August 11, 2025

Lutronic Corporation
Cynthia Aguirre
Sr. Regulatory Affairs Specialist
Lutronic Center
219, Sowon- Ro
Deogyang-Gu, Goyang 410220
Korea, South

Re: K251327
Trade/Device Name: Xerf
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting And Coagulation Device And Accessories
Regulatory Class: Class II
Product Code: GEI
Dated: July 11, 2025
Received: July 11, 2025

Dear Cynthia Aguirre:

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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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,

JAMES H. JANG -S

Digitally signed by JAMES H. JANG -S
Date: 2025.08.11 00:51:07 -04'00'

James Jang, Ph.D.
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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K251327	?
Please provide the device trade name(s).		?

XERF

Please provide your Indications for Use below.	?

The XERF is intended for use in dermatologic and general surgical procedures for electrocoagulation and hemostasis.

Please select the types of uses (select one or both, as applicable).	☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)	?

510(k) SUMMARY

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	888-588-7644
Fax number	N/A
Establishment Registration Number	3004483538
Name of contact person	Cynthia Aguirre Senior Regulatory Affairs Specialist 3/5 Carlisle Road Westford, MA, 01886
Date prepared	05 August 2025
807.92(a)(2) - Name of device	
Trade or proprietary name	XERF
Common or usual name	Electrosurgical Unit and Accessories
Classification name	Electrosurgical, Cutting & Coagulation & Accessories
Classification panel	General and Plastic Surgery
Regulation	21 CFR 878.4400
Product Code(s)	GEI
807.92(a)(3) - Legally marketed device(s) to which equivalence is claimed	
	Solta Medical K170758 (09/22/2017) Predicate Cutera Inc K221407 (07/13/2022) Reference
807.92(a)(4) - Device description	
	XERF is an electrosurgical unit which uses high frequency electrical currents for treatment. When high frequency is irradiated on the skin, the treated skin tissue is heated, resulting in coagulation. This equipment generates high frequency of 2 MHz and 6.78 MHz and is delivered non-invasively into skin through the tip of the handpiece. There are a total of 12 types of active electrode tips compatible with the handpiece; the different tips are intended for various applications and treatment zones. The system also includes a return pad corresponding to the neutral electrode which is intended to be attached to the patient's back to disperse the generated energy. For adjustment of treatment parameter, data can be used by adjusting the operator interface through LCD touch screen.

	Treatment is conducted using foot switch or finger switch after ready when applied treatment parameter is output to the tissue.
807.92(a)(5) Intended use of the device	
Indications for use	XERF is indicated for use in dermatologic and general surgical procedures for electrocoagulation and hemostasis.

807.92(a)(6) Summary of the technological characteristics of the device compared to the predicate			
Company	**Lutronic Corporation**	**Solta Medical**	**Cutera Inc.**
Model	**XERF**	**Thermage FLX**	**truSculpt iD**
K No.	TBD	K170758	K221407
Type	Monopolar RF	Monopolar RF	Bipolar/ Monopolar RF
Frequency [MHz]	2 MHz, 6.78MHz	6.78MHz	1 MHz and 2 MHz
Max Output Power [W]	6.78MHz: 400W 2MHz: 300W	400W	300 W
Duty Cycle	Intermittent	Intermittent	Unknown
Interval	off, 200, 500, 800ms (applies to handpiece mode only)	Unknown	Unknown
Energy	- 2 MHz : 1 ~ 120 J - 6.78 MHz : 1~ 250 J	6.78 MHz 15J ~ 600J	Unknown
Operational Conditions	Temperature range: 10°C - 30°C Humidity: Up to 90% RH	Temperature range: 10°C - 30°C Humidity: Up to 90% RH	Temperature range: 5°C - 30°C Humidity: Up to 90% RH
Tip Pattern Sizes (Treatment Width)	60 Tip : 27.6 x 17.6mm 40 Tip : 17.6 x 17.6mm 10 Tip : 9 x 9 mm 05 Tip : 9 X 4.5 mm	0.5 x 0.5cm = 0.25cm^2 1.73 x 1.73cm = 3cm^2 2.0 x 2.0cm =4cm^2 4.0 x 4.0cm =16cm^2	40 to 240 cm^2 16 and 40 cm^2
Patient Contact Material	Tip electrode Return pad	Treatment tips Coupling fluid Return pad	Polyvinylidene fluoride (PVDF) for handheld handpieces • Liquid resin adhesive for patient decals (for hands-free handpieces)
Contact duration	Less than 24 hours	Less than 24 hours	Less than 24 hours
Contact type	Intact skin	Intact skin	Intact skin
Single Use/Reusable	Single use accessories	Single use, provided clean	Single use accessories
Dimension (Including a part holder)	389mm (W) x 856.4mm (L) x 1604.1mm (H)	49.5cm (W) x 43cm (L) x 125.7cm (H)	14"W x 17.5"L x 41.5"H
Weight	47 kg	45 kg	39kg

	Type & Degree of Protection Against Shock	Class 1 / type BF applied part	Class 1 / type BF applied part	Class 1 / type BF applied part	
	Electrical Ratings	Single phase AC 100-120V, 50/60Hz	AC 100~240V, 50-60Hz, 10A	AC 100-240V. 50/60Hz Power: 2000VA	
		Power consumption:1kVA (Fuse: 125V / 10A)			
	User Interface	10.1" LCD Touch Display	LCD Touch Display	LCD Touch Display	
	Treatment Activation	Finger switch or Footswitch	Manual or Footswitch	Control Screen Button or Finger switch	

807.92(b)(1) NON-CLINICAL TESTS SUBMITTED

Electrical Safety
IEC 60601-1 :2005+ A 1:2012+ A2:2020 Medical electrical equipment -Part 1: General requirements for basic safety and essential performance, FDA Recognition# 19-49

IEC 60601-2-2:2017 + AMD1: 2013 Medical electrical equipment-Part 2-2: Particular requirements for the basic safety and essential performance of high frequency surgical equipment and high frequency surgical accessories, FDA Recognition# 6- 389

EMC
IEC 60601-1-2: 2014+Al :2020 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances -Requirements and tests, FDA Recognition# 19-36

IEC TS 60601-4-2:2024 Medical electrical equipment-Part 4-2: Guidance and interpretation - Electromagnetic immunity: performance of medical electrical equipment and medical electrical systems, FDA Recognition# 19-50

Usability
IEC 60601-1-6: 201 0+Al :2013+A2:2020 -Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability, FDA Recognition# 5-132

Biocompatibility
ISO 10993-1:2018 Biological evaluation of medical devices -Part 5: Tests for in vitro cytotoxicity, FDA Recognition# 2-258

ISO 10993-10:2021 Biological evaluation of medical devices -Part 10: Tests for skin sensitization, FDA Recognition# 2-296

ISO 10993-23:2021 Biological evaluation of medical devices - Part 23: Tests for irritation, FDA Recognition# 2-291

Software
IEC 62304:2006+Al :2015 Medical Device-Software Life Cycle Processes, FDA Recognition# 13-79

Performance
An ex-vivo thermal study was performed to assess the effect of the RF power on the tissue, healing of the tissue and potential side effects. Three different types of tissue were tested at a range of treatment settings as recommended by the FDA, ex vivo kidney, liver, and skin. Central sections from the fixed 12 mm biopsy samples were obtained, stained by standard H&E histology method, and analyzed under light microscope. Coagulation was observed when treatment was performed with five stacked pulses with the interval of 200ms (within the same treatment spot without moving the tip). Coagulation surface correlated to the perimeter of the RF tip treatment surface. Uniform coagulation at entire perimeter and depth was observed

in tested tissues. The correlations noted in the in vivo and ex vivo test data, as well as the uniformly coagulated tissue observed, confirms that treatment by the XERF device ,at the appropriate testing settings, will possess a desirable clinical treatment effect, such as tissue repair responses and establishing long-term dermal remodeling. A second ex-vivo thermal study was conducted comparing temperature-time curves of Thermage FLX (predicate) and XERF (subject device). Ex-vivo dermal temperature profiles were measured using fiber optic temperature sensors inserted at a depth of 3.0 mm of the skin layer under standardized treatment conditions. Temperature- time curves were measured at two levels representing worst-case scenario treatment condition and real-world treatment condition. The ex-vivo dermal temperature testing confirmed that the XERF device's thermal performance is equivalent to that of the Thermage FLX device in terms of time-dependent heating and cooling behavior.
807.92(b)(2) CLINICAL TESTS SUBMITTED
No clinical tests were included as part of this submission.
807.92(b)(3) Conclusion
Based on the comparison of the technological characteristics, the specifications for the XERF are the same or a subset of the predicate/reference device specifications. The indication is the same as the predicate device, Thermage FLX.