December 8, 2017

InMode MD Ltd.
% Amit Goren
Regulatory Manager
A. Stein - Regulatory Affairs Consulting Ltd.
20 Hata'as Str.
Suite 102 Kfar Saba, Israel 442520

Re: K172302
Trade/Device Name: InMode PLUS 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: November 7, 2017
Received: November 13, 2017

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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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)*

K172302

Device Name
InMode PLUS System

Indications for Use *(Describe)*
The InMode PLUS System with the PLUS/PLUS90/PLUS-PLUS Hand pieces is indicated for the temporary relief of minor muscle aches and pain, temporary relief of muscle spasm, and temporary improvement of local blood circulation

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 PLUS SYSTEM

510(k) Number K172302

Applicant Name:

Company Name: InMode MD Ltd

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Official Correspondent: Amit Goren

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Fax: +972-9-7668534
E-mail: amit@asteinrac.com

Date Prepared: November 29, 2017

Trade Name: InMode PLUS System

Classification Name: CFR Classification sections; 878.4400 and 890.5660 (Product codes; PBX and ISA)

Classification: Class II Medical Device

Predicate Device:

InMode PLUS System is substantially equivalent to the previously cleared, InMode PLUS System, also manufactured by InMode MD Ltd.

Device	Manufacturer	510(k) No.
InMode PLUS System	InMode MD Ltd.	K153568

Device Description:

The InMode PLUS System delivers RF energy to gradually heat the skin and subcutaneous tissue. The RF power levels used by the device can be adjusted from 10 to 50 Watts and the maximum skin temperature cutoff can be adjusted from 35ºC to a maximum of 42ºC. The hand pieces are operated while in continuous movement over the treatment area. This ensures uniform and safe heating of the entire treatment area.

Each InMode PLUS hand piece is comprised of the hand piece handle, a cable 250 cm long, and a connector, which connects to the rear connector of the InMode PLUS System.

Three InMode PLUS hand pieces are available:

- InMode PLUS hand piece
- InMode PLUS90 hand piece
- InMode PLUS-PLUS hand piece (

Following are the InMode PLUS System specifications:
Maximum Temperature (skin surface): 42°C ± 2°C

Device Specifications:

Main Line Frequency (nominal)	50 - 60 Hz
Input Voltage (nominal)	100 - 240 VAC
Electrosurgical Unit dimensions (inch)	14.2'' W x 14.2'' D x 40'' H
Platform weight (lb.)	66
RF Max Output Power (Watt)	50
RF Output Frequency (MHz)	1.0± 2%
Cut off temperature (C^0)	35-42

Intended Use/Indication for Use:

The InMode PLUS System with the PLUS/PLUS90/PLUS-PLUS Hand pieces is indicated for the temporary relief of minor muscle aches and pain, temporary relief of muscle spasm, and temporary improvement of local blood circulation

Performance Standards:

InMode PLUS System complies with the following FDA recognized consensus standards:

- AAMI/ANSI 60601-1 (2012), Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance (IEC 60601-1:2005, Mod).
- IEC 60601-1-2 (Edition 3.0, 2007), 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:

The following performance tests were conducted utilizing the InMode PLUS System with the PLUS-PLUS hand piece:

1) *Ex-vivo* tissue study to evaluate the safety and temperature tissue penetration/depth profile
2) Comparative test to evaluate the thermal effect of the InMode PLUS System with the PLUS-PLUS hand piece in comparison to the predicate device

The results of the performance tests demonstrated that the InMode PLUS System with the InMode PLUS-PLUS hand piece operates in compliance with the system requirements, emitting RF energy of up to 50W, while elevating the tissue temperature up to 42^0C. Moreover, the side by side bench test results showed that the InMode PLUS System with the InMode PLUS-PLUS hand piece 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 PLUS System with the InMode PLUS-PLUS hand piece compared to the predicate device, the InMode PLUS System with the InMode PLUS/PLUS90 hand pieces.

Animal Performance Data / Histology Data:

Not Applicable

Clinical Performance Data:

Not Applicable

Sterilization and Biocompatibility:

The InMode PLUS System is a non-sterile, reusable device, intended for multiple patients. The device had successfully passed the cleaning validation test. All of the hand piece materials are biocompatible based on the established biocompatibility of the materials and per ISO 10993-1.

Software & Cybersecurity:

The InMode PLUS System software is based on the software modules of the predicate device, the InMode PLUS System (K153568). The device software was adjusted to support the integration and operation of the PLUS-PLUS hand piece. The software is designed in accordance with ISO 62304 standard – Medical device software— Software life cycle processes.

The InMode PLUS System is a closed, standalone system and as such it is not effected by cybersecurity related issues.

Substantial Equivalence:

The indications for use and technological characteristics of the InMode PLUS System with the PLUS-PLUS hand piece are substantially equivalent to the indications for use and technological characteristics of the InMode PLUS System with the PLUS/PLUS90 hand pieces.

The design and components of the modified InMode PLUS System, including the console and its components (including the power supply, RF generator, controller and display panel) and the hand piece applicators (including the cable and connector to console) are similar to the design and components found in the predicate InMode PLUS System. The performance specifications (including frequency and RF output power) of the modified InMode PLUS System are substantially equivalent to those in the predicate device. The safety features and compliance with safety standards in the InMode PLUS System are similar to the safety features and compliance with safety standards found in the predicate device. Patient contact materials are identical. The minor differences in the LCD screen properties and in the dimensions of the PLUS-PLUS hand piece treatment area do not raise new safety or effectiveness concerns and are demonstrated to be substantially equivalent through relevant performance tests. Furthermore, the modified InMode PLUS System underwent additional performance tests, including software validation testing and electrical and mechanical safety testing according to IEC 60601-1 and electromagnetic compatibility testing according to IEC 60601-1-2. The performance tests demonstrated that the minor differences in the device specifications meet the system requirements and do not raise new safety or effectiveness concerns.

Conclusions:

Based on the substantial equivalence demonstration and the device performance tests, it can be concluded that the modified InMode PLUS System is substantially equivalent to the predicate InMode PLUS System, cleared under 510(k) K153568.