 - 800 mJ **C5 Tip** Static:	Not Applicable	C1 (Square, Comb Tip) Static: 4 mm x 10 mm Density: 100 mB/cm2 (40 Pulses per Shot) 40 - 800 mJ

	6 mm x 10 mm Density 100 mB/cm^2 (60 Pulses per Shot): 60 − 1200 mJ 6 mm x 10 mm Density 144 mB/cm^2 (84 Pulses per Shot): 84 − 1680 mJ 6 mm x 10 mm Density 225mB/cm^2 (135 Pulses per Shot): 135 − 2700 mJ		
Dimensions of Laser Console	460 mm (W) x 613 mm (L) x 1744 mm (H)	489 mm (W) x 451 mm (L) x 444.5 mm (D)	413 mm (W) x 324 mm (L) x 255.5 mm (D)
Weight of Laser System	33kg	33.1kg	33.1 kg
Electrical Rating	AC 100-240 V (Fuse AC250V/6.3A), 50/60 Hz, Power consumption	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 LEO Laser System is as follows:

An Animal Study Report is included to demonstrate the equivalence between the C1 tip of the Subject device and the Predicate devices.

Bench Testing

The LASEMD LEO 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. See in Appendix 7.

8. Conclusion

The intended use of the LASEMD LEO Laser System is virtually identical to the intended use of the predicate devices and the technological characteristics of the LASEMD LEO Laser System. Any differences between the LASEMD LEO Laser System and the predicate devices have no significant influence on safety or effectiveness of the LASEMD LEO

Laser System. Therefore, the LASEMD LEO Laser System is substantially equivalent to the predicate devices.