January 2, 2024

Lutronic Aesthetic
% Kevin O'connell
VP Global Regulatory Affairs
Lutronic Corporation
Lutronic Center
219, Sowon-Ro
Deogyang-Gu, Goyang-si 410220
Korea, South

Re: K233550
Trade/Device Name: MOSAIC 3D (Surgical Laser)
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: ONG, GEX
Dated: November 3, 2023
Received: November 3, 2023

Dear Kevin O'connell:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Jianting Wang -S

Digitally signed by Jianting Wang -S
Date: 2024.01.02 20:19:37 -05'00'

for Tanisha Hithe
Assistant Director
DHT4A: Division of General Surgery Devices

OHT4: Office of Surgical & 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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K233550

Device Name
MOSAIC 3D Laser System

Indications for Use *(Describe)*
The MOSAIC 3D Laser System is indicated for use in dermatological procedures requiring the coagulation of soft tissue, as well as for fractional skin resurfacing procedures.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) SUMMARY for K233550

A summary of 510(k) safety and effectiveness information in accordance with the requirements of 21 CFR 807.92.

807.92(a)(1) - Submitter Information	
Name	Lutronic Corporation
Address	Lutronic Center 219, Sowon-Ro Deogyang-Gu, Goyang-Si, KR 410220
Phone number	978-888-1426
Fax number	N/A
Establishment Registration Number	1222993
Name of contact person	Sarah Dunne Senior Regulatory Affairs Specialist, Lutronic Aesthetic 19 Fortune Drive Billerica, MA, 01821
Date prepared	02 JANUARY 2024
807.92(a)(2) - Name of device	
Trade or proprietary name	MOSAIC 3D
Common or usual name	Surgical Laser
Classification name	Laser Surgical Instrument for use in General and Plastic Surgery and in Dermatology
Classification panel	General and Plastic Surgery
Regulation	21 CFR 878.4810
Product Code(s)	ONG (primary), GEX (secondary)
807.92(a)(3) - Legally marketed device(s) to which equivalence is claimed	
	Lutronic Corporation K080932 (06/09/2008) Predicate Solta Medical, Inc K130193 (06/14/2013) Reference
807.92(a)(4) - Device description	
	The MOSAIC 3D Laser System is a non-ablative fractional Er:Glass (Erbium Glass) laser with a wavelength of 1550 nm. It uses Er:Glass to emit a laser beam that is then emitted onto the treatment area via the handpiece connected to the optical fiber of the main body of the system. It is comprised of a main body, a handpiece connected to an optical fiber, a tip, a footswitch, and goggles for laser protection. The laser beam is emitted onto the area to be treated through the tips (roller tip, sapphire tip, comb tip, pill tip) connected to the handpiece.

	When the beam contacts tissue the laser beam emits many separate microbeams and creates a microscopic treatment zone (MTZ). Thermal coagulation is then induced in the dermis using the principle of fractional photo thermolysis, sparing the normal skin tissue surrounding the MTZ area. When the laser beam is emitted onto skin tissue, the energy of the beam is absorbed by specific tissues or chromophores such as water and is then converted into thermal energy, causing thermal damage to produce a therapeutic effect. The MOSAIC 3D Laser System is controlled via a LCD touchscreen guided user interface in the front of the device, which is used to easily configure optimal treatment parameters and check parameters set in the device in the current system mode.
807.92(a)(5) Intended use of the device	
Indications for use	The MOSAIC 3D Laser System is indicated for use in dermatological procedures requiring the coagulation of soft tissue, as well as for fractional skin resurfacing procedures.

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510(k) SUMMARY for K233550

807.92(a)(6) Summary of the technological characteristics of the device compared to the predicate			
	MOSAIC 3D	MOSAIC HP K080932	Fraxel Dual 1550 K130193 (reference)
Indications for Use	The MOSAIC 3D laser system is indicated for use in dermatological procedures requiring the coagulation of soft tissue, as well as for fractional skin resurfacing procedures.	The MOSAIC laser system is indicated for use in dermatological procedures requiring the coagulation of soft tissue	The Fraxel 1550 nm laser is indicated for use in dermatological procedures requiring the coagulation of soft tissue, as well as for skin resurfacing procedures. It is also
Laser Type	Er:Glass Fiber laser	Er:Glass Fiber laser	Er:Glass Fiber laser
Wavelength	1550 nm	1550 nm	1550 nm
Pulse Energy/MTZ	4 - 70 mJ	4 - 70 mJ	4 - 70 mJ
Laser beam spot size	100um	100um	200um
Density	25 - 500 Spot/cm²	50 - 500 Spot/cm²	UNK or 2500 spots per cm^2 over 5 passes (per manual)
Pulse repetition Rate	169.8 - 447.4 Hz	42.3 - 588 Hz	0-3kHz
Interval	0.3s, 0.5s, 1.0s, single, CW	Single	Single
Pattern Shapes	square, rectangle, circle	Not applicable	Not applicable
Tip pattern / sizes	Circle: 4, 6, 8, 10, 12mm dia Square: 6x6, 8x8, 10x10, 12x12, 16x16, 18x18, 20x20mm - Rectangle: 2x12, 2x15, 4x12, 6x12, 8x12, 8x16, 8x20mm	L10×10, L6×6, L5×10, H10×10 mm	Width of 15mm and 7mm
Use of tip	Disposable / Reusable	Reusable	Disposable
Cooling Mechanism	Air cooling	Air cooling	Air cooling
Aiming Beam	658nm < 1mW	658nm < 1mW	unk
Delivery method	Fiber	Fiber	fiber

Type and Degree of protection against shock	Class I, Type B	Class I, Type B	Class I, Type B

807.92(b)(1) NON CLINICAL TESTS SUBMITTED

- IEC 60601-1: 2012, ed 3.1, Medical Electrical Equipment—Part 1: General Requirements for Basic Safety and Essential Performance
- IEC 60601-1-2 Edition 4: 2014, Medical Electrical Equipment—Part 1-2: General Requirements for Basic Safety and Essential Performance—Collateral Standard: Electromagnetic Compatibility—Requirements and Tests
- IEC 60601-2-22: 2012-10 ed 3.1, Medical Electrical Equipment—Part 2-22: Particular Requirements For Basic Safety And Essential Performance Of Surgical, Cosmetic, Therapeutic And Diagnostic Laser Equipment
- IEC 60825-1 Ed. 3.0 (2014) Safety Of Laser Products—Part 1: Equipment Classification and Requirements
- Cytotoxicity per ISO 10993-5:2009
- Skin sensitization per ISO 10993-10:2021
- Skin Irritation per ISO 10993-23:2021

807.92(b)(2) CLINICAL TESTS SUBMITTED

A clinical study was performed to assess the effect of the laser on the tissue, healing of the tissue and potential side effects. 15 patients were treated at a range of treatment settings. Biopsies were taken the day of treatment and multiple days after treatment. Histological evaluation showed signs of coagulation formation followed by healing within 4 days. All patients saw mild anticipated side effects of erythema and edema immediately following treatment which typically resolved by end of day. There were no adverse events noted in the duration of the study.

807.92(b)(3) Conclusion

Based on the comparison of the technological characteristics, the specifications for the Mosaic ED are the same or a subset of the Mosaic 3D specifications. The additional tips allow the users more options in how the same energy is shaped during delivery. The new indication of fractional skin resurfacing procedures is supported by clinical testing. Also, the indication is similar to the reference device, Fraxel Dual 1550.