June 20, 2019

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

Re: K183450
Trade/Device Name: EmBody System
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting and Coagulation Device and Accessories
Regulatory Class: Class II
Product Code: PBX, ISA
Dated: May 20, 2019
Received: May 23, 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,

Long Chen, Ph.D.
Assistant Director
DHT4A: Division of General Surgery Devices
OHT4: Office of Surgical
and Infection Control 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)*
K183450

Device Name
EmBody System

Indications for Use *(Describe)*
The InMode EmBody System with its designated hand pieces is intended for the treatment of the following medical conditions;
The EmBodyPLUS hand piece is intended for the temporary relief of minor muscle aches and pain, temporary relief of muscle spasm, and temporary improvement of local blood circulation.

The EmBodyFX Hand piece is intended for the treatment of the following medical conditions using RF combined with massage:

- Relief of minor muscle aches and pain, relief of muscle spasm, temporary improvement of local blood circulation.
- Temporary reduction in the appearance of cellulite.

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

EMBODY SYSTEM DEVICE

510(k) Number K183450

Applicant Name:

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Date Prepared: June 18, 2019

Trade Name: EmBody System

Classification Name: CFR Classification section 878.4400;
(Product codes: ISA &PBX)

Classification: Class II Medical Device

Predicate Device:

The EmBody System is substantially equivalent to the following predicate devices.

Device Main Predicate	Manufacturer	510(k) No.
InMode WMbody	InMode MD Ltd.	K131362
InMode PLUS System	InMode MD Ltd.	K172302

Device Description:

The EmBody System with the EmBodyFX and EmBodyPlus Applicators is a free hand, easy to operate system, designed to deliver non-thermal RF energy to the skin and subdermal fat. The EmBodyFX Applicator also incorporates a mechanical vacuum skin massaging mechanism.

The EmBody System is employing RF technology for various aesthetic applications.

The device provides individual adjustment of non-thermal RF power and vacuum pulse duration to achieve maximum efficiency and safety for each patient. The design of the device applicators allows efficient treatment of large tissue surfaces.

The EmBody System consists of an AC/DC power supply unit, two RF generators, controller and user interface including an LCD touch screen. The System RF non-invasive applicators are connected to the console via a cable. The delivery of the RF Energy is controlled by a Start/Stop button located on the LCD screen.

The EmBody System operates while connected to any of the following Applicators:

- EmBodyFX (Up to Six units connected simultaneously) or;
- EmBodyPlus (Up to Eight units connected simultaneously)

Each applicator unit is connected to the main console via a designated cable and a connection port. The applicator units are adjusted to the patient body using a designated belt set.

Following are the EmBody System specifications:

Main Line Frequency (nominal):	50-60 Hz
Input Voltage (nominal):	100-240 VAC
Dimension:	46cm W x 46cm D x 100cm H (18.2'' W x 18.2'' D x 44'' H)
System Weight:	20 Kg (44 lbs)
EMBodyPlus Applicator Weight:	0.17 Kg (0.375lb)
EMBodyFX Applicator Weight:	0.9 Kg (2.0lb)
Maximal RF Output Power:	50 Watt
RF Output Frequency:	1[MHz] ± 2%
Vacuum (available in EMBodyFX Applicator only):	200-500 mbar (Automatically controlled)

Intended Use/Indication for Use:

The EmBody System with its designated applicators is intended for the treatment of the following medical conditions;

The EmBodyPlus Applicator is intended for the temporary relief of minor muscle aches and pain, temporary relief of muscle spasm, and temporary improvement of local blood circulation

The EmBodyFX Applicator is intended for the treatment of the following medical conditions using RF combined with massage:

- Relief of' minor muscle aches and pain, relief of muscle spasm, temporary improvement of local blood circulation.
- Temporary reduction in the appearance of cellulite.

Performance Standards:

The EmBody System 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 (2005 +Am.1 2012, 3rd Ed.).
• IEC 60601-1-2 Medical electrical equipment Part 1-2: Collateral Standard: Electromagnetic compatibility -Requirements and tests (2014, 4th Ed.).
• IEC 60601-1-6 Medical Electrical Equipment Part 1-6: General requirements for safety – Collateral Standard: Usability (2010 + A1:2013, Ed. 3.1).
• IEC 60601-2-2 Medical Electrical Equipment Part 2-2: Particular requirements for the basic safety and essential performance of high frequency surgical equipment and high frequency surgical accessories (2017, 6th Ed.).
• IEC 62304 Medical device software: Software life-cycle processes (2006, 1st Ed. + A1:2015).

Sterilization/Disinfection/Cleaning/Shelf Life:

The device EmBodyFX and EmBodyPlus Applicators are intended for multiple use and therefore must be cleaned according to the instructions provided in the device Instructions for Use. The device belt set is intended for single use and should be discarded upon use completion.

There are no sterilized parts or accessories involved with this device.

The shelf life of the EmBody System console is 5 years and the shelf life of the EmBody Applicator components is 2 years.

Non-Clinical (Bench) Performance Data:

A comparative bench test was performed utilizing the EMBody System with the EMBodyFX and EMBodyPlus Applicators and the respective predicate devices; the InMode WMBody and InMode Plus to evaluate the thermal effect on human volunteers. Both the subject device and predicate devices were operated using the same performance specifications according to the devices' operation recommendations. The study results showed of similar thermal effect for both the subject and predicate devices indicating on equivalent mechanism of operation.

Pre-Clinical (Animal) Performance Data:

The EmBody System with the EmBodyFX and EmBodyPlus Applicators was evaluated for its thermal effect in an *ex-vivo* animal study model. The device safety assessment included tissue vitality evaluation and tissue temperature profiling following a single treatment with either the EmBodyPlus or EmBodyFX Applicators on porcine tissue. The device applicators were operated in different power outputs for the recommended treatment time. The study results revealed no signs of tissue necrosis in all of the animal tissues treated with the device applicators in all power levels. The measured temperature on tissue surface was around 43^0C and lower in deeper tissue layers following the treatment with the device applicators in all power levels.

Clinical Performance Data:

The EmBody System with the EmBodyFX and EmBodyPlus Applicators was further evaluated for its safe performance on thirty eligible human subject participants with different age, gender, and Fitzpatrick skin types.

The study consisted of a single treatment followed by immediate photography and thermal measurements of the treatment area per each applicator treatment. Skin

observation was done immediately and 24h post treatment and was extended up to 48h following treatment to assess possible skin transient response. Subjects were treated on their abdomen, back, arms and thighs with either the EmBodyPlus or EmBodyFX Applicator. Treatment included a maximal number of applicator units according to area size, utilizing maximal RF power setting (50W), at the highest cut-off temperature value (43^0C).

The study results clearly show the safe use of the EmBody System with the EmBodyPlus and the EmBodyFX Applicators for its intended use while utilized in accordance with the device operator manual treatment instructions. The temperature measurements along with the skin observation for adverse events show that the treatment methodology of both EmBody device Applicators contribute for the same thermal outcomes obtained by using the respective predicate devices for the same intended use. The safe use of the EmBody device applicators was shown on all potential end-users with different age, gender and skin type and on all potential treatment body areas. No adverse events were reported in this study and the skin thermal profile showed a desirable temperature level of around 43^0C. Most of the subjects endured the maximal treatment parameters with mild to moderate discomfort levels. The device safety was shown using the device applicators with the maximal performance specifications applied. Additionally, lower performance specifications that were applied on subjects with low tolerance to maximal performance parameters showed of similar safety outcomes.

Substantial Equivalence:

The below table summarizes the main comparison aspects between the EMBody System and its proposed predicate devices; the InMode PLUS (FDA cleared in K172302) and InMode WMBody (FDA cleared in K131362).

Characteristic	**Subject Device**	**Main Predicate**	**Main Predicate**
510(k) file No.	**–**	**K131362**	**K172302**
Device Name	**EmBody System**	**InMode WMBody**	**InMode PLUS System**
Manufacturer	**InMode MD Ltd.**	**InMode MD Ltd.**	**InMode MD Ltd.**
Product Code, Class	ISA PBX Class II	ISA NUV Class II	ISA PBX Class II
Energy Used / Delivered	RF energy,	RF energy	RF energy
Physical specifications: Dimensions	Dimensions: W*D*H 18.2 x 18.2 x 40 in / 46 x 46 x 100 cm	Dimensions: W*D*H 14.2 x 14.2 x 40 in / 36 x 36 x 100 cm	Dimensions: W*D*H 18.2 x18.2 x40 in / 46 x 46 x 100cm

Characteristic	**Subject Device**	**Main Predicate**	**Main Predicate**
510(k) file No.	**—**	**K131362**	**K172302**
Device Name	**EmBody System**	**InMode WMBody**	**InMode PLUS System**
Manufacturer	**InMode MD Ltd.**	**InMode MD Ltd.**	**InMode MD Ltd.**
Weight Console Weight Hand pieces	Weight: 20 Kg / 44 lbs EmBodyPLUS Hand piece 0.17kg [0.375lb] EmBodyFX Hand piece 0.90kg [2.00lb]	Weight: 30 Kg / 66 lbs WMBody HP: 0.90 Kg [2.00 lbs.]	Weight: 30 Kg / 66 lbs. PLUS Applicator 0.170 Kg [0.352 lbs]
Performance Specifications: Main Line Frequency (nominal) Input Voltage (nominal) Input Current (rms) RF Frequency: Vacuum: RF electrical power: Pulse duration: Cut off Temperature:	 50-60Hz 100-240VAC 4A 1 MHz 200-500 mbar Up to 50 watts EMBodyPlus Applicator: 2-7 seconds EMBodyFX Applicator: 2 seconds 35-43^{0}C	 50-60 Hz 100-240VAC 2A 1 MHz 200-500 mbar Up to 50 watts 2-7 seconds 35-43^{0}C	 50-60 Hz 100-240V 2A 1 MHz Up to 50 watts Pulse duration mode: Continuous (during movement within target area) or Pulsed (maximal pulse duration: 30sec) 35-43^{0}C
Standards Met	IEC 60601-1 IEC 60601-1-2 IEC60601-2-2	IEC 60601-1 IEC 60601-1-2 IEC 60601-2-2	IEC 60601-1 IEC 60601-1-2 IEC 60601-2-2

The device classification and indications for use of the EmBody System are substantially equivalent to the device classification and indications for use of the predicate devices.

The technological characteristics of the subject device is based and that of the predicate devices. The EMBody System comprise similar platform components; AC/DC power supply unit, RF generators, controller and user interface including an LCD touch screen and similar applicators; EMBodyFX equivalent to the InMode WMBody applicator and EMBodyPlus equivalent to the InMode PLUS applicator. The EMBody System design mainly differentiate from its predicate devices with the option to perform a free hand

treatment using multiple applicator units, operated sequentially. The device is provided with up to six units of EMBodyFX and up to eight units of EMBodyPlus applicators. With this design change, the applicators' performance specifications, mainly the RF frequency and electrical power, pulse duration and vacuum pressure, were left unchanged, but the treatment technique has been modified to provide the same performance outcomes to the target area; warm heating of the skin and subdermal layers by non-thermal RF energy. In order to support this design change, a few platform modifications were made including an additional RF generator to support the multi applicators functionality and an upgrade in system software and hardware components to support the aforementioned change. The EMBody System is backed up with the safety features as applied in the predicate device systems. The EMBody System was tested and complies with the safety and EMC standards as requested for RF technology-based devices. The EMBody System with the EMBodyFX and EMBodyPlus Applicators was further evaluated for its safe performance in *ex-vivo* animal study and in a human clinical study. The results of these studies showed that the EmBody System is safe for us as intended and that the minor design differences between the subject and predicate device, mainly in the treatment methodology, do not raise any new safety or effectiveness concerns.

Consequently, it can be concluded that the EmBody System is substantially equivalent to the InMode WMbody and to the InMode PLUS System predicate devices, FDA cleared under 510(k) file no. K131362 and K172302, respectively.

Conclusions:

Based on the comparison to the predicate devices and on the non-clinical and clinical performance testing results demonstrating that the EmBody System is as safe and effective as the predicate devices, it can be concluded that the EmBody System is substantially equivalent to the predicate devices and therefore, may be legally marketed in the USA.