September 26, 2018

Inmode MD Ltd.
% Mr. Amit Goren
Regulatory Manager
A. Stein-Regulatory Affairs Consulting Ltd.
20 Hata'as Str., Suite 102
Kfar Saba, 4442520 Il

Re: K182325
Trade/Device Name: InMode RF System
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting And Coagulation Device And Accessories
Regulatory Class: Class II
Product Code: GEI
Dated: August 22, 2018
Received: August 27, 2018

Dear Mr. 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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 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)*

K182325

Device Name
InMode RF system

Indications for Use *(Describe)*
The InMode RF System is indicated for use in dermatological and general surgical procedures for electro-coagulation and hemostasis

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(K) SUMMARY

INMODE RF SYSTEM

510(k) Number K 182325

Applicant Name:

Company Name: InMode MD Ltd

Address: Tabor Building, Shaar Yokneam
POB 44, Yokneam 20692
Israel
Tel: +972-4-9097470
Fax: +972-4-9097471
E-mail: amit@asteinrac.com

Contact Person:

Official Correspondent: Amit Goren

Company Name: A. Stein – Regulatory Affairs Consulting Ltd.

Address: 20 Hata'as Str., Suite 102
Kfar Saba 4442520 Israel
Tel: + 972-9-7670002
Fax: +972-9-7668534
E-mail: amit@asteinrac.com

Date Prepared: August 22, 2018

Trade Name: InMode RF System

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

Classification: Class II Medical Device

Predicate Device:

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

Device	Manufacturer	510(k) No.
InMode RF System	InMode MD Ltd.	K171593

Device Description:

The InMode RF System (InMode MD Ltd.) is a computerized system generating RF energy with integral temperature and impedance feedback mechanism for procedures requiring electrocoagulation and hemostasis. The InMode RF System constantly monitors the temperature and impedance of the target treatment tissue, automatically adjusting energy delivery to maintain effective and safe tissue heating.

The InMode RF System consists of an AC/DC power supply unit, RF generator, controller and user interface including touch screen. The RF hand piece is connected to the console via a cable and a foot switch activates the energy delivery to the hand piece. The hand piece is comprised of a disposable, single use; internal and external electrodes.

The InMode RF System is compatible with the following hand pieces:

- HP060909A (Non-sterilized)
- HP101306A (Non-sterilized/Sterilized)
- HP172206A (Non-sterilized/Sterilized)
- HP172246A (Non-sterilized/Sterilized)
- HP172248A (Sterilized)

Device Specifications:

Main Line Frequency (nominal)	50 - 60 Hz
Input Voltage (nominal)	100 - 240 VAC
Electrosurgical Unit dimensions (inch)	13.8''W x18.2''D x40''H
Platform weight (lb.)	33
RF Max Output Power (Watt)	40
RF Output Frequency (MHz)	1± 2%

Intended Use/Indication for Use:

The InMode RF System is indicated for use in dermatological and general surgical procedures for electrocoagulation and hemostasis.

Performance Standards:

InMode RF 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.
- AAMI / ANSI / ISO 11137-1:2006/(R)2010, Sterilization Of Health Care Products - Radiation - Part 1: Requirements For Development, Validation, And Routine Control Of A Sterilization Process For Medical Devices
- AAMI / ANSI / ISO 11137-2:2013, Sterilization Of Health Care Products - Radiation - Part 2: Establishing The Sterilization Dose.
- AAMI / ANSI / ISO 11737-1:2006 (R) 2011, Sterilization Of Health Care Products - Microbiological Methods - Part 1: Determination Of The Population Of Microorganisms On Product.
- AAMI / ANSI / ISO 11737-2:2009/(R) 2014, Sterilization Of Medical Devices - Microbiological Methods - Part 2: Tests Of Sterility Performed In The Definition, Validation And Maintenance Of A Sterilization Process.
- AAMI / ANSI / ISO 11607-1:2006/(R)2010, Packaging For Terminally Sterilized Medical Devices - Part 1: Requirements For Materials, Sterile Barrier Systems And Packaging Systems
- ASTM F1980-07 (Reapproved 2011), Standard Guide For Accelerated Aging Of Sterile Barrier Systems For Medical Devices.
- IEC 60601-1-6:2013-10; Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance- Collateral Standard: Usability.
- IEC 62366-1:2015 - Medical devices - Part 1: Application of usability engineering to medical devices [Including CORRIGENDUM 1 (2016)]

Non-Clinical (Bench) Performance Data:

The modified InMode RF System was evaluated in a bench test for its system performance specifications. The tests were performed in a similar manner as to the tests performed with the cleared predicate device. The results of the bench tests demonstrate that the modified InMode RF System performed as expected and in a similar fashion to the predicate device.

The modified device software/firmware was retested to verify the system configuration and the system integration with all of the ancillary hand pieces.

Animal Performance Data / Histology Data:

The thermal effects of the modified InMode RF System on the target tissue were evaluated in an *ex-vivo* study. The study was conducted on three different porcine tissue models (muscle, liver & fat) and included a single RF treatment followed by TTC staining analysis. The *ex-vivo* study results show that the modified InMode RF System is safe for use and effective in achieving the specified indications of dermatological and general electrocoagulation and hemostasis.

Clinical Performance Data:

Not Applicable

Substantial Equivalence:

The subject of this special 510(k) pre-market notification is the InMode RF System. It is composed of the same main device components as its predicate device the InMode RF System FDA cleared under 510(k) file No.K171593 except for the addition of two new hand piece versions; HP060909A and HP172248A. The modified InMode RF System, similarly to the FDA cleared, predicate device, generate its mechanism of operation using the same underlying technology for the same intended use. Delivery of monopolar RF energy through each specific hand piece is monitored and controlled by the device ESU. The user interface control panel provides the user with the optimal treatment settings. While using the modified or FDA cleared InMode RF System the user can decide on the optimal treatment settings and adjust these treatment settings through the control panel. Furthermore, the modified device, as the FDA cleared device, introduces similar safety features and comply with same relevant consensus standards.

The device modifications were evaluated under design control activities and in the frame of conformity with relevant consensus standards and all potential hazards were mitigated in a set of performance activities. Performance bench, ex-vivo and Software validation test results show that the modified InMode RF System was able to produce and deliver the desired RF energy according to the design requirements, which are comparable with the performance specifications of the predicate device. Labeling material was revised to support the device modifications. All performance activates show that the modifications made to the FDA cleared device do not pose any new safety and effectiveness concerns.

Conclusions:

Based on the comparison to the predicate device and on the performance testing, the modified InMode RF System is substantially equivalent to the predicate InMode RF System for the mentioned indication for use.