July 12, 2021

InMode MD Ltd.
% Amit Goren
Regulatory Consultant
A. Stein -Regulatory Affairs Consulting Ltd.
18 Hata'as Str., Suite 21
Kfar Saba, 4442518
Israel

Re: K210492
Trade/Device Name: InMode RF Pro System
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting and Coagulation Device and Accessories
Regulatory Class: Class II
Product Code: GEI, PBX, ISA, NUV
Dated: February 9, 2021
Received: June 10, 2021

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K210492

Device Name
InMode RF Pro System

Indications for Use *(Describe)*
The InMode RF Pro System with the Non-invasive Applicators employs RF energy for various applications:

• i-Forma, Forma (Plus), Plus (Plus Plus) and Plus90 for relief of minor muscle aches and pain, relief of muscle spasm, and temporary improvement of local blood circulation.

• WMface is intended for use in dermatologic procedures for non-invasive treatment of mild to moderate facial wrinkles and rhytids.

• BodyFX™ (WMBody)/MiniFX™ for Relief of minor muscle aches and pain, relief of muscle spasm, temporary improvement of local blood circulation and temporary reduction in the appearance of cellulite.

The InMode RF Pro System with the Fractional Applicators employs RF energy for various applications:

• Fractora Applicator with 60 pins tip is designed for use in dermatological procedures requiring ablation and resurfacing of the skin.

• Fractora Applicator with 24 pins tip is intended for use in dermatological and general surgical procedures for electrocoagulation and hemostasis.
At higher energy levels greater than 62mJ/pin, use of the applicator is limited to skin types I-IV

• Morpheus8™ for dermatological and general surgical procedures for electrocoagulation and hemostasis.
At higher energy levels greater than 62mJ/pin, use of the applicator is limited to skin types I-IV

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
INMODE RF PRO SYSTEM

510(k) Number K210492

Applicant Name:
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E-mail: amit@asteinrac.com

Date Prepared: July 11, 2021

Trade Name: InMode RF Pro System

Classification Regulation:

Classification Name	Regulation No.	Product Code
Electrosurgical cutting and coagulation device and accessories.	878.4400	GEI, PBX
Therapeutic massager.	890.5660	ISA
Laser surgical instrument for use in general and plastic surgery and in dermatology.	878.4810	NUV

Classification: Class II Medical Device

Predicate Device: The InMode RF Pro System is substantially equivalent to the previously cleared predicate devices;

Manufacturer	Device	510(k) No.
InMode Ltd.	InMode RF Multi System	K201150

Device Description:

The InMode RF Pro System supports multiple radiofrequency (RF) applications and accessories. The InMode RF Pro System is compatible with the Fractional RF Applicators and the Non-Invasive RF Applicators, and employs RF energy for various applications.
The InMode RF Pro System consists of platform console with an AC/DC power supply unit, two applicator connectors, RF generator, RF measuring circuit, controller, footswitch and user interface including a touch screen. The RF Applicator is connected to the console via a cable and a footswitch activates the energy delivery to the applicator. The applicators are comprised of a handle and electrodes, and some of them are used with a single-use tip.

The below list comprises the set of applicators to be registered under the subject device:

- Non-Invasive RF Applicators:
  - i-Forma
  - Forma (Plus)
  - Plus (Plus Plus)
  - Plus90
  - WMface
  - BodyFX™ (WMBody)
  - MiniFX™

- Fractional RF Applicators:
  - Fractora
    - 24 pins tip (FRF)
    - 60 pins tip
  - Morpheus8™
    - 12 pins tip (Prime Tip)
    - 24 pins tip (Fractora 3D)
    - 40 pins tip (Body Tip)
    - T tip

Following are the InMode RF Multi-System device specifications:

RF Max Output Power	65 Watt
RF Output Frequency	1[MHz] ± 2%
Dimensions	36.5cm W x 39.3cm D x 111cm H [14.4'' W x 15.5'' D x 43.7'' H]
Console Weight	20.0Kg [44.0lb]
Main Line Frequency (nominal)	50-60 Hz
Input Voltage (nominal)	100-240 VAC

Intended Use/Indication for Use:

The InMode RF Pro System with the Non-invasive RF Applicators employs RF energy for various applications:

- i-Forma, Forma (Plus), Plus (Plus Plus) and Plus90 for relief of minor muscle aches and pain, relief of muscle spasm, and temporary improvement of local blood circulation.
- WMface is intended for use in dermatologic procedures for non-invasive treatment of mild to moderate facial wrinkles and rhytids.
- BodyFX™ (WMBody)/MiniFX™ for relief of minor muscle aches and pain, relief of muscle spasm, temporary improvement of local blood circulation and temporary reduction in the appearance of cellulite.

The InMode RF Pro System with the Fractional Applicators employs RF energy for various applications:

- Fractora Applicator with 60 pins tip is designed for use in dermatological procedures requiring ablation and resurfacing of the skin.
- Fractora Applicator with 24 pins tip is intended for use in dermatological and general surgical procedures for electrocoagulation and hemostasis.
  At higher energy levels greater than 62mJ/pin, use of the applicator is limited to skin types I-IV
- Morpheus8™ for dermatological and general surgical procedures for electrocoagulation and hemostasis.

  At higher energy levels greater than 62mJ/pin, use of the applicator is limited to skin types I-IV

Performance Standards:
The InMode RF Pro System complies with the following 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 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
- [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 6-389] IEC 60601-2-2 Edition 6.0 2017-03 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
-

The test report documents conclude that the InMode RF Pro System complies with the requirements of all the above-mentioned standards. The test reports for the InMode RF Pro System are provided in section 17 of this 510(k) submission.

Non-Clinical (Bench) Performance Data:

The following performance data was provided in support of the substantial equivalence determination:

Electrical safety and electromagnetic compatibility (EMC)

Electrical safety and EMC testing were conducted on the InMode RF Pro system. The system complies with the IEC 60601-1, IEC 60601-2-2 standards for safety and the IEC 60601-1-2 standard for EMC.

Software Verification and Validation Testing

Software verification and validation testing were conducted and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, *"Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices."*

The software for this device was considered as a "major" level of concern, since a failure or latent flaw in the software could directly result in serious injury or death to the patient or operator.

Additional Bench Testing

Bench performance tests were conducted to evaluate the performance specifications and thermal profiling of the new applicator – the i-Forma Applicator in comparison to the Forma Applicator (predicate device).

1) Accuracy testing of the RF output parameters, temperature sensor accuracy and temperature build-up in *ex-vivo* model.
2) *Ex-vivo* tissue study to evaluate the safety and temperature tissue penetration/depth profile
3) Comparative test on human volunteers to evaluate the thermal effect of the InMode Pro System with the i-Forma Applicator in comparison to the predicate device

The results of the performance tests demonstrated that the InMode Pro System with the i-Forma Applicator operates in compliance with the system requirements, emitting RF energy of up to 12W, while elevating the tissue temperature up to 42^0C. Moreover, the side-by-side bench test results showed that the InMode Pro System with the i-Forma Applicator is as safe and effective as the predicate device for the same intended use.

In all, the results of the performance tests demonstrated substantial equivalence of the InMode Pro System with the i-Forma Applicator compared to the predicate device, the InMode RF Multi System with the Forma Applicator.

Animal Performance Data / Histology Data:

Non-Applicable

Clinical Performance Data:

Non-Applicable

Substantial Equivalence:

The following tables provide a comparison information for the InMode RF Pro system and its predicate device, the InMode RF Multi System:

	Subject Device **InMode RF Pro System**	**Predicate Device** **InMode RF Multi System** **K201150**
General		
Product Code Class	GEI Class II	GEI Class II
Manufacturer	InMode Ltd.	InMode Ltd.

	Subject Device InMode RF Pro System	**Predicate Device InMode RF Multi System K201150**
RF platform	InMode RF Pro System	InMode RF Multi System
Prescription or OTC	Prescription use only	Idem
Target Population	Adults requiring treatment as specified in the indication for use	Idem
Anatomical sites	Body/facial parts requiring treatment as specified in the indication for use	Idem
Environment Used	Hospital or Clinic setting	Idem
Device description / Design	The InMode RF Pro System is a line power, electro thermal, radio frequency system with integral temperature and impedance feedback. The system is capable of delivering up to 65 watts of power.	Idem
Device components	The InMode RF Pro System consists of the same following components as the InMode RF Multi System, with additional applicators as described in next table: ▪ Electrosurgical Unit which includes the power supply, RF generator, controller and LCD touch screen control and display panel • RF measuring circuit • AC/DC power supply • Designated applicators • 2 Applicator connectors • Footswitch	Idem
Input Power		
Main Line Frequency (nominal) Input Voltage (nominal) Input Current (rms)	60 - 50Hz 100-240VAC 2A	idem
Dimensions		
System	36.5cm W x 39.3cm D x 111cm H [14.4’’ W x 15.5’’ D x 43.7’’ H]	46cm W x 46cm D x 100cm H [18.2’’ W x 18.2’’ D x 40’’ H]

	Subject Device **InMode RF Pro System**	**Predicate Device** **InMode RF Multi System** **K201150**
Weight		
System	20.0Kg [44.0lb]	32.0Kg [70.5lb]
RF Output Parameters		
Maximum Output Power	65[W]	idem
Frequency	1MHz	idem
Crest Factor (Rated Load)	1.4± 2%	idem
Safety & adherence to consensus standards		
Standards Met	System adheres to: • IEC 60601-1 • IEC 60601-1-2 • IEC 60601-2-2	idem
Biocompatibility	Materials are biocompatible.	idem
Compatibility with Environment and Other Devices	InMode RF Pro System is compliant with the IEC 60601-1-2 (EMC Safety) standard	idem
Electrical Safety	Power Requirements: 100-240 VAC 50-60 Hz The InMode RF Pro System is compliant with the IEC 60601-1 standard.	idem
Mechanical Safety	The InMode RF Pro System is compliant with the IEC 60601-1 standard.	idem
Chemical Safety	Not Applicable	idem
Thermal Safety	The InMode RF Pro System is compliant with the IEC 60601-1 standard.	idem
Radiation Safety	The InMode RF Pro System is compliant with the IEC 60601-1-2 (EMC Safety) standard	idem

Fractional RF Applicators

Technological Characteristic	**Subject Device InMode RF Pro System**	**Predicate Device InMode RF Multi System K201150**
Product Code Class	GEI Class II	idem
Manufacturer	InMode Ltd.	Idem
Device Technological Characteristics		
Energy Used	Fractional RF	idem
Specifications		
Max RF Energy output	65W	idem
RF Frequency	1 MHz	idem
Max RF Energy levels	**FRACTORA 60 pin:** 60W **InMode FRF 24 pin:** 60W **Morpheus8 12, 24, 40:** 60W **Morpheus8 T:** 30W	idem
Tip needles penetration depth	**FRACTORA 60 pin:** 0.2mm **InMode FRF 24 pin:** 2.5mm **Morpheus8 12 pin:** 4.0mm **Morpheus8 24, 40 pins:** 7.0mm **Morpheus8 T:** 0.5mm	idem
General Aspects		
Biocompatibility	Materials are biocompatible.	idem
Sterility	All tips are Gamma-sterilized	idem
Reprocessing	Handle to be reprocessed in accordance with user manual instructions. Tips are for single-use	idem

Non-Invasive Applicators

Technological Characteristic	**Subject Device InMode RF Pro System**	**Predicate Device InMode RF Multi System K201150**
Product Code Class	GEI, PBX, ISA/NUV Class II	idem
Manufacturer	InMode Ltd.	idem
Device Technological Characteristics		
Energy Used	Bipolar RF	idem
Specifications		
Maximal RF output power	**BodyFX (WMBody):** 50 [W] **WMFace:** 65 [W] **MiniFX:** 25 [W]	Idem

Technological Characteristic	**Subject Device InMode RF Pro System**	**Predicate Device InMode RF Multi System K201150**
	Forma (Plus), Plus (Plus-Plus): 50 [W] **i-Forma:** 12 [W] **Plus90:** 50 [W]	NA
RF Frequency	1 MHz	idem
General Aspects		
Biocompatibility	Materials are biocompatible.	idem
Sterility	NA	NA
Reprocessing	Applicators to be reprocessed in accordance with user manual instructions.	idem

The indications for use and technological characteristics of the InMode RF Pro System are substantially equivalent to the indications for use and technological characteristics of the InMode RF Multi System (predicate device, subject of K201150).

The design of and components included in the InMode RF Pro System, including the main system platform, with power supply, RF generator, controller and display panel are similar to the design and components found in the predicate device except for slight design modifications to support the utilization of the i-Forma applicator in addition to all previously FDA cleared device applicators, mainly in software design. The subject device applicators possess identical technological principals to the predicate device applicators. Both the subject and predicate device present identical performance specifications (for the specified indications for use) and identical monitoring features (where applicable) in order to maintain the desired performance specifications. The safety features and compliance with safety standards in the InMode RF Pro System are similar to the safety features and compliance with safety standards found in the predicate device. Patient contacting materials are also identical. Any minor differences in the technological characteristics do not raise new safety or effectiveness concerns. Furthermore, the subject device underwent performance testing including software validation testing, electrical and mechanical safety testing according to IEC 60601-1, electromagnetic compatibility testing according to IEC 60601-1-2 and high frequency of surgical equipment testing according to IEC 60601-2-2. User interface was slightly changed in order to support all applicators, and labelling was updated to allow appropriate use.

Conclusions:

Based upon the intended use, technological characteristics and performance testing comparison data, the K210492 subject device has been determined to be substantially equivalent to and as safe and effective as the K201150 predicate device.