October 14, 2022

Lutronic Corporation
Haewon Park
Regulatory Affairs Specialist
Lutronic Center, 219, Sowon-Ro
Deogyang-Gu, Goyang-si, Gyeonggi-do 410220
Korea, South

Re: K213748
Trade/Device Name: CoreLevee
Regulation Number: 21 CFR 890.5850
Regulation Name: Powered Muscle Stimulator
Regulatory Class: Class II
Product Code: NGX
Dated: August 30, 2022
Received: August 31, 2022

Dear Haewon Park:

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,

Tushar Bansal, PhD
Acting Assistant Director, Acute Injury Devices Team
DHT5B: Division of Neuromodulation
and Physical Medicine Devices
OHT5: Office of Neurological
and Physical Medicine Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K213748

Device Name
CoreLevée

Indications for Use *(Describe)*

CoreLevée is indicated to be used for:
- Improvement of abdominal tone, strengthening of the abdominal muscles, development of firmer abdomen.
- Strengthening, toning and firming of buttocks and thighs.

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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510(K) SUMMARY (K213748)

Lutronic Corporation
CoreLevée

I. SUBMITTER

510(k) Owner	Lutronic Corporation Lutronic Center 219, Sowon-ro, Deogyang-gu, Goyang-si, Gyeonggi-do, 10534 Republic of Korea
Submission Correspondent	Haewon Park, Ph.D., Regulatory Affairs Specialist, Lutronic USA 19 Fortune Drive Billerica, MA 01821 Tel: 888-588-7644 Email: hpark@lutronic-usa.com
Date Prepared	August 26, 2022

II. DEVICE

Trade Name:	CoreLevée
Common or Usual Name:	Electromagnetic stimulator
Classification Name:	NGX - Powered Muscle Stimulator 21 CFR 890.5850, Class II

III. PREDICATE DEVICE

Trade Name:	BTL 799-2
Regulation Number:	21 CFR 890.5850
Classification Name:	NGX - Powered Muscle Stimulator 21 CFR 890.5850, Class II
Premarket Notification:	BTL Industries Inc. K180813 (6/14/2018)

IV. DEVICE DESCRIPTION

CoreLevée is a non-invasive electromagnetic muscle stimulator that applies high-intensity electromagnetic field to the treatable body areas through two applicators. The coil enclosed in each applicator produces a magnetic field that induces electric currents within neuromuscular tissues. At its optimal level, these electric currents depolarize neuromuscular tissues causing effective muscle contraction.

CoreLevée consists of a Main Body, a software integrated color-touch LCD screen, two applicators, three applicator fixing belts, and a patient switch. The Main Body allows the proper operation of the entire system. The LCD screen works as a control panel and displays step-by-step guides through the entire therapy procedure. The therapeutic parameters such as treatment time, location, and stimulation frequency and intensity are easily set using the touch screen and the dial knob on the device. The micro-controller within the software continuously monitors the device system for its operation and functional normalcies. Two applicators can be used alone or together on top of clothing.

The device is a mobile standalone equipment with four wheels. The device housing protects the patient from electrical shock and mechanical injuries.

V. INDICATIONS FOR USE

CoreLevée is indicated to be used for:

• Improvement of abdominal tone, strengthening of the abdominal muscles, development of firmer abdomen.

• Strengthening, Toning and Firming of buttocks and thighs.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

CoreLevée has the same indications for use and similar technological characteristics and principles of operation as its predicate device. Both subjective device and its predicate are comprised of a main body and applicators. The main body consists of the electromagnetic field generators, computer, and the touchscreen as a control panel. Both subjective device and its predicate control the treatment parameters using the touchscreen, and the magnetic field intensity using the touchscreen and a dial knob. Both subjective device and its predicate use the same type of energy and operation and have the same pulse characteristics and therapy time. When using the applicators, both subjective device and its predicate use two outputs with comparable magnetic field intensities. They also produce similar induced current in tissues. Therefore, CoreLevée is substantially equivalent to the predicate device and the technological differences between CoreLevée and its predicate do not raise any new types of safety or effectiveness questions.

Characteristic	Subject device	Predicate device
Device Name	**CoreLevée**	**BTL 799-2**
Manufacturer	Lutronic Corporation	BTL Industries Ltd
510(k) Number	K213748	K180813
Product Code and Regulation	NGX-Stimulator Muscle, Powered, Muscle conditioning 21 CFR 890.5850	NGX-Stimulator Muscle, Powered, Muscle conditioning 21 CFR 890.5850
Indications For Use	• Improvement of abdominal tone, strengthening of the abdominal muscles, development of firmer abdomen. • Strengthening, Toning and Firming of buttocks and thighs.	• Improvement of abdominal tone, strengthening of the abdominal muscles, development of firmer abdomen. • Strengthening, Toning and Firming of buttocks and thighs.
Primary Function	Muscle stimulation	Muscle stimulation
Principle of Action	Initiating action potential of nerves results in muscle contraction	Initiating action potential of nerves results in muscle contraction
Electrical Protection	Class II, BF	Class II, BF
User Interface	Touch screen	Touch screen
Touch Screen Size	10.1”	15.6”
Firmware Controlled	Yes	Yes
Type of Energy	Magnetic field	Magnetic field
Number of Outputs	2	2
Number of Magnetic Coils in the Applicator	1	1
Applicator dimensions	181 x 266 x 93mm (W * L * H)	Not publicly available
Surface area of Applicators	152 ㎠	Not publicly available
Magnetic Field Intensity at the Applicator center	0 - 1.2 T (+/- 20%)	0.5 - 1.154 T (+/- 20%)
Magnetic Field Intensity at Core	0-1.45 T (+/- 20%)	0.5 – 1.8 T (+/- 20%)
Total Induced Current in Tissue (mA)	262 mA	285 mA
Type of Operation	Continuous	Continuous
Pulse Repetition Rate	1 – 150 Hz	1 – 150 Hz
Pulse Duration	280µs	280µs
Pulse Amplitude	Up to 100%	Up to 100%
Selection of parameters (intensity, time)	Yes	Yes

Treatment Time	Up to 60 min	Up to 60 min
Pulse Type	Sine, Biphasic wave	Sine, Biphasic wave
Electrical Requirements	AC 100-120V, 50/60Hz Max2500VA (Fuse: 125V / 25A)	AC 100-240 V, 50-60 Hz
System dimensions (WxHxD mm)	400.6 x 1182.4 x 661mm	500 x 1380 x 580mm
Environmental Specifications	For indoor use only	For indoor use only

VII. PERFORMANCE DATA

The following performance data were provided in support of the substantial equivalation determination.

Biocompatibility Testing

The applicators of CoreLevée do not contact patients' skin directly. They are directed to be used on top of clothing. Therefore, the biocompatibility evaluation according to ISO 10993-1, 10993-5, or 10993-10 for CoreLevée were not conducted.

Electric Safety and Electromagnetic Compatibility Testing

CoreLevée was tested for electrical safety and electromagnetic compatibility, and found to be in compliance with the following applicable medical device safety standards:

IEC 60601-1	Medical electrical equipment – Part 1: General requirements for basic safety and essential performance
IEC 60601-1-2	Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic disturbances – Requirements and tests
IEC 60601-1-6	Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral standard: Usability
IEC 60601-2-10	Medical electrical equipment – Part 2-10: Particular requirements for the Basic Safety and Essential Performance of Nerve and Muscle Stimulators
IEC 62366-1	Medical devices – Application of usability engineering to medical devices
IEC 62304	Medical devices software – software life cycle processes
ISO14971	Medical devices – Application of risk management to medical devices

Sterilization and Shelf Life

CoreLevée is not provided sterile and does not need to be sterilized. The applicators and the main body are cleaned with a soft cloth moistened with isopropyl alcohol or ethanol of 70% strength or higher. Applicator fixing belts can be reused after washing them with mild detergent. CoreLevée is reusable and does not have a restricted shelf-life. The expected service life of applicators and the main body are about 5 years.

Software Validation and Verification Testing

Software verification and valuation 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 "moderate" level of concern since a failure of the software could result in minor injury to a patient or to a user of the device.

Performance Bench Testing

Bench tests were performed to ensure that CoreLevée performs as intended and documentation was provided. Tested parameters include the magnetic field intensity and its oscilloscopic characterization, pulse repetition and duration, and induced current in tissues was theoretically derived based on the bench test results. These results confirmed that both applicators operate within the magnetic field intensity specifications and the induced current in tissues at its maximum intensity is within the values comparable to its predicate.

VIII. CONCLUSIONS

CoreLevée has the same intended use and almost identical technological characteristics to its predicate device. Any differences between the predicate device and CoreLevée, such as the system dimensions and the size of touchscreen have no significant effect on safety or effectiveness of CoreLevée. Therefore, CoreLevée is as safe, as effective, and performs as well as the legally marketed predicate device.