DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

July 12, 2016

InMode MD Ltd.
Ms. Ahava Stein
A. Stein – Regulatory Affairs Consulting Ltd.
20 Hata'as Str., Suite 102
Kfar Saba, 44425
Israel

Re: K153568
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
Additional Product Code: ISA
Dated: June 7, 2016
Received: June 10, 2016

Dear Ms. Stein:

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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Jennifer R. Stevenson -A

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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K153568

Device Name
InMode PLUS System

Indications for Use *(Describe)*
The InMode PLUS System with the PLUS/PLUS90 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 K153568

Applicant Name:

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Date Prepared: July 10, 2016

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:

The InMode Plus System is substantially equivalent to the following predicate device:

Manufacturer	Device	510(k) No.
Viora Ltd.	Viora V-ST Handpiece (cleared together with the Viora V-10 System)	K150035

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 continuously moving them 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.

Two InMode PLUS hand pieces are available:

- InMode PLUS hand piece (held perpendicular to the treatment area)
- InMode PLUS90 hand piece (held parallel to the treatment area)

Following are the InMode PLUS System specifications:
Maximal RF Output Power: 50 Watt
RF Output Frequency: 1.0[MHz] ± 2%
Maximum Temperature (skin surface): 42°C ± 2°C

Intended Use/Indication for Use:
The InMode PLUS System with the PLUS/PLUS90 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:
The InMode Plus device complies with the following voluntary recognized standards:

- IEC 60601-1:2005, Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance; + CORR. 1 (2006) + CORR. 2 (2007) + Amd.1(2012)
- IEC 60601-1-2 (2007): Medical Electrical Equipment-Part 1: General requirements for safety and Part 1-2 Collateral standard: Electromagnetic Compatibility-Requirements and tests; and IEC 60601-2-2 (2009): Medical Electrical Equipment - Part 2-2: Particular requirements for the safety of high frequency surgical equipment (section 202.6.1 (Emission) and section 202.6.2 (Immunity).
- IEC 60601-2-2 (2009): Medical Electrical Equipment - Part 2: Particular requirements for the safety of high frequency surgical equipment; for use in conjunction with IEC 60601-1:2005

Non-Clinical (Bench) Performance Data:

The following performance tests were conducted utilizing the InMode PLUS System with the Plus/Plus90 hand piece:

1) RF output power settings and temperature elevation profile
2) *Ex-vivo* tissue study to evaluate the safety and temperature tissue penetration/depth profile
3) Side by side bench tests to evaluate the device RF performance settings in comparison to the predicate device

The results of the performance tests demonstrated that the InMode Plus System 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 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 compared to the predicate device, the Viora V10 System with the ST hand piece.

Clinical Performance Data:

Not Applicable

Sterilization and Biocompatibility:

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

Substantial Equivalence:

The indications for use and technological characteristics of the InMode Plus System are substantially equivalent to the indications for use and technological characteristics of the Viora V10 System with the ST hand piece.

The design and components of the 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 Viora V10 System. The performance specifications (including RF Frequency and output power) of the 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 technological characteristics (electrode configuration and pulse vs. continuous mode) do not raise new safety or effectiveness concerns and are demonstrated to be substantially equivalent through relevant performance tests. Furthermore, the InMode Plus System underwent additional performance tests, including software verification and validation testing and electrical and mechanical safety testing according to IEC 60601-1, IEC60601-2-2 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 InMode Plus System is substantially equivalent to the predicate Viora V10 System, cleared under 510(k) K150035.