May 5, 2020

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

Re: K200293
Trade/Device Name: InMode System with vTone Applicator
Regulation Number: 21 CFR§ 876.5320
Regulation Name: Nonimplanted electrical continence device
Regulatory Class: II
Product Code: KPI
Dated: January 30, 2020
Received: February 5, 2020

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,

Purva Pandya
Acting Assistant Director
DHT3B: Division of Reproductive,
Gynecology and Urology Devices
OHT3: Office of Gastrorenal, ObGyn,
General Hospital and Urology 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)*
K200293

Device Name
InMode System with vTone Applicator

Indications for Use *(Describe)*
The InMode System with the vTone Applicator is intended to provide electrical stimulation and neuromuscular re-education for the purpose of rehabilitation of weak pelvic floor muscles for the treatment of stress, urge, and mixed urinary incontinence in women.

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 THE VTONE APPLICATOR

510(k) Number K200293

Applicant Name:

Company Name: InMode MD Ltd.
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Israel
Tel: +972-4-9097470
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E-mail: amit@asteinrac.com

Date Prepared: April 21, 2020

Trade Name: The InMode System with vTone Applicator

Classification Name: CFR Classification section 876.5320;
(Product code: KPI)
Nonimplanted Electrical Continence Device

Classification: Class II Medical Device

Predicate Device:
The InMode System with vTone Applicator is substantially equivalent to the following predicate device.

Predicate	Manufacturer	510(k) No.
Kegel8 device	Mantra International (HK) Ltd	K081480

Device Description:

The InMode System is a computerized device intended to provide electrical stimulation and neuromuscular reeducation for the purpose of rehabilitation of weak pelvic floor muscles for the treatment of stress, urge, and mixed urinary incontinence in women. . The System consists of an AC/DC power supply unit, controller and user interface including an LCD touch screen. The single use vTone Applicator is connected to the console via pulse generator adaptor.

The delivery of the electrical energy is controlled by a Start/Stop button positioned on the LCD screen.

The System emits an electrical signal of rectangular bi-phasic wave, and allows selecting intensity level of stimulation pulses from 1 to 50 intensity levels (equivalent to 5-54V). The system pulse width ranges from 50 to 450μsec.

The system pulse frequency ranges from 3 to 100Hz. In addition, the device emits the pulses in bursts of 1-60 sec, with a succeeding relaxation time of 1-60 sec, depending on the intensity level chosen by the user.

The System supports the following components:

- LCD display touch screen
- Audio loudspeaker
- 48V AC/DC power supply
- Controller
- Fans

The System operates while connected to the following applicator:

- vTone Applicator

Following are The InMode System with vTone Applicator specifications:

Main Line Frequency (nominal):	50-60 Hz
Input Voltage (nominal):	100-240 VAC
Input Current (rms)	2A
Dimensions: Console [W x H x D] vTone Applicator	 35cm W x 35cm D x 100cm H [18.2'' W x 18.2'' D x 40'' H] 8.8cm L x 2.8cm D

[L x D]	[3.5'' L x 1.1'' D]
Console Weight:	20 Kg (44 lbs)
vTone Applicator Weight:	0.11 Kg [0.25 lbs.]
vTone electrode material	Chrome coated plastic
vTone electrode size	9.58cm2
Platform modules AC/DC power supply	Converts AC input voltage (100-240VAC) to 48Vdc, 300W
Waveform	Biphasic
Shape	Rectangular
Intensity (output Voltage)	Up to 50 intensity level (=54 Vpeak)
Pulse Width	50 to 450 µsec
Frequency	3 to 100 Hz

Intended Use/Indication for Use:

The InMode System with the vTone Applicator is intended to provide electrical stimulation and neuromuscular re-education for the purpose of rehabilitation of weak pelvic floor muscles for the treatment of stress, urge, and mixed urinary incontinence in women.

Performance Standards:

The InMode System with vTone 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)
- 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 vTone 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 vTone Applicator outer components (handle and electrodes) was verified in a set of Biocompatibility Tests in accordance with the Biocompatibility classification set forth in ISO 10993-1:2018 and in compliance with the FDA Guidance Document on Medical Device Biocompatibility; "*Use of International Standard ISO*

10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process" Issued June 16, 2016.

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
ISO Vaginal Irritation sensitization in rabbit	The test article extract was considered a nonirritant to vaginal tissue of the rabbit	No irritation

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 vTone Applicator and the proposed predicate devices; The InMode System with the vTone Applicator is substantially equivalent to the previously FDA cleared Kegel 8 device (manufactured by Mantra International (HK) Ltd.), subject of 510(k) files no. K081480

Characteristic	**Subject Device**	**Predicate**
510(k) file No.	K200293	K081480
Device Name	InMode System with vTone Applicator	Kegel8
Equivalence	• Platform • vTone Applicator	• NA • Applicator
Manufacturer	InMode Ltd.	Mantra International (HK) Ltd
Prescription/OTC	Prescription	Prescription
Class, Product Code.	Class II KPI	Class II KPI
Indications for Use	The InMode System with the vTone Applicator is intended to provide electrical stimulation and neuromuscular re-education for the purpose of rehabilitation of weak pelvic floor muscles for the treatment of stress, urge, and mixed urinary incontinence in women	The 'Kegel8' Pelvic Muscle Trainer is intended to provide electrical stimulation and neuromuscular re-education for the purpose of rehabilitation of weak pelvic floor muscles for the treatment of stress urge and mixed urinary incontinence in women
Target Population	Adult Population which require treatment as specified in the indication for use	Idem
Anatomical Sites	Body parts requiring treatment as specified in the indication for use	Idem
Environment Used	Hospital or Clinic setting	Idem

Characteristic	Subject Device	Predicate
510(k) file No.	K200293	K081480
Device Name	InMode System with vTone Applicator	Kegel8
Equivalence	• Platform • vTone Applicator	• NA • Applicator
Manufacturer	InMode Ltd.	Mantra International (HK) Ltd
Design:	The InMode System with vTone 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 The System operates while connected to the following applicator: • vTone Applicator	The Kegel8 Pelvic Muscle Trainer is a small lightweight battery powered dual channel neuromuscular stimulation device supplied with a vaginal two electrode stimulation probe. The probe connects to the control unit by cable and plug.
- Mechanism of Action	Muscle contraction by electrical pulsing	Idem

Characteristic	Subject Device	Predicate
510(k) file No.	K200293	K081480
Device Name	InMode System with vTone Applicator	Kegel8
Equivalence	• Platform • vTone Applicator	• NA • Applicator
Manufacturer	InMode Ltd.	Mantra International (HK) Ltd
- 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. • vTone Applicator connected to the console via a cable.	The Kegel 8 treatment unit consists of the following components: • 9V PP3 Battery, user interface and LCD display • Probe and lead
Dimensions 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] 8.8cm L x 2.8cm D [3.5'' L x 1.1'' D]	 6.2cm W x 2.3cm D x 10.8cm H [2.4'' W x 0.9'' D x 4.25'' H] 8.7 cm L x 2.6 cm D [3.41'' L x 1.01'' D]
Weight Console Weight applicator	20.0 Kg [44 lbs.] 0.11 Kg [0.25 lbs.]	0.07 Kg without battery, 0.1KG with battery Not publicly available
Performance Specifications: System		
Power Source(s)	Main Line Frequency (nominal) 50-60Hz Input Voltage (nominal) 100-240VAC Input Current (rms) 2A	9V PP3
Method of Line Current Isolation	Independent transformer isolated	NA – Battery powered

Characteristic	**Subject Device**	**Predicate**
510(k) file No.	K200293	K081480
Device Name	InMode System with vTone Applicator	Kegel8
Equivalence	• Platform • vTone Applicator	• NA • Applicator
Manufacturer	InMode Ltd.	Mantra International (HK) Ltd
Electrical Type	Type BF	Type BF
Patient Leakage Current - Normal Condition (µA)	<100 µA	NA – Battery powered
Patient Leakage Current - Single Fault Condition (µA)	<500 µA	NA – Battery powered
Number of Output Modes	1	1
Number of Output Channels	1	2
- Synchronous or Alternating	NA – 1 Channel	Synchronous/ Alternating
- Method of Channel Isolation	NA – 1 Channel	Individually isolated circuits
Regulated Current or Regulated Voltage (output signals only)	Regulated Voltage with current limit	Regulated Current
Software/Firmware/Microprocessor Control	Yes	Yes
Automatic Overload Trip	No	Not publicly available
Automatic No-Load Trip	Yes	Not publicly available

Characteristic	**Subject Device**	**Predicate**
510(k) file No.	K200293	K081480
Device Name	InMode System with vTone Applicator	Kegel8
Equivalence	• Platform • vTone Applicator	• NA • Applicator
Manufacturer	InMode Ltd.	Mantra International (HK) Ltd
Automatic Shut Off	Yes, On/off switch	Yes
Patient Override Control	No	Not publicly available
Indicator Display: - On/Off Status - Battery - Voltage/Current level	 Yes No Yes	 Yes Yes Yes
Timer Range (Minutes)	Up to 60	Up to 90
Performance Specifications: Applicator		
Applicator Name	vTone Applicator	Kegel8 Applicator
Output Specifications: Waveform	Biphasic	Biphasic
Pulse Shape	Rectangular	Rectangular
Maximum Output Voltage (± 10%)	45V @500Ω	45V @ 500 Ω
	54V @2 kΩ	100V @ 2 kΩ
	54V @10kΩ	190V @ 10 kΩ
Maximum Output Current (± 10%)	90 mA @ 500 Ω current limit	90mA @ 500 Ω
	28 mA @ 2 kΩ	50mA @ 2 kΩ
	5.6 mA @ 10 kΩ	19mA @ 10 kΩ And thus, shuts off
Pulse Width (µsec.) - The output active positive pulse width	50 to 450 [µsec]	50 to 450 [µsec] Program dependent

Characteristic	**Subject Device**	**Predicate**
510(k) file No.	K200293	K081480
Device Name	InMode System with vTone Applicator	Kegel8
Equivalence	• Platform • vTone Applicator	• NA • Applicator
Manufacturer	InMode Ltd.	Mantra International (HK) Ltd
Pulse Frequency (Hz)	3 to100 [Hz]	2 to 100 Hz
Net Charge @ 500 ohms [µC/pulse]	0 [µC] @ 500Ω	0 [µC] @ 500Ω
Maximum Phase Charge [µC]	40.5 µC @ 500Ω	40.5 µC @ 500Ω
Maximum Current (RMS) Density [mA/cm^2]	9.4 [mA/cm^2]	14.1 [mA/cm^2]
Maximum Power Density [mW/cm^2]	33.8 [mW/cm^2]	57 [mW/cm^2] At maximum frequency of 100Hz, pulse width 450µS and current of 90mA PC Electrode area: 6.4 cm^2
On Time (sec.)	1-60	Not publicly available
Off Time (sec.)	1-60	Not publicly available
Standards Met	IEC 60601-1 for basic safety and essential performance IEC 60601-1-2 for electromagnetic compatibility IEC 60601-2-10 for performance	IEC 60601-1 for basic safety and essential performance IEC 60601-1-2 for electromagnetic compatibility
Compatibility with Environment and Other Devices	The InMode System is compliant with the IEC 60601-1-2 (EMC Safety) standard.	The kegel8 device is compliant with the IEC 60601-1-2 (EMC Safety) standard.

The InMode System with vTone Applicator indications for use are substantially equivalent to the indications for use of the predicate device. The predicate device possesses the same design, mode of action, mode of operation and similar technological specifications. The Kegel8 device (K081480) has a slightly different design to the subject device. It is operated by a 9V PP3 battery instead of an AC lined power as with the subject device. Apart from that, it bears similar design features to the subject device; main control unit that operates the system functions, user interface, pulse generator and a vaginal applicator with a pair of electrodes to emit the electrical currents as with the subject device. All of the subject device performance specifications are in range or equal to those of its predicate devices. 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 vTone Applicator is substantially equivalent to its predicate devices and can be sold in the US market.

Conclusions:

Based on the comparison to the predicate devices and on the non-clinical performance testing results demonstrating that The InMode System with vTone Applicator is as safe and effective as the predicate devices, it can be concluded that The InMode System with vTone Applicator is substantially equivalent to the predicate devices; the Kegel8 device cleared under 510(k) K081480 and therefore, may be legally marketed in the USA.