



December 10, 2018

Lutronic Corporation
James Childs, Ph.D.
Clinical Science Director, Lutron Global
19 Fortune Drive
Billerica, Massachusetts, 01863

Re: K180945

Trade/Device Name: LUTRONIC GENIUS Radiofrequency System
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting and Coagulation Device and Accessories
Regulatory Class: Class II
Product Code: GEI
Dated: November 9, 2018
Received: November 13, 2018

Dear Dr. 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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm>); 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 <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm>.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (<https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/>) and CDRH Learn (<http://www.fda.gov/Training/CDRHLearn>). 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 (<http://www.fda.gov/DICE>) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Long H. Chen -S
Digitally signed by Long H.
Chen -S
Date: 2018.12.10 15:54:22
-05'00' 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

Indications for Use

510(k) Number (if known)

K180945

Device Name

LUTRONIC GENIUS Radiofrequency system

Indications for Use (Describe)

The LUTRONIC GENIUS Radiofrequency System is intended for use in dermatologic and general surgical procedures for electrocoagulation and hemostasis.

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 the
LUTRONIC GENIUS Radiofrequency 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

Submitter: Lutronic Aesthetics
Lutronic Center, 219, Sowon-ro
Deogyang-gu, Goyang-si, Gyeonggi-do, 410-220
Republic of Korea

Contact Person: James J Childs, Ph.D.
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Summary Preparation Date: December 6, 2018

2. Names

Trade Name: LUTRONIC GENIUS Radiofrequency System
Classification Name: Electrosurgical, cutting & coagulation device
& accessories
Product Code: GEI
Panel: General and Plastic Surgery

3. Predicate Devices

The INFINI Radiofrequency System (K121481).
This predicate device has not been subject to a design-related recall.
No reference devices were used in this submission.

4. Device Description

The LUTRONIC GENIUS Radiofrequency System consists of the system control module and RF power supply in a main body on locking castor wheels, a handpiece equipped with disposable handpiece tips with microneedle array, footswitch, handpiece hanger and holder, and an LCD

touch screen control panel. The sterilized handpiece tips include the tip body containing the microneedle array and a protective cap. The treatment parameters are entered via a touchscreen console that also displays system output information during treatment. The microneedles come in light contact with the epidermis of the patient and minimally penetrate the epidermis during the treatment. Needle depth, Power level and Duration (Power x Duration = RF Energy), are user-selectable via the GUI console. The RF Power output is controlled to insure for a given Duration that a determinate RF Energy is delivered to the 7x7 bipolar microneedle array of the handpiece tips. The handpiece is 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 surrounding the uninsulated portion of the needles.

5. Indications for Use

The LUTRONIC GENIUS Radiofrequency System is intended for use in dermatologic and general surgical procedures for electrocoagulation and hemostasis.

6. Device Modifications

The following changes to the Predicate device, INFINI Radiofrequency System, were applied in the LUTRONIC GENIUS Radiofrequency System:

- Change in dimensions of device and accessories
- Change in electrical requirements
- Change in RF frequency from 1 MHz to 460 kHz
- Change in GUI design
- Change in disposable tip packaging
- Change in shelf life of disposable tip
- Change in coating of disposable tip needle

7. Comparison of Technological Characteristics with the Predicate Device

The Subject device has the same intended use and indications for use and the same fundamental scientific technology as the Predicate device, the INFINI Radiofrequency System cleared in K121481. The Subject device design, technology, and the principles of operation are the same as the Predicate device. The LUTRONIC GENIUS Radiofrequency System and the Predicate device are bipolar radiofrequency systems, with delivery methods through microneedles inserted from the handpiece and the tip. The LUTRONIC GENIUS Radiofrequency System and the Predicate device are minimally invasive radiofrequency devices employing bipolar microneedle electrode system. The Subject device has the same power, same treatment duration, needle diameter, and needle depth as the original device. Therefore, the minor differences do not raise any new safety and effectiveness questions because the LUTRONIC GENIUS parameters are similar to those of the Predicate device.

8. SUBSTANTIAL EQUIVALENCE TABLE

Device	LUTRONIC GENIUS Radiofrequency System	INFINI Radiofrequency System
Manufacturer	Lutronic Corporation	Lutronic Corporation
510(k) #	K180945	K121481
Indication for Use	Dermatologic and general surgical procedures for electrocoagulation and hemostasis.	Dermatologic and general surgical procedures for electrocoagulation and hemostasis, and the percutaneous treatment of facial wrinkles
System Type	Bipolar RF (Radiofrequency)	Bipolar RF (Radiofrequency)
Frequency	460 KHz	1 MHz
Max Output Power	50W	50W
Operation Mode	Microneedle Fractional RF	Microneedle Fractional RF
Treatment Duration (Time)	10 - 1000 msec	10 – 1000 msec
Tip	49 tip: 7x7 microneedles; 10x10 mm Microneedle depth adjustment 0.5 - 3.5 mm	49 tip: 7x7 microneedles; 10x10 mm Microneedle depth adjustment 0.5 - 3.5 mm
Needle Diameter	200 micrometers	200 micrometers
Weight	27 kg	28 kg
Dimension	452 mm (W) x 582 mm (L) x 1540 mm (H) RF (Radiofrequency)	362 mm (W) x 409 mm (L) x 1713 mm (H) RF (Radiofrequency)

Lutronic has removed from the Subject device the percutaneous treatment of facial wrinkles as an Indication for Use. The LUTRONIC GENIUS Radiofrequency System and the INFINI Radiofrequency System have the same Indication for Use.

9. Performance Data

The following performance data were provided in support of the substantial equivalence determination:

Biocompatibility testing

Biocompatibility evaluation for the GENIUS handpiece tip body and microneedles was conducted in accordance with the FDA Blue Book memorandum #G95-1 “Use of the International Standard ISO-10993, Biological Evaluation of Medical Devices”, and ISO 10993-1 “Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing Within a Risk

Management Process,” as recognized by FDA. The battery of testing included the following tests:

- Cytotoxicity: ISO 10993 – 5 (2009)
- Intradermal Irritation and Skin Sensitization: ISO 10993 – 10 (2010)
- Acute Systemic toxicity: ISO 10993 – 11 (2017) & ISO10993 – 12 (2012)

Sterilization Validation

Sterilization validation of the GENIUS handpiece tip with microneedle array has been conducted per the standard ISO 10993 – 7 (2008) for Ethylene Oxide (standard ISO 11135 (2014)).

Electrical safety and electromagnetic compatibility (EMC)

Electrical safety and EMC testing were conducted on LUTRONIC GENIUS Radiofrequency System consisting of the console, main body and GENIUS handpiece. The system complies with the IEC 60601-1 standards for safety and the IEC 60601-1-2 standard for EMC.

Software Verification and Validation Testing

Software verification and validation testing were conducted and documentation was provided as recommended by FDA’s Guidance for Industry and FDA Staff, “Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices.” The software for this device was considered as a “major” level of concern, since a failure or latent flaw in the software could directly result in serious injury or death to the patient or operator.

Ex Vivo Animal Study

An *ex vivo* animal study utilized a porcine tissue model and standardized H&E staining techniques to quantitatively compare the height, width and volume of thermal coagulative zones created by the LUTRONIC GENIUS and INFINI Radiofrequency Systems operating over a range of treatment parameters. No statistically significant differences in the coagulation profiles between the two systems were observed either in the ANOVA analyses for each measure or student t-tests for each parameter tested. When validating the affect of the design changes between the original device and the modified device, the LUTRONIC GENIUS Radiofrequency System fell within the 95% confidence interval of the INFINI Radiofrequency System for coagulation profile height, width and volume at each setting.

Cleaning and Disinfection Testing

A low-level disinfection protocol and a cleaning protocol were developed for the LUTRONIC GENIUS Radiofrequency System's handpiece, the GENIUS handpiece, to mitigate cross-contamination. The study to validate the protocols conformed to 21 CFR Part 820 GMP and was based on the following references:

- AAMI TIR12:2010, Designing, Testing, and Labeling Reusable Medical Devices for Reprocessing in Health Care Facilities: A Guide for Medical Device Manufacturers, 7 September 2010.
- AAMI TIR30:2011/(R)2016, A Compendium of Processes, Materials, Test Methods, and Acceptance Criteria for Cleaning Reusable Medical Devices, 15 December 2016.
- ASTM E1837-96 (2014). Standard Test Method to Determine Efficacy of Disinfection Processes for Reusable Medical Devices (Simulated Use Test), December 1, 2014.
- ISO/IEC 17025, 2017, General Requirements for the Competence of Testing and Calibration Laboratories.
- Guidance for Industry and Food and Drug Administrator Staff, Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling, Document issued March 17, 2015, U.S. Department of Health and Human Services, Food and Drug Administration, Center for Devices and Radiological Health, Office of Device Evaluations.

No clinical data was provided in this submission.

10. Conclusion

The intended use, dermatologic and general surgical procedures for electrocoagulation and hemostasis, of the LUTRONIC GENIUS Radiofrequency System is identical to the intended use of the Predicate device, the INFINI Radiofrequency System. The technological characteristics of the LUTRONIC GENIUS Radiofrequency System are similar to the technological characteristics of the Predicate device. The Animal study demonstrates that the Subject and Predicate devices' coagulative effect on tissue are statistically equivalent for the same treatment parameters. Any differences between the LUTRONIC GENIUS Radiofrequency System and the Predicate device have therefore no significant influence on safety and effectiveness of the LUTRONIC GENIUS Radiofrequency System. Therefore, the LUTRONIC GENIUS Radiofrequency System is substantially equivalent to the Predicate device.