December 17, 2019

InMode Ltd.
% Amit Goren
Regulatory Manager
A. Stein - Regulatory Affairs Consulting Ltd.
20 Hata'as Str., Suite 102
Kfar Saba, 4442520 Israel

Re: K192249
Trade/Device Name: InMode System with Tone Applicator
Regulation Number: 21 CFR 890.5850
Regulation Name: Powered Muscle Stimulator
Regulatory Class: Class II
Product Code: IPF, GZJ
Dated: September 16, 2019
Received: September 18, 2019

Dear Amit Goren:

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,

For Vivek Pinto, Ph.D.
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)*
K192249

Device Name
InMode System with Tone Applicator

Indications for Use *(Describe)*
The InMode System with Tone Applicator is used 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

THE INMODE SYSTEM WITH TONE APPLICATOR

510(k) Number K192249

Applicant Name:

Company Name: InMode Ltd.
Address: Tabor Building, Shaar Yokneam
Yokneam 20692
Israel
Tel: +972-4-9097470
Fax: +972-4-9097471
E-mail: amit@asteinrac.com

Contact Person:

Official Correspondent: Amit Goren
Company Name: A. Stein – Regulatory Affairs Consulting Ltd.
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Kfar Saba 4442520 Israel
Tel: + 972-9-7670002
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E-mail: amit@asteinrac.com

Date Prepared: December 11, 2019

Trade Name: The InMode System with Tone Applicator

Classification Name: Powered Muscle Stimulator

Common Name: Powered Muscle Stimulator

Regulation Number: 890.5850 & 882.5890

Product Code: IPF & GZJ

Classification: Class II Medical Device

Predicate Device:

The InMode System with Tone Applicator is substantially equivalent to the following predicate device.

Predicate	Manufacturer	510(k) No.
Vectra Neo Clinical Therapy System	DJO, LLC	K132284

Device Description:

The InMode System in combination with Tone Applicator (manufactured by InMode Ltd.), is a versatile device intended to employ EMS (Electrical Muscle Stimulation) and TENS (Transcutaneous Electrical Nerve Stimulation) technologies for various medical applications. 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.

Following are The InMode System with Tone Applicator specifications:

Main Line Frequency (nominal):	50-60 Hz
Input Voltage (nominal):	100-240 VAC
Input Current (rms)	2A
Dimension: Console [W x H x D] Applicator [L x D]	 35cm W x 35cm D x 100cm H [18.2'' W x 18.2'' D x 40'' H] Tone Applicator 12cm L x 10cm D [4.7'' L x 4'' D]
Weight Console:	20 Kg (44 lbs)
Tone Applicator Weight:	0.22 Kg [0.5 lbs.]
Platform modules AC/DC power supply	Converts AC input voltage (90-264Vac) to 48Vdc, 300W
Waveform	Symmetrical Biphasic
Shape	Rectangular
Intensity (output Voltage)	Up to 50 intensity level (=54 Vpeak)
Pulse Width Tone Applicator	 20 to 400 μS
Frequency Tone Applicator	 3 to 200 Hz

Intended Use/Indication for Use:

The InMode System with Tone Applicator is used 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

Performance Standards:

The InMode System with Tone Applicator has been tested and complies with the following FDA recognized consensus standards:

- IEC 60601-1: Medical Electrical Equipment - Part 1: General Requirements For Basic Safety And Essential Performance ES60601-1:2005/(R)2012 And A1:2012,C1:2009/(R)2012 And A2:2010/(R)2012 (Consolidated Text) Medical Electrical Equipment - Part 1: General Requirements For Basic Safety And Essential Performance (IEC 60601-1:2005 Edition 3rd, MOD)
- Appendix 6-Clause 3.2.2.1 and Clause 3.2.2.2 from ANSI/AAMI NS4:2013/(R)2017

- IEC 60601-1-2: Medical electrical equipment; Part 1-2: Collateral Standard: Electromagnetic compatibility - Requirements and tests, Edition 4.0 (2014). Environment of intended uses: Professional Healthcare Facility Environment

- IEC 60601-2-10 Medical electrical equipment Part 2: Particular requirements for the basic safety and essential performance of nerve and muscle stimulators (IEC 60601-2-10 Edition 2.1 2016-04) IEC 60601-2-10: 2012, AMD1:2016 for use in conjunction with IEC 60601-1:2005/AMD1:2016

- IEC 60601-1-6 Medical Electrical Equipment - Part 1-6: General Requirements For Basic Safety And Essential Performance - Collateral Standard: Usability (60601-1-6 Edition 3.1 2013-10, AMD1:2013)

Non-Clinical (Bench) Performance Data:

Bench testing was conducted to demonstrate that the InMode System with Tone Applicator 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 Tone Applicator outer components (handle and electrodes)

was justified using a biocompatibility assessment performed on a family of related products and by scientific evidence. The following biocompatibility tests were performed as part of the biocompatibility assessment:

Test	Test Summary	Conclusions
Cytotoxicity Study Using the ISO Elution Method	The test article extract showed no evidence of causing cell lysis or toxicity	Non-toxic
ISO Acute Systemic Toxicity Study in Mice	The test article extracts showed no evidence of causing delayed dermal contact sensitization in the guinea pig.	Non-toxic
ISO Guinea Pig Maximization Sensitization Test	There was no mortality or evidence of systemic toxicity from the extracts injected into mice	No irritation/ sensitization

Pre-Clinical (Animal) Performance Data:

Non-Applicable.

Clinical Performance Data:

Non-Applicable.

Substantial Equivalence:

The below table summarizes the main comparison aspects between the InMode System with Tone Applicators and the proposed predicate device.

Characteristic	Subject Device	Predicate
510(k) file No.	K192249	K132284
Device Name	InMode System with Tone Applicator	Vectra Neo Clinical Therapy System
Manufacturer	InMode Ltd.	DJO, LLC
Class, Product Code.	Class II IPF GZJ	Class II IPF, GZJ IMG, HCC, GZI

Characteristic	**Subject Device**	**Predicate**
510(k) file No.	K192249	K132284
Device Name	InMode System with Tone Applicator	Vectra Neo Clinical Therapy System
Manufacturer	InMode Ltd.	DJO, LLC
		LIH, ILY
Design:	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.	The Vectra Neo Vlinical Therapy System consists of an AC/DC power supply unit, controller and user interface including color display. The delivery of the electrical energy is controlled by a Start/Stop button positioned on the front panel.
Mechanism of Action	Muscle contraction by electrical pulsing.	Idem
Components Console	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.	Vectra Neo Clinical Therapy System consists of the following components: • Console, including a power supply unit, controller and user interface including an LCD touch screen. • Several types of applicators for different

Characteristic	**Subject Device**	**Predicate**
510(k) file No.	K192249	K132284
Device Name	InMode System with Tone Applicator	Vectra Neo Clinical Therapy System
Manufacturer	InMode Ltd.	DJO, LLC
		indications (EMS, Ultrasound, EMG & Laser) connected to the console via a cable.
Dimension Console [W x H x D] Applicator [L x D]	35cm W x 35cm D x 100cm H [18.2'' W x 18.2'' D x 40'' H] Tone Applicator 12cm L x 10cm D [4.7'' L x 4'' D]	not publicly available
Weight Console Weight applicator	20.0 Kg [44 lbs.] Tone: 0.22 Kg [0.5 lbs.]	not publicly available
Performance Specifications: Components Console	Main Line Frequency (nominal) 50-60Hz Input Voltage (nominal) 100-240VAC Input Current (rms) 2A	not publicly available
Method of Line Current Isolation	Independent transformer isolated	not publicly available
Electrical Type	Type BF	not publicly available
Patient Leakage Current - Normal Condition (μA)	<100uA patient leakage	not publicly available
Patient Leakage Current - Single Fault Condition (μA)	<300uA line leakage	not publicly available
Number of Output Modes	2	not publicly available
Number of Output Channels	2	not publicly available

Characteristic	**Subject Device**	**Predicate**
510(k) file No.	K192249	K132284
Device Name	InMode System with Tone Applicator	Vectra Neo Clinical Therapy System
Manufacturer	InMode Ltd.	DJO, LLC
Synchronous or Alternating	See Output Specifications Below	not publicly available
Method of Channel Isolation	Through transformers and isolators	not publicly available
Regulated Current or Regulated Voltage (output signals only)	Regulated voltage on all channels With current limit	not publicly available
Software/Firmware/Microprocessor Control	Yes	not publicly available
Automatic Overload Trip	Yes	not publicly available
Automatic No-Load Trip	Yes	not publicly available
Automatic Shut Off	Yes, On/off switch	not publicly available
Patient Override Control	Yes	not publicly available
Indicator Display	Yes	not publicly available
On/Off Status	Yes	not publicly available
Battery	No battery	not publicly available
Voltage/Current level	Yes, voltage levels	not publicly available
Timer Range (Minutes)	0-60 [minutes]	not publicly available
Compliance with 21 CFR 890.5850 (IPF)	Yes	not publicly available
Compliance with 21 CFR 882.5890 (GZJ)	Yes	not publicly available
Applicator Name	Tone Applicator	Vectra Neo Clinical Therapy System Applicator

Characteristic	**Subject Device**	**Predicate**
510(k) file No.	K192249	K132284
Device Name	InMode System with Tone Applicator	Vectra Neo Clinical Therapy System
Manufacturer	InMode Ltd.	DJO, LLC
EMS Output Mode		
Output Specifications: Waveform	Symmetrical Biphasic Waveform	not publicly available
Pulse Shape	Rectangular	not publicly available
Maximum Output Voltage (± 10%)	56V @500Ω	not publicly available
	56V @2 kΩ	not publicly available
	56V @10kΩ	not publicly available
Maximum Output Current (± 10%)	112 mA @ 500 Ω	not publicly available
	28 mA @ 2 kΩ	not publicly available
	5.6 mA @ 10 kΩ	not publicly available
Pulse Width (µsec.) - The output active positive pulse width	20 to 400 [µs]	not publicly available
Frequency (Hz)	3 to 200 [Hz]	not publicly available
Net Charge @ 500 ohms [µC/pulse]	0 [µC] @ 500Ω	not publicly available
Maximum Phase Charge [µC]	44.8 [µC] @ 500Ω	not publicly available
Maximum Current Density [mA/cm2]	1 [mA/cm2] Surface = 12cm²	not publicly available
Maximum Power Density [mW/cm2]	55[mW/cm2] @500Ω	not publicly available
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. 1-60 sec d. Time on / off	not publicly available
On Time (sec.)	1 – 60 [sec]	not publicly available
Off Time (sec.)	1 – 60 [sec]	not publicly available
Treatment Time (min) - the time limit that will put the system in STOP state	Up to 60 min.	not publicly available

Characteristic	**Subject Device**	**Predicate**
510(k) file No.	K192249	K132284
Device Name	InMode System with Tone Applicator	Vectra Neo Clinical Therapy System
Manufacturer	InMode Ltd.	DJO, LLC
Level - The output intensity level	1 to 50 (5-54v)	
TENS Output Mode		
Output Specifications: Waveform	Symmetrical Biphasic Waveform	not publicly available
Pulse Shape	Rectangular	not publicly available
Maximum Output Voltage (± 10%)	36V @500Ω	not publicly available
	36V @2 kΩ	not publicly available
	36V @10kΩ	not publicly available
Maximum Output Current (± 10%)	72 mA @ 500 Ω	not publicly available
	18 mA @ 2 kΩ	not publicly available
	3.6 mA @ 10 kΩ	not publicly available
Pulse Width (µsec.) - The output active positive pulse width	20 to 400 [µs]	not publicly available
Frequency (Hz)	3 to 200 [Hz]	not publicly available
Net Charge @ 500 ohms [µC/pulse]	0 [µC] @ 500Ω	not publicly available
Maximum Phase Charge [µC]	28.8 [µC] @ 500Ω	not publicly available
Maximum Current Density [mA/cm2]	0.65 [mA/cm2] Surface = 12cm²	not publicly available
Maximum Power Density [mW/cm2]	22.7 [mW/cm2] @500Ω	not publicly available
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. 1 – 60 sec d. Time on / off	not publicly available
On Time (sec.)	1 – 60 [sec]	not publicly available
Off Time (sec.)	1 – 60 [sec]	not publicly available

Characteristic	**Subject Device**	**Predicate**
510(k) file No.	K192249	K132284
Device Name	InMode System with Tone Applicator	Vectra Neo Clinical Therapy System
Manufacturer	InMode Ltd.	DJO, LLC
Treatment Time (min) - the time limit that will put the system in STOP state Level - The output intensity level	Up to 60 min. 1 to 50 (5-54v)	not publicly available
Electrode area	12 cm^2	not publicly available
Housing Material	PC Makrolon 2458	not publicly available

The subject device and predicate device utilize the same technology, for the same indication for use, and with similar design specifications. The device emits electrical signals with similar power and current densities, pulse characteristics, and bear similar system components to its predicate device such as; user interface, and hardware components. All of the subject device performance specifications are in range or equal to those of its predicate device. The minor differences in technical specifications should not alter the device safety and effectiveness. Furthermore, the subject device had underwent the required performance testing and validation testing and demonstrates its conformance with device design requirements and with applicable standards. The safety features and compliance with safety standards of the subject device are similar to the safety features and compliance with safety standards of the predicate device. All user-contacting materials were tested for biocompatibility and found to comply with the ISO 10993-1 standard. Furthermore, the design and development phases of the subject device were validated throughout a set of performance tests, including software validation testing, electrical and mechanical safety testing according to IEC 60601-1 standard, electromagnetic compatibility testing according to IEC 60601-1-2 standard, safety and essential performance of nerve and muscle stimulators testing according to IEC 60601-2-10 standard, and bench performance tests. All in all, these performance tests demonstrated that the device specifications meet the system requirements and do not raise new safety or effectiveness concerns.

Consequently, it can be concluded that the InMode System with the Tone Applicator is substantially equivalent to its predicate device and can be sold in the US market.

Conclusions:

Based on the comparison to the predicate device and on the non-clinical performance testing results demonstrating that The InMode System with Tone Applicator is as safe and effective as the predicate device, it can be concluded that The InMode System with Tone Applicator is substantially equivalent to the predicate device; the Vectra Neo Clinical Therapy System cleared under 510(k) K132284, and therefore, may be legally marketed in the USA.