September 1, 2023

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

Re: K232334
Trade/Device Name: Deka Simon
Regulation Number: 21 CFR 890.5850
Regulation Name: Powered Muscle Stimulator
Regulatory Class: Class II
Product Code: IPF
Dated: August 2, 2023
Received: August 4, 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 (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,

Jitendra V. Virani -S

CDR Jitendra Virani, MS, MBA
Assistant Director
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

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.

Submission Number *(if known)*

K232334

Device Name

DEKA SIMON

Indications for Use *(Describe)*

The DEKA SIMON device is intended for

- Prevention or retardation of disuse atrophy
- Maintaining or increasing range of motion
- Muscle re-education
- Relaxation of muscle spasms
- Increasing local blood circulation
- Immediate postsurgical stimulation of calf muscles to prevent venous thrombosis

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

SIMON – Special 510(k)

Submitter:
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Contact:
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Date Summary Prepared:
August 2, 2023

Device Trade Name:
DEKA SIMON

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:
IPF

Predicate Devices:
DEKA PHYSIQ (K202079)

Device Description:

The DEKA SIMON is a device provided with 4 applicators by 2 electrodes each intended to employ EMS (Electrical Muscle Stimulation) technologies for various medical applications.

The DEKA SIMON consists of:

- an AC/DC power supply unit,
- EMS driving electronic board
- CPU controller;
- user interface with LCD touch screen,
- 4 EMS applicator with interconnecting cables

The modifications to the device consist of a restriction of indications for use (removal of TENS mode), a restyling of the device (chassis, cover plastics and GUI) and of modifications to the applicator (different dimensions).
The indications for use of the modified device, as described in the labelling, has been restricted to those referred to EMS mode only as a result of the modifications. Labelling itself has been updated also to include general improvements that have been implemented since predicate device clearance and considered as minor changes.

Intended Use:

The DEKA SIMON device is intended for:

- Prevention or retardation of disuse atrophy
- Maintaining or increasing range of motion
- Muscle re-education
- Relaxation of muscle spasms
- Increasing local blood circulation
- Immediate postsurgical stimulation of calf muscles to prevent venous thrombosis

Substantial equivalence discussion:

The DEKA SIMON device is substantially equivalent to the DEKA PHYSIQ (K202079)

Device Trade Name	Subject Device **SIMON**	Predicate Device **K202079** **PHYSIQ**	Comment
Design	The SIMON device with consists of AC/DC power supply units, controller and user interface including an LCD touch screen. The delivery of the electrical energy is controlled by a Start/Stop button positioned on the front panel. The System support the following components: • LCD display touch screen • Buzzer • 24V AC/DC power supply • Controller • Fans The System operates while connected to the handpiece.	The PHYSIQ System with consists of AC/DC power supply units, controller and user interface including an LCD touch screen. The delivery of the electrical energy is controlled by a Start/Stop button positioned on the front panel. The System support the following components: • LCD display touch screen • Buzzer • 24V AC/DC power supply • Controller • Fans The System operates while connected to the handpiece.	Identical
Mechanism of Action	Muscle contraction by electrical pulsing	Muscle contraction by electrical pulsing	Identical
Class, Product Code	Class II, IPF	Class II, IPF GZJ	Principal product code is identical
Rx/OTC	Rx only	Rx only	Identical
Indications for use	The DEKA SIMON device is intended for • Prevention or retardation of disuse atrophy • Maintaining or increasing range of motion • Muscle re-education	The PHYSIQ device is intended in EMS mode for: • Prevention or retardation of disuse atrophy	The indications for use are a subset of the predicate device, the change does not affect

Device Trade Name	Subject Device **SIMON**	Predicate Device **K202079** **PHYSIQ**	Comment
	• Relaxation of muscle spasms • Increasing local blood circulation • Immediate postsurgical stimulation of calf muscles to prevent venous thrombosis	• Maintaining or increasing range of motion • Muscle re-education • Relaxation of muscle spasms • Increasing local blood circulation • Immediate postsurgical stimulation of calf muscles to prevent venous thrombosis and in TENS mode for: • Symptomatic relief and management of chronic, intractable pain • Post-surgical acute pain • Post-traumatic acute pain	safety and efficacy
Basic Unit Characteristics			
Components Console	The DEKA SIMON device consists of the following components: • Console (including controller, power supply units and all needed electronic boards), and user interface including an LCD touch screen. • Four Applicators connected to the console via a cable.	The PHYSIQ System consists of the following components: • Console (including controller, power supply units and all needed electronic boards), and user interface including an LCD touch screen. • Four Applicators connected to the console via a cable.	Identical

Device Trade Name	Subject Device **SIMON**	Predicate Device **K202079** **PHYSIQ**	Comment
Dimensions Console [W x H x D] Applicator [L x D]	 41 cm x 99 cm x 88 cm 9cm x 11cm	 34cm x 67cm x 90cm 9cm x 9cm	Similar, changes do not affect safety and effectiveness of the device
Weight: Console Applicator	 ~ 70 Kg 0.5 Kg	 51.0 Kg 0.5 Kg	Similar, changes do not affect safety and effectiveness of the device
Performance Specifications: Components Console	Main Line Frequency (nominal) 50/60Hz Input Voltage (nominal) 115-230VAC Input Current (rms) 7A max	Main Line Frequency (nominal) 50-60Hz Input Voltage (nominal) 115-230VAC Input Current (rms) 9A max	Similar, changes do not affect safety and effectiveness of the device

Device Trade Name	Subject Device **SIMON**	Predicate Device **K202079** **PHYSIQ**	Comment
Method of line current isolation	AC/DC isolation	AC/DC isolation	Identical
Electrical Type	Type BF	Type BF	Identical
Patient Leakage Current - Normal Condition (μA)	<100uA patient leakage	<100uA patient leakage	Identical
Patient Leakage Current – Single Fault Condition (μA)	<500uA line leakage	<500uA line leakage	Identical
Number of output modes	1	2	Change does not affect safety and effectiveness of the device. (TENS mode removed)
Number of Output channels	4	4	Identical
Synchronous or alternating	Synchronous	Synchronous	Identical
Method of Channel Isolation	Through AC/DC and transformers	Through AC/DC and transformers	Identical
Regulated Current or Regulated Voltage (output signals only)	Regulated voltage on all channels with current limit	Regulated voltage on all channels with current limit	Identical

Device Trade Name	Subject Device **SIMON**	Predicate Device **K202079** **PHYSIQ**	Comment
Software/Firmware/Microprocessor Control	Yes	Yes	Identical
Automatic Overload Trip	Yes	Yes	Identical
Automatic No-Load Trip	Yes	Yes	Identical
Automatic Shut Off	Yes, On/off switch	Yes, On/off switch	Identical
Patient Override Control	Yes	Yes	Identical
Indicator Display	Yes	Yes	Identical
On/Off Status	Yes	Yes	Identical
Battery	No battery	No battery	Identical
Voltage/Current level	Yes, voltage levels	Yes, voltage levels	Identical
Timer Range (minutes)	1-60 minutes	0-60 minutes	Almost identical, changes do not affect safety and effectiveness of the device

Device Trade Name	Subject Device **SIMON**	Predicate Device **K202079** **PHYSIQ**	Comment
Compliance with 21 CFR 898	Yes	Yes	Identical
Compliance with 21 CFR 890.5850 (IPF)	Yes	Yes	Identical
Housing Material	Delrin	Delrin	Identical
Output Specifications			
Waveform	Symmetrical Biphasic Waveform	Symmetrical Biphasic Waveform	Identical
Pulse Shape	Rectangular	Rectangular	Identical
Maximum output voltage (± 10%)	50V@500Ω 50V@2kΩ 50V@10kΩ	50V@500Ω 50V@2kΩ 50V@10kΩ	Identical
Maximum output current (± 10%)	100mA@500 Ω 25mA@2 kΩ 5mA@10 kΩ	100mA@500 Ω 25mA@2 kΩ 5mA@10 kΩ	Identical
Pulse Width (µs)	25 to 400 µs	25 to 400 µs	Identical

Device Trade Name	Subject Device **SIMON**	Predicate Device **K202079** **PHYSIQ**	Comment
Frequency (Hz)	3 to 200 Hz	3 to 200 Hz	Identical
Net Charge @ 500 ohms (µC/pulse)]	0µC @ 500Ω	0µC @ 500Ω	Identical
Maximum Phase Charge (µC)	40 µC @ 500Ω	40 µC @ 500Ω	Identical
Maximum Current Density (mA/cm2)	1.mA/cm² @ 500Ω	1.1 mA/cm² @ 500Ω	Almost identical, changes do not affect safety and effectiveness of the device. Specification is in compliance with IEC 60601-2-10 standard
Maximum Power Density (mW/cm2)]	6.35mW/cm² @500Ω	6.4mW/cm² @500Ω	Almost identical, changes do not affect safety and effectiveness of the device. Specification is in compliance with IEC 60601-2-10 standard
Burst Mode (i.e., pulse trains)	Yes:	Yes:	Identical

Device Trade Name	Subject Device **SIMON**	Predicate Device **K202079** **PHYSIQ**	Comment
a. Pulses per burst b. Bursts per second c. Burst duration (seconds) d. Duty Cycle [Line (b) x Line (c)]	a. 3 - 200 b. 1 c. 0.2-60 s d. Time on / off	a. 3 - 200 b. 1 c. 0.2-60 s d. Time on / off	
ON time	0.2 – 60 s	0.2 – 60 s	Identical
OFF time	0.5 - 60 s	0.5 - 60 s	Identical
Treatment Time (min) -	Up to 60 min	Up to 60 min	Identical
Output intensity levels	1 to 50	1 to 50	Identical

The DEKA SIMON device has a subset of the indications for use of the above mentioned predicate device, with same principle of operation and same performances.

Performance Data:

Electrical safety and electromagnetic compatibility (EMC)

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

- AAMI/ANSI ES60601-1- 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 60601-2-10 - Medical electrical equipment - Part 2-10: Particular requirements for basic safety and essential performance of nerve and muscle stimulators.

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"

Conclusion:

Based on the comparison of indications for use and the technological characteristics, we can conclude that the DEKA SIMON device is as safe, as effective, and performs as well as the legally marketed predicate device (K202079)

Additional Information:

None.