June 29, 2026

Cynosure Lutronic Technology Corporation
Nicole Getman
Sr. Regulatory Affairs Specialist
55 Samwon-Ro
Deogyang
Goyang Gyeonggi, 10550
Republic Of Korea

Re: K253484
Trade/Device Name: Lutronic Genius
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting And Coagulation Device And Accessories
Regulatory Class: Class II
Product Code: GEI
Dated: May 29, 2026
Received: May 29, 2026

Dear Nicole Getman:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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,

Colin K. Chen -S

Digitally signed by Colin K. Chen -S
Date: 2026.06.29 13:31:05 -04'00'

Colin K. Chen, 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.	K253484

Please provide the device trade name(s).

LUTRONIC GENIUS

Please provide your Indications for Use below.

The LUTRONIC GENIUS is intended for use in dermatologic and general surgical procedures for electrocoagulation/contraction 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)

CYNOSURE
LUTRONIC

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	Nicole Getman Manager, Regulatory Affairs 3/5 Carlisle Road Westford, MA, 01886
Date prepared	06/26/2026
807.92(a)(2) - Name of device	
Trade or proprietary name	LUTRONIC GENIUS
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	
	Lutronic GENIUS Radiofrequency System K180945(12/10/2018) Predicate The InMode System with the Morpheus8 Applicators K231790 (07/20/2023) Secondary Predicate
807.92(a)(4) - Device description	
	The LUTRONIC GENIUS includes the system main body, a handpiece equipped with disposable handpiece tips, footswitch, and an LCD touch screen control panel. The RF energy is delivered using disposable handpiece tips consisting of a 7x7 bipolar microneedle array. The bipolar microneedle array delivers radiofrequency energy to the target tissue: The microneedles come in light contact with the epidermis of the patient and minimally penetrate the epidermis during the treatment. The handpiece being held at right angles to the target tissue. As the RF energy passes into the skin via the needles, it generates an electro-thermal reaction capable of coagulating the tissue.

807.92(a)(5) Intended use of the device	
Indications for use	The LUTRONIC GENIUS is intended for use in dermatologic and general surgical procedures for electrocoagulation/contraction and hemostasis.

Company	**Lutronic Corporation**	**Lutronic Corporation**	**InMode Ltd.**
Model	**LUTRONIC GENIUS**	**LUTRONIC GENIUS Radiofrequency System**	**The InMode System with the Morpheus8 Applicators**
K No.	TBD	K180945	K231790
Type	Bipolar RF (Radiofrequency)	Bipolar RF (Radiofrequency)	Bipolar RF (Radiofrequency)
Frequency	460 kHz	460 kHz	50-60 Hz
Max Output Power [W]	50W	50W	65W
Treatment Activation	Footswitch or Fingerswitch	Footswitch or Fingerswitch	Footswitch or Fingerswitch
Rx/OTC	Prescription	Prescription	Prescription
Treatment Duration (Time)	10 – 600 ms	10 -1000 ms	UKN
Needle Depth	Max 4.0 mm	Max 3.5 mm	Max 4mm Max 7 mm
No. of Needles	M49D: 49 each (7*7) G49D: 49 each (7*7) P16D: 16 each (4*4) P14D: 14 each (7*2) G25D: 25 each (1st line: 4, 2nd line: 3, Total 7 lines)	G49D: 49 each (7*7)	12, 24, T-pin, & 40 pin tip head Resurfacing Tip: 24 each Prime Tip: 12 each Morpheus 8 Tip: 24 each Body 3D Tip: 40 each
Needle Diameter	200 micrometers	200 micrometers	UKN
Accessories	G49D Tip M49D Tip P16D Tip P14D Tip G25D Tip GeniusM Handpiece	G49D Tip M49D Tip GeniusSkin Handpiece Genius M Handpiece GeniusX Handpiece	Resurfacing Tip Prime Tip, Morpheus8 Tip Body 3D Tip Morpheus8 Applicator Morpheus8 Body

User Interface	10.1" Touch LCD Display	10.1" Touch LCD Display	UKN
Sterilization Method	EO gas sterilization	EO gas sterilization	Gamma sterilization
Material of Contact Part	Handpiece Tip	Handpiece Tip	Handpiece Tip
System Cooling	Air Cooling	Air Cooling	UKN
Electrical Rating	Single phase AC110-120V, 60Hz Power consumption: 300VA (Fuse: 250V/6.3A)	Single phase AC110-120V, 60Hz Power consumption: 300VA (Fuse: 250V/6.3A)	100-240 VAC
Cold Air Chiller Device Compatible	Yes	Yes	UKN
Weight	27 kg	27 kg	30 kg
Dimension	452 mm (W) x 582 mm (L) x 1824.5 mm (H)	452 mm (W) x 582 mm (L) x 1540 mm (H)	46cm W x 46cm D x 100cm H

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: 2023 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+A1 :2015 Medical Device-Software Life Cycle Processes, FDA Recognition# 13-79

Performance
Study Title: Thermal Tests for the Evaluation of GENIUS RF Microneedling Device Vs Morpheus8 As predicate on Three Different Types of Ex Vivo Tissues

The purpose of the study is to assess the thermal effect of the Genius RF microneedling Device, equipped with M49D and P14D tips, using various parameters applied to ex vivo three types of tissues, Yucatan pig skin, Bovine liver, and muscle (derived from bovine heart). The study aims to evaluate the thermal effects of different modes and settings in accordance with the criteria outlined in the FDA Guidance for Industry: Premarket Notification (510(k)) Submissions for Electrosurgical Devices for General Surgery.

Morpheus8 microneedling device, equipped with Tip 40 (body) and Tip 12 (prime) is used as a predicate device in the proposed study. The study is being conducted for regulatory considerations by the sponsor to provide performance data for the Genius RF, demonstrating equivalence in its safety and treatment effect features.

The treatment of an ex vivo tissue model, bovine skin, liver, and muscle, using the Genius RF device, equipped with M49D and P14D tips compared to the predicate Morpheus8 RF device equipped with Tip 40 (body) and Tip 12 (prime) was performed. Treatment at various penetration depths demonstrated the expected correlation with energy levels and consistent thermal lesion profiles across the range of energy level settings, within the accuracy expected in histology analyses. Morpheus8 served as the predicate for the Genius device. The Genius, equipped with different tip configurations, demonstrated the formation of CMZs and tissue contraction comparable to those formed by Morpheus8. Considering the above, the Test and Predicate Devices demonstrated the expected correlation with energy levels and consistent thermal lesion profiles across the range of energy level settings, within the accuracy expected in histology analyses. It may be concluded that the Test Device is equally safe when compared to the predicate device.

807.92(b)(2) CLINICAL TESTS SUBMITTED

No clinical tests were performed for this submission.

807.92(b)(3) Conclusion

Based on the comparison of the technological characteristics, the specifications for the LUTRONIC GENIUS are the same or a subset of the predicate/secondary predicate device specifications. The indication is the same as the secondary predicate device, The InMode System with the Morpheus8 Applicators.