June 1, 2018

InMode MD Ltd.
% Amit Goren
Regulatory Manager
A. Stein - Regulatory Affairs Consulting Ltd.
20 Hata'as Str., Suite 102
Kfar Saba, 44425 Israel

Re: K180189
Trade/Device Name: InMode System with Fractora3D/3D-90 Applicators
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting and Coagulation Device and Accessories
Regulatory Class: Class II
Product Code: GEI
Dated: May 1, 2018
Received: May 4, 2018

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. 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); good

manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Jennifer R. Stevenson -S3

For Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
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)*
K180189

Device Name
InMode System with the Fractora3D/3D-90 Applicators

Indications for Use *(Describe)*
The InMode System with the Fractora3D/3D-90 Applicators is intended for use in Dermatological and General Surgical procedures for Electrocoagulation and Homeostasis.
At higher energy levels greater than 62 mJ/pin, use of the FRF 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 FRACTORA3D/3D-90 APPLICATORS

510(k) Number K180189

Applicant Name:

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Date Prepared: April 29, 2018

Trade Name: InMode System with the Fractora3D/3D-90 Applicators

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

Classification: Class II Medical Device

Predicate Device:
The InMode System with the Fractora3D/3D-90 Applicators is substantially equivalent to the following predicate device;

Manufacturer	Device	510(k) No.
EndyMed Medical Ltd.	Intensif Applicator	K130501
InMode MD Ltd.	InMode FRF Applicator	K151273

Device Description:

The InMode System with the Fractora3D/3D-90 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 for InMode FRF Applicator (K151273). The InMode System with the Fractora3D/3D-90 Applicators employs fractional RF multi-electrode technology for procedures requiring electrocoagulation and hemostasis. The Fractora3D/3D-90 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 Fractora3D/3D-90 Applicators consists of an AC/DC power supply unit, RF generator, controller and user interface including LCD touch screen. The Fractora3D/3D-90 Applicators are connected to the console via a cable and a foot switch activates the energy delivery to the hand piece. The hand piece comprises a disposable, single use, 24 electrode pins tip.

Following are the InMode System with the Fractora3D/3D-90 Applicators specifications:

RF Max Output Power: 65 Watt
RF Output Frequency: 1[MHz] ± 2%
Dimension: 46cm W x 46cm D x 100cm H (18.2'' W x 18.2'' D x 40'' H)
Weight: 30 Kg (66 lbs.)
Main Line Frequency (nominal): 50-60 Hz
Input Voltage (nominal): 100-240 VAC

Intended Use/Indication for Use:

The InMode System with the Fractora3D/3D-90 Applicators is intended for use in Dermatologic and General Surgical procedures for Electrocoagulation and Hemostasis.
At higher energy levels greater than 62 mJ/pin, use of the FRF applicator is limited to Skin Types I-IV.

Performance Standards:

The InMode System with the Fractora3D/3D-90 Applicators has been tested and complies with the following voluntary recognized standards:

- AAMI/ANSI 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 60601-1:2005, Mod).
- IEC 60601-1-2 Edition 3: 2007-03, Medical Electrical Equipment - Part 1-2: General Requirements for Basic Safety and Essential Performance - Collateral Standard: Electromagnetic Compatibility - Requirements and Tests.

- IEC 60601-2-2 Edition 5.0 2009-02, 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:

Performance bench tests were performed to measure the accuracy and consistency of the RF output parameters of the InMode System and compare them to the specific design requirements and to the RF output parameters of the predicate device. The results of the bench tests demonstrate that the InMode System complies with the design requirements and consists of similar RF output specifications as the predicate device and therefore, is substantially equivalent to the predicate device.

Animal Performance Data / Histology Data:

The thermal effects of the InMode System with the Fractora3D/3D-90 Applicators and tissue healing process were evaluated in a preclinical study. The study was conducted on porcine model and included a single RF treatment followed by histology analysis performed immediately, 7, 14 and 21 days post treatment. The animal study results show that the InMode System with the Fractora3D/3D-90 Applicators are safe for use and effective in achieving the specified indications of dermatological and general electrocoagulation and hemostasis.

Clinical Performance Data:

Not Applicable

Biocompatibility

All device materials which come in direct contact with the patient skin are biocompatible. The following 510(k)s were mentioned as reference devices for Biocompatibility determination: K102461, K082451, K142438, K151019 and K081365.

Substantial Equivalence:

A comparison table is provided below comparing the intended use and basic technological characteristics of the InMode System with the Fractora3D/3D-90 Applicators to the intended use and basic technological characteristics of the predicate devices.

Technological Characteristic	**InMode System with the Fractora3D/3D-90 Applicators InMode MD Ltd. (Subject Device)**	**Intensif Applicator EndyMed Medical Ltd. K130501 (Main Predicate)**	**InMode FRF Applicator InMode MD Ltd. K151273 (Reference Predicate)**
Dimensions	46cm W x 46cm D x 100cm H [18.2'' W x 18.2'' D x 40'' H]	30cm W x 19cm D x 115cm H [12'' W x 8'' D x 45'' H]	46cm W x 46cm D x 100cm H [18.2'' W x 18.2'' D x 40'' H]
Weight Platform weight Applicator weight	30 Kg (70.4 lbs.) 0.4 Kg (0.88 lbs.) Tip weight - 0.02 Kg	33 Kg (72.6 lbs.) 0.28 Kg (0.62 lbs.)	30 Kg (70.4 lbs.) 0.22 Kg (0.5 lbs.) Tip weight - 0.02 Kg
Applicator Dimensions:	Applicator Footprint Area: 1.6cm x 1.2cm Applicator needles field area: 0.95cm X 1.1 cm Maximum volume of treatment : 16mm x 12mm x 4.0mm	Applicator Footprint Area: 1.1cm x 1.1cm Maximum volume of treatment : 11mm x 11mm x 3.5mm	Applicator Footprint Area: 1.6cm x 1.2cm Applicator needles field area: 0.9cm X 1.2 cm Maximum volume of treatment: 16mm x 12mm x 2.5mm
Number of pins	24 pins	25 pins	24 pins
Maximal Treatment depth	4.0mm	3.5mm	2.5mm
Cable Dimensions:	250 cm	idem	idem
Performance	Frequency: 1 MHz Maximal RF output power: 65W Maximal pulse duration: up to 74msec	Frequency: 1 MHz Maximal RF output power: 25W Maximal pulse duration: up to 200msec	Frequency: 1 MHz Maximal RF output power: 65W Maximal pulse duration: up to 74msec
Standards Met	IEC 60601-1 IEC 60601-1-2	idem	idem

Technological Characteristic	InMode System with the Fractora3D/3D-90 Applicators InMode MD Ltd. (Subject Device)	Intensif Applicator EndyMed Medical Ltd. K130501 (Main Predicate)	InMode FRF Applicator InMode MD Ltd. K151273 (Reference Predicate)
	ANSI AAMI 60601-2-2 for safety of high frequency surgical equipment		

Comparison Discussion:

The indications for use and technological characteristics of the InMode System with the Fractora3D/3D-90 Applicators are substantially equivalent to the indications for use and technological characteristics of the EndyMed Intensif Applicator.

The design and components in the InMode System, including the console (with power supply, RF generator, controller and display panel) and the hand piece Applicator (with cable, connector to console, handle and tip) are similar to the design and components found in the predicate Endymed Intensif System. The performance specifications (including RF frequency, pulse duration and RF energy per pin) of the InMode System were shown to be similar and yielded similar RF energy per pin values to those of the EndyMed Intensif Applicator. The safety features and compliance with safety standards in the InMode System with the Fractora3D/3D-90 Applicators are similar to the safety features and compliance with safety standards found in the predicate device. Patient contact materials are also similar. Any minor differences in the technological characteristics do not raise new safety or effectiveness concerns. Furthermore, the new InMode System with the Fractora3D/3D-90 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 animal preclinical testing to evaluate the thermal effect of the device and the tissue healing process. 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 Fractora3D/3D-90 Applicators are substantially equivalent to the predicate EndyMed Intensif Applicator, FDA cleared in 510(k) K130501, and therefore, may be legally marketed in the USA.