November 25, 2020

El. En. Electronic Engineering SPA
Paolo Peruzzi
Regulatory Affairs Manager
Via Baldanzese 17
Calenzano, FI 50041
Italy

Re: K202079
Trade/Device Name: Physiq
Regulation Number: 21 CFR 890.5850
Regulation Name: Powered Muscle Stimulator
Regulatory Class: Class II
Product Code: IPF, GZJ
Dated: August 28, 2020
Received: August 31, 2020

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,

Vivek Pinto, PhD
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K202079

Device Name
PHYSIQ

Indications for Use *(Describe)*
Intended Use:

The PHYSIQ device is intended in EMS mode 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

and in TENS mode for:

- Symptomatic relief and management of chronic, intractable pain
- Post-surgical acute pain
- Post-traumatic acute pain

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

Date: **November 27, 2020**
Submission number: **K202079**

Submitter:
El.En. S.p.A.
Via Baldanzese, 17
50041 Calenzano (FI), Italy

Contact:
Paolo Peruzzi
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Date Summary Prepared:
November 10, 2020

Device Trade Name:
PHYSIQ

Manufacturer:
DEKA M.E.L.A. srl
Via Baldanzese, 17
50041 Calenzano (FI), Italy

Common Name:
Electro Muscle Stimulator

Classification Name:
Powered Muscle Stimulator (IPF)
Stimulator, nerve, transcutaneous, for pain relief (GZJ)

Classification Number:
21 CFR 890.5850
21 CFR 890.5890

Predicate Devices:
The InMode System with Tone Applicator (K192249)

Device Description:
The PHYSIQ is a device provided with 4 handpieces by 2 electrodes each intended to employ EMS (Electrical Muscle Stimulation) and TENS (Transcutaneous Electrical Nerve Stimulation) technologies for various medical applications.

The PhysiQ consists of :

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

EMS or TENS treatment is enabled at the same time on all 4 handpieces. The operator can choose how many handpieces to use and leave the unused ones in the proper holder.

Through the handpieces the electrical energy is delivered to the patient, which repeatedly contracts muscles by passing electrical currents through electrodes on the affected body area.
During TENS treatments, PHYSIQ generates electrical pulses and transmits it to the electrodes which are in contact with the patient's skin. Consequently, the electrical pulses would then pass through the skin to the underlying peripheral nerves to aid in the blocking of pain signals traveling to the brain.
During EMS treatments, PHYSIQ generates electrical pulses and transmits it to the electrodes in contact with the patient skin, causing the muscle to expand and contract. It is used to relax muscle spasms, prevent or retard atrophy, maintain or increase range of motion, increase local blood circulation, re-educate muscle and provide immediate post-surgical stimulation of calf muscle to prevent venous thrombosis.
Handpieces are directly applied on the area to be treated, such as upper and lower back, abdomen, legs and arms.

The user interface allows to fully control the treatment parameters. The operator can manage Electro Muscle Stimulation (EMS) or Transcutaneous Electrical Nerve Stimulation (TENS) (OFF or ON from 1 to 50, with selection step of 1).
Treatment time can be changed regardless of the suggested one.

Intended Use:
The PHYSIQ device is intended in EMS mode 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

and in TENS mode for:

- Symptomatic relief and management of chronic, intractable pain
- Post-surgical acute pain

- Post-traumatic acute pain

Substantial equivalence discussion:

The PHYSIQ device is substantially equivalent to the The InMode System with Tone Applicator (K192249)

Device Trade Name	Subject Device **PHYSIQ**	Predicate Device **K192249 The InMode System with Tone Applicator**
Design	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.	The InMode System with Tone Applicator consists of an AC/DC power supply unit, 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 • Audio loudspeaker • 48V AC/DC power supply • Controller • Fans The System operates while connected to the Tone Applicator.
Mechanism of Action	Muscle contraction	Muscle contraction

Device Trade Name	Subject Device **PHYSIQ**	Predicate Device **K192249 The InMode System with Tone Applicator**
	by electrical pulsing	by electrical pulsing
Class, Product Code	Class II, IPF GZJ	Class II, IPF GZJ
Rx/OTC	Rx only	Rx only
Basic Unit Characteristics		
Components Console	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 Handpieces connected to the console via a cable.	The InMode System consists of the following components: • Console, including a power supply unit, controller and user interface including an LCD touch screen. • Tone Applicator connected to the console via a cable.
Dimensions Console [W x H x D] Applicator [L x D]	 34cm x 67cm x 90cm Handpiece 9cm x 9cm	 35cm x 35cm x 100cm Tone Applicator 12cm x 10cm
Weight: Console Applicator	 51.0 Kg Handpiece: 0.5 Kg	 20.0 Kg [44 lbs.] Tone: 0.22 Kg [0.5 lbs.]
Performance Specifications: Components Console	Main Line Frequency (nominal) 50-60Hz	Main Line Frequency (nominal) 50-60Hz

Device Trade Name	Subject Device **PHYSIQ**	Predicate Device **K192249 The InMode System with Tone Applicator**
	Input Voltage (nominal) 115-230VAC Input Current (rms) 9A max	Input Voltage (nominal) 100-240VAC Input Current (rms) 2A
Method of line current isolation	AC/DC isolation	Indipendent transformer isolated
Electrical Type	Type BF	Type BF
Patient Leakage Current - Normal Condition (μA)	<100uA patient leakage	<100uA patient leakage
Patient Leakage Current – Single Fault Condition (μA)	<500uA line leakage	<300uA line leakage
Number of output modes	2	2
Number of Output channels	4	2
Synchronous or alternating	Synchronous	Not Publicly Available
Method of Channel Isolation	Through AC/DC and transformers	Through transformers and isolators
Regulated Current or Regulated Voltage (output signals only)	Regulated voltage on all channels with current limit	Regulated voltage on all channels with current limit
Software/Firmware/Microprocessor Control	Yes	Yes
Automatic Overload Trip	Yes	Yes
Automatic No-Load Trip	Yes	Yes
Automatic Shut Off	Yes, On/off switch	Yes, On/off switch

Device Trade Name	Subject Device **PHYSIQ**	Predicate Device **K192249 The InMode System with Tone Applicator**
Patient Override Control	Yes	Yes
Indicator Display	Yes	Yes
On/Off Status	Yes	Yes
Battery	No battery	No battery
Voltage/Current level	Yes, voltage levels	Yes, voltage levels
Timer Range (minutes)	0-60 minutes	0-60 minutes
Compliance with 21 CFR 898	YES	Not Publicly Available
Compliance with 21 CFR 882.5890 (GZJ)	Yes	Yes
Compliance with 21 CFR 890.5850 (IPF)	Yes	Yes
Electrode area	11 cm^2	12 cm^2
Housing Material	Delrin	PC Makrolon 2458
Output Specifications		
EMS output mode		
Waveform	Symmetrical Biphasic Waveform	Symmetrical Biphasic Waveform
Pulse Shape	Rectangular	Rectangular
Maximum output voltage (± 10%)	50V@500Ω 50V@2kΩ 50V@10kΩ	56V@500Ω 56V@2kΩ 56V@10kΩ

Device Trade Name	Subject Device **PHYSIQ**	Predicate Device **K192249 The InMode System with Tone Applicator**
Maximum output current (± 10%)	100mA @500 Ω 25mA @2 kΩ 5mA @10 kΩ	112mA @500 Ω 28mA @2 kΩ 5.6mA @10 kΩ
Pulse Width (μs)	25 to 400 μs	20 to 400 μs
Frequency (Hz)	3 to 200 Hz	3 to 200 Hz
Net Charge @ 500 ohms (μC/pulse)]	0μC @ 500Ω	0μC @ 500Ω
Maximum Phase Charge (μC)	40 μC @ 500Ω	44.8 μC @ 500Ω
Maximum Current Density (mA/cm2)	1.1 mA/cm2 @ 500Ω Surface = 11cm²	1 mA/cm2 @ 500Ω Surface = 12cm²
Maximum Power Density (mW/cm2)]	6.4mW/cm2 @500Ω	55mW/cm2 @500Ω
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)]	Yes: a. 3 - 200 b. 1 c. 0.2-60 s d. Time on / off	Yes: a. 3 - 200 b. 1 c. 1-60 s d. Time on / off
ON time	0.2 – 60 s	1 – 60 s
OFF time	0.5 - 60 s	1 – 60 s
Treatment Time (min) -	Up to 60 min	Up to 60 min
Output intensity levels	1 to 50	1 to 50
TENS output mode		
Waveform	Symmetrical Biphasic Waveform	Symmetrical Biphasic Waveform
Pulse Shape	Rectangular	Rectangular
Maximum output voltage (± 10%)	35V@500Ω 35V@2kΩ	36V@500Ω 36V@2kΩ

Device Trade Name	Subject Device **PHYSIQ**	Predicate Device **K192249 The InMode System with Tone Applicator**
	35V@10kΩ	36V@10kΩ
Maximum output current (± 10%)	70mA@500 Ω 17.5mA@2 kΩ 3.5mA@10 kΩ	72mA@500 Ω 18mA@2 kΩ 3.6mA@10 kΩ
Pulse Width (μs)	25 to 400 μs	20 to 400 μs
Frequency (Hz)	3 to 200 Hz	3 to 200 Hz
Net Charge @ 500 ohms (μC/pulse)	0μC @ 500Ω	0μC @ 500Ω
Maximum Phase Charge (μC)	28 μC @ 500Ω	28.8 μC @ 500Ω
Maximum Current Density (mA/cm2)	0.81 mA/cm2 @500Ω Surface = 11cm²	0.65 mA/cm2 @500Ω Surface = 12cm²
Maximum Power Density [mW/cm2]	3.6 mW/cm2 @500Ω	22.7 mW/cm2 @500Ω
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)]	Yes: a. 3 - 200 b. 1 c. 0.2-60 s d. Time on / off	Yes: a. 3 - 200 b. 1 c. 1-60 s d. Time on / off
ON time	0.2 – 60 s	1 – 60 s
OFF time	0.5 – 60 s	1 – 60 s
Treatment Time (min) -	Up to 60 min	Up to 60 min
Output intensity levels	1 to 50	1 to 50

The PHYSIQ device has the same indications for use as the above mentioned predicate device, with same principle of operation and similar performances.

Clinical Performance Data:

None

Non-Clinical Performance Data:

Bench testing was conducted to demonstrate that the PHYSIQ performs as expected under anticipated conditions of use and to verify that the device performance meets the device design requirements. The device was tested for validation of output waveform, basic unit characteristics, and output specifications.

The bench testing results demonstrated that the device performs as expected under anticipated conditions of use.

The biocompatibility of the PHYSIQ handpieces was justified using a biocompatibility assessment performed on representative test article.

The following biocompatibility tests were performed as part of the biocompatibility assessment:

Test Summary Conclusions

Test	Test Summary	Conclusions
Cytotocity by elution test	Qualitative and quantitavie evalution showed no cytotoxic effect	Not Cytotoxic
In vivo skin irritation test in albino rabbit – single exposure	Animals exposed to the test article showed no local toxic effects	Not irritant
Delayed Hypersensitivity Test (GPMT)	Animals exposed to the test article showed no sensitizing effects	Not sensitizing

In addition, the PHYSIQ has been tested and found in compliance with 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.
- IEC 60601-1-6 - Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Usability.

Conclusion:

Based on the comparison to the predicate device and on the outcome of non-clinical performance tests carried out, demonstrating that the proposed device is as safe, as effective, and performs as well as the legally marketed predicate device, we can conclude that the PHYSIQ device is substantially equivalent to the predicate device.