July 2, 2020

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

Re: K200947/S001
Trade/Device Name: InMode System with the Morhpeus8 Applicators
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting and Coagulation Device and Accessories
Regulatory Class: Class II
Product Code: GEI
Dated: June 10, 2020
Received: June 12, 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,

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)*
K200947

Device Name
InMode System with the Morpheus8 Applicators

Indications for Use *(Describe)*
The InMode System with the Morpheus8 Applicators is intended for use in dermatological procedures for electrocoagulation and hemostasis.
At higher energy levels greater than 62 mJ/pin, use of the Morpheus8 (Fractora) 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 SYSTEM WITH THE MORPHEUS8 APPLICATORS

510(k) Number K200947

Applicant Name:

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Date Prepared: July 02, 2020

Trade Name: InMode System with the Morpheus8 Applicators

Classification Name: CFR Classification section 878.4400; (Product code GEI)

Classification: Class II Medical Device

Predicate Device:

The InMode System with the Morpheus8 Applicators is substantially equivalent to the following predicate device;

Manufacturer	Device	510(k) No.
InMode Ltd.	InMode System with the Morpheus8 Applicators	K192695

Device Description:

The InMode System with the Morpheus8 Applicators is a computerized, programmed, RF technology based device intended for dermatological applications which requires skin electrocoagulation and hemostasis.

The device platform is basically constituted on the same system platform as FDA-Cleared InMode System with the Morpheus8 Applicators (K192695). The InMode System with the Morpheus8 Applicators employs fractional RF multi-electrode technology for procedures requiring electrocoagulation and hemostasis. The Morpheus8 Applicators are designed to deliver radiofrequency energy to the skin in a fractional manner, via an array of multi-electrode pins. The Device provides enhanced safety while minimizing possible side effects by monitoring RF parameters.

The InMode System with the Morpheus8 Applicators consists of an AC/DC power supply unit, RF generator, controller and user interface including LCD touch screen. The Morpheus8 Applicators are connected to the console via a cable and a foot switch activates the energy delivery to the applicator. The Morpheus8 Applicator comprises handle and detachable, sterilized, disposable, single use 12, 24, 40 pin and T tip head accessory.

Following are the InMode System with the Morpheus8 Applicators specifications:

RF Max Output Power:	65 Watt
RF Output Frequency:	1[MHz]
Dimension:	46cm W x 46cm D x 100cm H (18.2'' W x 18.2'' D x 40'' H)
Weight:	30 Kg (70.4 lbs.)
Main Line Frequency (nominal):	50-60 Hz
Input Voltage (nominal):	100-240 VAC

Intended Use/Indication for Use:

The InMode System with the Morpheus8 Applicators is intended for use in dermatological procedures for electrocoagulation and hemostasis.

At higher energy levels greater than 62 mJ/pin, use of the Morpheus8 (Fractora) Applicator is limited to Skin Types I-IV.

Performance Standards:

The InMode System with the Morpheus8 Applicators has been tested and complies with the following voluntary recognized standards:

- 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.

- 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.

- 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.

Non-Clinical (Bench) Performance Data:

The performance and safety of the InMode System with the Morpheus8 Applicators treatment in dermatological procedures requiring electrocoagulation and hemostasis in deeper tissues of up to 5, 6 and 7 mm was evaluated in an *ex-vivo* tissue study. The study was conducted on a porcine animal model and included a single treatment of two different harvested porcine tissues: muscle and fat utilizing the InMode System with the Morpheus8 applicator 40 pin tip head. Treatment was followed by biopsy sampling of slices trimmed along the pin's penetration path and collection immediately stained by TTC staining to visualize the tissue coagulation necrosis pattern. The *ex-vivo* study results show that the Morpheus8 Applicators is safe for use and effective in achieving the specified indications of dermatological and general electrocoagulation and hemostasis.

Animal Performance Data / Histology Data:

Not Applicable

Clinical Performance Data:

Not Applicable

Substantial Equivalence:

A comparison table is provided below comparing the intended use and basic technological characteristics of the subject device to the intended use and basic technological characteristics of the predicate device.

Technological Characteristic	**InMode System with the Morpheus8 Applicators InMode Ltd. K200947 (Subject Device)**	**InMode System with the Morpheus8 Applicators InMode Ltd. K192695 (Predicate Device)**
Product Code, Class	GEI Class II	GEI Class II
Indications for Use	The InMode System with the Morpheus8 Applicators is intended for use in dermatological and general surgical procedures for electrocoagulation and hemostasis. At higher energy levels greater than 62 mJ/pin, use of these Applicators is limited to Skin Types I-IV.	The InMode System with the Morpheus8 Applicators is intended for use in dermatological procedures for electrocoagulation and hemostasis. At higher energy levels greater than 62 mJ/pin, use of these Applicators is limited to Skin Types I-IV.
Anatomical Sites	Body parts requiring treatment as specified in the indication for use	idem
Target Population	Adults requiring treatment as specified in the indication for use	idem
Environment Used	Hospital or Clinic setting	idem
Energy Used / Delivered	RF energy	idem
Design:	Fractional RF: Use of RF energy delivered through a matrix of multiple pin electrodes allocated on the applicator tip	idem
- Mechanism of Action	Treatment is based on fractional RF technology for localized dermis and	idem

Technological Characteristic	**InMode System with the Morpheus8 Applicators InMode Ltd. K200947 (Subject Device)**	**InMode System with the Morpheus8 Applicators InMode Ltd. K192695 (Predicate Device)**
	sub dermis coagulation triggering slow collagen regeneration and fibroblast cells' proliferation.	
- Components	The InMode Morpheus8 Applicators are add-on applicators to the FDA cleared InMode System (K192695). The system consists of the following components: - Console, including a power supply, RF generator, controller, and touch screen control and display panel. - Applicator connected to the console via a cable, with tip including 12, 24, 40 & T tip heads. - Footswitch	idem
- System Dimensions	46cm W x 46cm D x 100cm H [18.2'' W x 18.2'' D x 40'' H]	idem
- Weight Platform weight Applicator weight	30 Kg (70.4 lbs.) Applicator – 0.4 Kg (0.88 lbs.) Tip – 0.02 Kg	idem
Number of pins	12, 24 and 40 pins	idem
Maximal Treatment depth	0.5mm (for T tip head) 4.0mm (for 12 pin tip head) 7.0mm (for 24 and 40 pin tip heads)	0.5mm (for T tip head) 4.0mm (for 12 pin tip head) 4.0mm (for 24 and 40 pin tip heads)

Technological Characteristic	**InMode System with the Morpheus8 Applicators InMode Ltd. K200947 (Subject Device)**	**InMode System with the Morpheus8 Applicators InMode Ltd. K192695 (Predicate Device)**
RF energy level	5-30 (for 24 tip head up to 1 mm) 5-30 (for T tip head and for 12 tip head) 5-60 (for 24 and 40 in the range of 2-7mm)	5-30 (for 24 tip head up to 1 mm) 5-30 (for T tip head and for 12 tip head up to 1 mm) 5-60 (for 12 tip head in the range of 2-4mm) 5-60 (for 24 and 40 in the range of 2-4mm)
Cable Dimensions:	270 cm	idem
Performance	Frequency: 1 MHz Maximal RF output power: 65W Maximal pulse duration: up to 74msec	idem
Standards Met	AAMI/ANSI ES 60601-1 IEC 60601-1-2 IEC 60601-2-2	idem
Biocompatibility	All materials are biocompatible	idem
Compatibility with Environment and Other Devices	InMode System with the Morpheus8 Applicators is compliant with the IEC 60601-1-2 (EMC Safety) standard	idem
Sterility	The 12, 24, 40 and T tip head are Gamma sterilized and for single use. The Morpheus8 Applicator handle is for multiple use	idem
Electrical Safety	Power Requirements:	idem

Technological Characteristic	InMode System with the Morpheus8 Applicators InMode Ltd. K200947 (Subject Device)	InMode System with the Morpheus8 Applicators InMode Ltd. K192695 (Predicate Device)
	100-240 VAC 50-60 Hz The InMode System with the Morpheus8 Applicators is compliant with the IEC 60601-1 standard.	
Mechanical Safety	The InMode System with the Morpheus8 Applicator is compliant with the IEC 60601-1 standard.	idem
Chemical Safety	Not Applicable	Not Applicable
Thermal Safety	The InMode System with the Morpheus8 Applicators is compliant with the IEC 60601-1 standard.	idem
Radiation Safety	The InMode System with the Morpheus8 Applicators is compliant with the IEC 60601-1-2 (EMC Safety) standard.	idem

The indications for use and technological characteristics of the InMode System with the Morpheus8 Applicators are substantially equivalent to the indications for use and technological characteristics of the FDA-Cleared InMode System with the Morpheus8 Applicators (K192695).

The design and components in the InMode System, including the console (with power supply, RF generator, controller and display panel) and the Applicator (with cable, connector to console, handle and tip) are similar to the design and components found in the predicate. The performance specifications (including RF frequency, pulse duration and RF energy per pin) of the subject device were shown to be identical and yielded the same RF energy per pin values to those of the predicate device. The safety features and compliance with safety standards in the InMode System with the Morpheus8 Applicators are identical to the safety features and compliance with safety standards found in the predicate device. Patient contact materials are also identical. Any minor differences in the technological characteristics do not raise new safety or effectiveness

concerns. Furthermore, the new InMode System with the Morpheus8 Applicators underwent performance testing, including software validation testing, electrical and mechanical safety testing according to IEC 60601-1 and electromagnetic compatibility testing according to IEC 60601-1-2 and IEC 60601-2-2, comparative bench testing and *ex-vivo* tissue testing to evaluate and compare the fractional coagulation necrosis pattern of target tissues, formed by thermal effect of the InMode System with the Morpheus8 Applicators 24 and 40 pin tip heads in different tissue depths. These performance tests demonstrated that the minor differences in the device design and 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 Morpheus8 Applicators are substantially equivalent to the predicate InMode System with the Morpheus8 Applicators, FDA-Cleared in 510(k) K192695, and therefore, may be legally marketed in the USA.