December 19, 2023

El.En. S.p.A.
Paolo Peruzzi
Regulatory Affairs Manager
Via Baldanzese 17
Calenzano, Fl 50141
Italy

Re: K233470
Trade/Device Name: DEKA LILY
Regulation Number: 21 CFR 890.5850
Regulation Name: Powered Muscle Stimulator
Regulatory Class: Class II
Product Code: NGX
Dated: October 25, 2023
Received: October 25, 2023

Dear Paolo Peruzzi:

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,

Heather L. Dean -S

Heather Dean, PhD
Assistant Director
DHT5B: Division of Neuromodulation
and Rehabilitation Devices
OHT5: Office of Neurological
and Physical Medicine 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K233470

Device Name
DEKA LILY

Indications for Use *(Describe)*
The LILY device is indicated for muscle conditioning to stimulate healty muscles.

The device is not intended to be used in conjunction with therapy or treatment of medical disease or medical conditions of any kind.

The device is intended to be operated by a trained professional who is present to monitor treatment.

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

LILY

Submitter:

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Contact:

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Date Summary Prepared:

December 19, 2023

Device Trade Name:

DEKA LILY

Manufacturer:

DEKA M.E.L.A. srl

Via Baldanzese, 17

50041 Calenzano (FI), Italy

Common Name:

Electro Muscle Stimulator

Regulation Number:

21 CFR 890.5850

Regulation Name:

Powered Muscle Stimulator

Regulatory Class:

Class II

Product Code:

NGX

Predicate Devices:

Legend Pro DMA (K200545)

Device Description:

The DEKA LILY device consists of a main unit that generates electrical pulses and delivers rectangular biphasic waveforms via electrodes incorporated in an EMS applicator connected to the main unit.

The delivery of the electrical energy is controlled by a footswitch.

The DEKA LILY is provided with an applicator to perform EMS (Electrical Muscle Stimulation).

The applicator is provided with two different tips: Large and Medium, used to treat areas having different sizes, which include 3 stainless-steel equidistant electrodes.

The Applicator is directly applied on the area to be treated and moved by the operator across the skin.

The overall weight is approximately 62 kg and the sizes 47cm x 56cm x 106cm (L x W x H).

Electrical requirements: 115V, 50/60Hz, 2300VA.

Intended Use:

The LILY device is indicated for muscle conditioning to stimulate healthy muscles.

The device is not intended to be used in conjunction with therapy or treatment of medical disease or medical conditions of any kind.

The device is intended to be operated by a trained professional who is present to monitor treatment.

Comparison with the Predicate Device:

Device Trade Name	Subject Device **LILY**	Predicate Device **K200545** **Legend Pro DMA**	Comment
Product Code	NGX	NGX	Identical
Type of Use	Prescription Use (Part 21 CFR 801 Subpart D)	Prescription Use (Part 21 CFR 801 Subpart D)	Identical
Mechanism of Action	Muscle contraction by electrical pulsing	Muscle contraction by electrical pulsing	Identical
Indications for use	The LILY device is indicated for muscle conditioning to stimulate healthy muscles. The device is not intended to be used in conjunction with therapy or treatment of medical disease or medical conditions of any kind. The device is intended to be operated by a trained professional who is present to monitor treatment.	Legend Pro DMA is intended for muscle conditioning to stimulate healthy muscles. Legend Pro DMA is not intended to be used in conjunction with therapy or treatment of medical diseases or medical conditions. Legend Pro DMA is intended to be operated by a trained professional who is present to monitor treatment.	Identical

Device Trade Name	Subject Device **LILY**	Predicate Device **K200545** **Legend Pro DMA**	Comment
Mode of Operation	Application of transcutaneous electrical muscle stimulation (EMS) through skin contact electrodes	Application of transcutaneous electrical muscle stimulation (EMS) through skin contact electrodes	Identical
Mode of application	Metal (Stainless steel) electrodes in the System Applicator emit electric energy to the skin while the system applicator is rolled across the treatment area	Metal (Stainless steel) electrodes in the System Applicator emit electric energy to the skin while the system applicator is rolled across the treatment area	Identical
Basic Unit Characteristics			
Dimensions	47cm x 56cm x 106cm	45 x 110 x 45 cm	Differences do not affect safety and effectiveness of the device, as the subject is compliant with requirements of IEC 60601-1 and IEC 60601-2-10 Standards
Weight:	~ 62 Kg	~30 Kg;	Differences do not affect safety and effectiveness of the device, as the subject is compliant with requirements of

Device Trade Name	Subject Device **LILY**	Predicate Device **K200545** **Legend Pro DMA**	Comment
			IEC 60601-1 and IEC 60601-2-10 Standards
Power Source(s)	115V, 50/60Hz	110-240 V, 50-60 Hz	Differences do not affect safety and effectiveness of the device, as the subject is compliant with requirements of IEC 60601-1 and IEC 60601-2-10 Standards
Method of line current isolation	Medical Power Supply, Transformer in output stage	Medical Power Supply, Transformer in output stage	Identical
Patient Leakage Current - Normal Condition (μA)	0.1 μA	1.5 μA	Different. Value reported for the subject device is in compliance with the limit of 100uA set out in FDA's "Guidance Document for Powered Muscle Stimulator 510(k)" and with IEC 60601-1 and IEC

Device Trade Name	Subject Device **LILY**	Predicate Device **K200545** **Legend Pro DMA**	Comment
			60601-2-10 Standards
Patient Leakage Current – Single Fault Condition (μA)	2 μA	40 μA	Different Value reported for the subject device is in compliance with the limit of 500uA set out in FDA's "Guidance Document for Powered Muscle Stimulator 510(k)" and with IEC 60601-1 and IEC 60601-2-10 Standards
Number of output modes	1	1	Identical
Number of Output channels	1	1	Identical
Synchronous or alternating	Single output channel	Single output channel	Identical
Method of Channel Isolation	Single output channel	Single output channel	Identical

Device Trade Name	Subject Device **LILY**	Predicate Device **K200545** **Legend Pro DMA**	Comment
Regulated Current or Regulated Voltage (output signals only)	Voltage	Voltage	Identical
Software/Firmware/Microprocessor Control	Yes	Yes	Identical
Automatic Overload Trip	No	No	Identical
Automatic No-Load Trip	No	No	Identical
Automatic Shut Off	Yes, On/off switch	Yes, On/off switch	Identical
Patient Override Control	No	Yes	Differences do not affect safety and effectiveness of the device, as the subject is compliant with requirements of IEC 60601-1 and IEC 60601-2-10 Standards
Indicator Display	Yes	Yes	Identical
On/Off Status	Yes	Yes	Identical

Device Trade Name	Subject Device **LILY**	Predicate Device **K200545** **Legend Pro DMA**	Comment
Low Battery	N/A	N/A	Identical
Voltage/Current level	Voltage	Voltage	Identical
Timer Range (minutes)	1-30 minutes	1-99 min	Differences do not affect safety and effectiveness of the device, as the subject is compliant with requirements of IEC 60601-1 and IEC 60601-2-10 Standards
Compliance with 21 CFR 898	Yes	Yes	Identical
Housing Material	Metal, Plastics	Metal, Plastics	Identical
Output Specifications			
Waveform	Biphasic	Biphasic	Identical
Shape	Rectangular	Rectangular	Identical

Device Trade Name	Subject Device **LILY**	Predicate Device **K200545** **Legend Pro DMA**	Comment
Maximum output voltage (± 10%)	60V@500Ω 3.95V_{RMS}@500Ω 200V@2kΩ 12.3V_{RMS}@2kΩ 360V@10kΩ 17.6V_{RMS}@10kΩ	60V@500Ω 3.95V_{RMS}@500Ω 200V@2kΩ 12.3V_{RMS}@2kΩ 360V@10kΩ 17.6V_{RMS}@10kΩ	Identical
Maximum output current (± 10%)	120mA@500 Ω 100mA@2 kΩ 36mA@10 kΩ	120mA@500 Ω 100mA@2 kΩ 36mA@10 kΩ	Identical
Pulse Width (μs)	25 to 400 μs	20 to 400 μs	Almost identical. Differences do not affect safety and efficacy of the device
Frequency (Hz)	0.78, 1.56, 3.13, 6.25, 12.5 Hz	0.78, 1.56, 3.13, 6.25, 12.5 Hz	Identical
Net Charge @ 500 ohms (μC/pulse)]	0μC @ 500Ω biphasic waveform Zero net charge is achieved by using	0μC @ 500Ω biphasic waveform Zero net charge is achieved by using	Identical

Device Trade Name	Subject Device **LILY**	Predicate Device **K200545** **Legend Pro DMA**	Comment
	symmetrical biphasic waveforms	symmetrical biphasic waveforms	
Maximum Phase Charge (μC)	24 μC @ 500Ω @12.5 Hz	24 μC @ 500Ω @12.5 Hz	Identical
Maximum Current Density (mA/cm2)	1.mA/cm² @ 500Ω	1.1 mA/cm² @ 500Ω	Identical
Maximum Power Density (mW/cm2)]	0.0044mW/cm² @500Ω	0.0044mW/cm² @500Ω	Identical
Burst Mode (i.e., pulse trains) a. Pulses per burst b. Bursts per second c. Burst duration (seconds) d. Duty Cycle [Line (b) x Line (c)]	N/A no burst mode	N/A no burst mode	Identical
ON time	30 minutes	Not Publicly available	N/A
OFF time	5 minutes	Not Publicly available s	N/A

Clinical Performance Data:

None

Non-Clinical Performance Data:

Electrical safety and electromagnetic compatibility (EMC)

Electrical safety and EMC testing were conducted on the DEKA LILY device, according to the following standards:

ANSI AAMI ES60601-1Medical 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.

Software Validation and Verification Testing

Software verification and validation testing were conducted and documented as recommended by FDA's Guidance for Industry and FDA Staff, "Content of Premarket Submissions for Device Software Functions".

Biocompatibility evaluation

Biocompatibility evaluation was performed according to the FDA Guidance "Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process".

Additional non-clinical testing conducted

Additional tests were conducted on the DEKA LILY device, according to the following standards:

IEC 60601-2-10 - Medical electrical equipment - Part 2-10: Particular requirements for basic safety and essential performance of nerve and muscle stimulators.

Conclusion:

Based on the comparison of indications for use and the technological characteristics, DEKA LILY is deemed to be substantially equivalent to the predicate device for the proposed indications for use.

Additional Information:

None