March 5, 2021

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

Re: K201285
Trade/Device Name: Evolve System with the Tone Applicator
Regulation Number: 21 CFR 890.5850
Regulation Name: Powered Muscle Stimulator
Regulatory Class: Class II
Product Code: IPF, GZJ
Dated: May 10, 2020
Received: May 13, 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,

Jitendra Virani
Acting 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.

510(k) Number *(if known)*
K201285

Device Name
EVOLVE System with the Tone Applicator

Indications for Use *(Describe)*
The EVOLVE System with the Tone Applicator is an electro-muscle and transcutaneous nerve stimulation device for the treatment of different body areas.

The EVOLVE System with Tone Applicator is designed to operate in two modes – EMS and TENS.

In EMS mode it is used for:
- Relaxation of muscle spasms
- Prevention or retardation of disuse atrophy
- Increasing local blood circulation
- Muscle re-education
- Maintaining or increasing range of motion
- Immediate post-surgical stimulation of calf muscles to prevent venous thrombosis

And in TENS mode is intended for
- Symptomatic relief and management of chronic, intractable pain
- Post-surgical acute pain
- Post-trauma 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 EVOLVE SYSTEM WITH THE TONE APPLICATOR

510(k) Number K201285

Applicant Name:
Company Name: InMode Ltd.
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Yokneam 20692
Israel
Tel: +972-4-9097470
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E-mail: amit@asteinrac.com

Date Prepared: February 11, 2021

Trade Name: EVOLVE System with the Tone Applicator

Classification Name: Powered muscle stimulator, Transcutaneous electrical nerve stimulator for pain relief

Regulation No.: 890.5850, 882.5890

Product Codes: IPF, GZJ

Classification: Class II Medical Device

Predicate Device:

The EVOLVE System with the Tone Applicator is substantially equivalent to the following main and reference predicate devices.

Manufacturer	Device	510(k) No.
Main Predicate		
InMode System with the Tone Applicator	InMode Ltd.	K192249
Reference Predicate		
The EVOLVE System	InMode Ltd.	K183450

Device Description:

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

The EVOLVE System with the Tone Applicator consists of an AC/DC power supply unit, controller and user interface including an LCD touch screen. The Tone Applicator is connected to the console via a cable, each of the subject device applicator units consist of a designated cable and of a connection port to be directly connected to one of the four connectors positioned on the rear side of the console. Up to four Tone Applicator units can be connected to the console simultaneously.
The delivery of the electrical energy is controlled by a Start/Stop button positioned on the LCD screen.

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 Tone Applicator.

Following are The EVOLVE System with the Tone Applicator specifications:

Main Line Frequency (nominal):	50-60 Hz
Input Voltage (nominal):	100-240 VAC
Input Current (rms)	4A
Dimension: Console [W x H x D] Applicator [L x D]	 46cm W x 46cm D x 100cm H [18.2'' W x 18.2'' D x 44'' H] Tone Applicator 12cm L x 10cm D [4.7'' L x 4'' D]
Weight Console:	33 Kg (73 lbs.)

Tone Applicator Weight:	0.22 Kg [0.5 lbs.]
Platform modules AC/DC power supply	Converts AC input voltage (100-240Vac) to 6Vdc
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 EVOLVE System with the Tone Applicator is an electro-muscle and transcutaneous nerve stimulation device for the treatment of different body areas.

The EVOLVE System with Tone Applicator is designed to operate in two modes – EMS and TENS.

In EMS mode it is used for:

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

And in TENS mode is intended for:

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

Performance Standards:

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

[Rec. Number 19-4] ANSI AAMI ES 60601-1:2005/(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
[Rec. Number 19-8] IEC 60601-1-2 Edition 4.0 2014-02 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
[Rec. Number 17-16] IEC 60601-2-10 Edition 2.1 2016-04 Medical Electrical Equipment - Part 2-10: Particular Requirements for The Basic Safety and Essential Performance of Nerve and Muscle Stimulators
[Rec. Number 5-89] IEC 60601-1-6 Edition 3.1 2013-10 Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability

Sterilization/Disinfection/Cleaning:

The cleaning and reprocessing instructions set forth in the device user manual for all of the reprocessed device Applicator components. The handle should be thoroughly cleaned by the user by using 70% alcohol absorbed pad for at least 30 sec. The user should carefully examine the applicator components prior to their assembly and usage for complete drying and for any visible damage.

The device user manual and device labels, provide users with the proper symbolling and instructions/warnings for safe and effective device use and for a safe discard of the single use components upon their usage.

All device materials in contact with the patient are biocompatible.

Non-Clinical (Bench) Performance Data:

Bench testing was conducted to demonstrate that the EVOLVE System with the 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.

Pre-Clinical (Animal) Performance Data:

Non-Applicable.

Clinical Performance Data:

Non-Applicable.

Substantial Equivalence:

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

Characteristic	**Subject Device**	**Predicate**
510(k) file No.	**K201285**	K192249
Device Name	EVOLVE System with the Tone Applicator	InMode System with the Tone Applicator
Manufacturer	InMode MD Ltd.	InMode MD Ltd.
Class, Product Code.	Class II IPF GZJ	Class II IPF, GZJ
Design:	The EVOLVE 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 supports the following components: • LCD display touch screen • Audio loudspeaker • 48V AC/DC power supply • Controller • The System operates while connected to the Tone Applicator.	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 supports the following components: • LCD display touch screen • Audio loudspeaker • 48V AC/DC power supply • Controller The System operates while connected to the Tone Applicator.
Mechanism of Action	Muscle contraction by electrical pulsing.	Muscle contraction by electrical pulsing.
Components Console	The EVOLVE System consists of the following components: • Console, including a power supply unit, controller and user interface including an LCD touch screen.	The InMode System consists of the following components: • Console, including a power supply unit, controller and user interface including an LCD touch screen.

Characteristic	Subject Device	Predicate
510(k) file No.	**K201285**	K192249
Device Name	EVOLVE System with the Tone Applicator	InMode System with the Tone Applicator
Manufacturer	InMode MD Ltd.	InMode MD Ltd.
	• Tone applicator with up to 4 units connected to the console via 4 designated cables and 4 designated connection ports.	• Tone applicator with up to 2 units connected to the console via a cable with splitter and a single connection port.
Dimension Console [W x H x D] Applicator [L x D]	46cm W x 46cm D x 100cm H [18.2'' W x 18.2'' D x 44'' H] Tone Applicator 12cm L x 10cm D [4.7'' L x 4'' 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 Weight applicator	33.0 Kg [73 lbs.] Tone: 0.22 Kg [0.5 lbs.]	20.0 Kg [44 lbs.] Tone: 0.22 Kg [0.5 lbs.]
Performance Specifications: Components Console	Main Line Frequency (nominal) 50-60Hz Input Voltage (nominal) 100-240VAC Input Current (rms) 4A	Main Line Frequency (nominal) 50-60Hz Input Voltage (nominal) 100-240VAC Input Current (rms) 2A
Method of Line Current Isolation	Independent transformer isolated	Independent 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)	<300uA line leakage	<300uA line leakage
Number of Output Modes	2	2
Number of Output Channels	2	2
Synchronous or Alternating	See Output Specifications Below	See Output Specifications Below
Method of Channel Isolation	Through transformers and isolators	Through transformers and isolators

Characteristic	**Subject Device**	**Predicate**
510(k) file No.	**K201285**	K192249
Device Name	EVOLVE System with the Tone Applicator	InMode System with the Tone Applicator
Manufacturer	InMode MD Ltd.	InMode MD Ltd.
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
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 890.5850 (IPF)	Yes	Yes
Compliance with 21 CFR 882.5890 (GZJ)	Yes	Yes
Applicator Name	Tone Applicator	Tone Applicator
EMS Output Mode		
Output Specifications: Waveform	Symmetrical Biphasic Waveform	Symmetrical Biphasic Waveform
Pulse Shape	Rectangular	Rectangular
Maximum Output Voltage (± 10%)	56V @500Ω	56V @500Ω
	56V @2 kΩ	56V @2 kΩ
	56V @10kΩ	56V @10kΩ
Maximum Output Current (± 10%)	92.86 mA @ 500 Ω	98.46 mA @ 500 Ω
	26.7 mA @ 2 kΩ	27.3 mA @ 2 kΩ
	5.4 mA @ 10 kΩ	5.4 mA @ 10 kΩ
Pulse Width (µsec.) - The output active positive pulse width	20 to 400 [µs]	20 to 400 [µs]
Frequency (Hz)	3 to 200 [Hz]	3 to 200 [Hz]
Net Charge @ 500 ohms [µC/pulse]	0 [µC] @ 500Ω	0 [µC] @ 500Ω

Characteristic	**Subject Device**	**Predicate**
510(k) file No.	**K201285**	K192249
Device Name	EVOLVE System with the Tone Applicator	InMode System with the Tone Applicator
Manufacturer	InMode MD Ltd.	InMode MD Ltd.
Maximum Phase Charge [µC]	43.2 [µC] @ 500Ω	43.2 [µC] @ 500Ω
Maximum Current Density [mA/cm^2]	0.72 [mA/cm^2] Surface = 12cm²	0.72 [mA/cm^2] Surface = 12cm²
Maximum Power Density [mW/cm^2]	55[mW/cm^2] @500Ω	55[mW/cm^2] @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. 1-60 sec d. Time on / off	Yes: a. 3 - 200 b. 1 c. 1-60 sec d. Time on / off
On Time (sec.)	1 – 60 [sec]	1 – 60 [sec]
Off Time (sec.)	1 – 60 [sec]	1 – 60 [sec]
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)	Up to 60 min. 1 to 50 (5-54v)
TENS Output Mode		
Output Specifications: Waveform	Symmetrical Biphasic Waveform	Symmetrical Biphasic Waveform
Pulse Shape	Rectangular	Rectangular
Maximum Output Voltage (± 10%)	36V @500Ω	36V @500Ω
	36V @2 kΩ	36V @2 kΩ
	36V @10kΩ	36V @10kΩ
Maximum Output Current (± 10%)	67.8 mA @ 500 Ω	72 mA @ 500 Ω
	17.7 mA @ 2 kΩ	18 mA @ 2 kΩ
	3.6 mA @ 10 kΩ	3.6 mA @ 10 kΩ
Pulse Width (µsec.) - The output active positive pulse width	20 to 400 [µs]	20 to 400 [µs]
Frequency (Hz)	3 to 200 [Hz]	3 to 200 [Hz]
Net Charge @ 500 ohms [µC/pulse]	0 [µC] @ 500Ω	0 [µC] @ 500Ω

Characteristic	**Subject Device**	**Predicate**
510(k) file No.	**K201285**	K192249
Device Name	EVOLVE System with the Tone Applicator	InMode System with the Tone Applicator
Manufacturer	InMode MD Ltd.	InMode MD Ltd.
Maximum Phase Charge [μC]	28.8 [μC] @ 500Ω	28.8 [μC] @ 500Ω
Maximum Current Density [mA/cm2]	0.48 [mA/cm2] Surface = 12cm²	0.65 [mA/cm2] Surface = 12cm²
Maximum Power Density [mW/cm2]	17.3 [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. 1 – 60 sec d. Time on / off	Yes: a. 3 - 200 b. 1 c. 1 – 60 sec d. Time on / off
On Time (sec.)	1 – 60 [sec]	1 – 60 [sec]
Off Time (sec.)	1 – 60 [sec]	1 – 60 [sec]
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)	Up to 60 min. 1 to 50 (5-54v)
Electrode area	12 cm^2	12 cm^2
Housing Material	PC Makrolon 2458	PC Makrolon 2458

The EVOLVE System with the Tone Applicator is a versatile machine, offering potential users with EMS and TENS technology-based treatment methods for several medical indications. The subject device and predicate devices utilize the same technology, for the same indication for use, and with almost identical design specifications. The device emits electrical signals with identical power and current densities, pulse characteristics, and bear almost identical system components to its predicate devices such as; user interface, and hardware components. All of the subject device performance specifications are 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 EVOLVE 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 devices and on the non-clinical performance testing results demonstrating that the EVOLVE System with the Tone Applicator is as safe and effective as the predicate device, it can be concluded that The EVOLVE System with the Tone Applicator is substantially equivalent to the predicate device; InMode System with the Tone Applicator cleared under 510(k) K192249, and therefore may be legally marketed in the USA.