DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

January 4, 2016

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

Re: K151273
Trade/Device Name: InMode FRF Applicator
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: Class II
Product Code: OUH
Dated: December 1, 2015
Received: December 4, 2015

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,

David Krause -S

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)*
K151273

Device Name
InMode FRF Applicator

Indications for Use *(Describe)*
The InMode FRF Applicator 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.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"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 FRF APPLICATOR

510(k) Number K151273

Applicant Name:

Company Name: InMode MD Ltd.
Address: Tabor Building, Shaar Yokneam
Yokneam 20692
Israel
Tel: +972-4-9097470
Fax: +972-4-9097471
E-mail: ahava@asteinrac.com

Contact Person:

Official Correspondent: Ahava Stein
Company Name: A. Stein – Regulatory Affairs Consulting Ltd.
Address: 20 Hata'as Str., Suite 102
Kfar Saba 44425
Israel
Tel: +972-9-7670002
Fax: +972-9-7668534
E-mail: ahava@asteinrac.com

Date Prepared: December 29, 2015

Trade Name: InMode FRF Applicator

Classification Name: CFR Classification section 878.4400;
Classification Product Code: OUH
Subsequent Product Code: GEI

Classification: Class II Medical Device

Predicate Device:

The InMode FRF Applicator is substantially equivalent to the following predicate device;

Manufacturer	Device	510(k) No.
EndyMed Medical Ltd.	Intensif Applicator	K130501

Device Description:

The InMode FRF Applicator is a treatment hand piece attached the FDA cleared InMode WMFace treatment system (K140926).
The InMode WMFace device with the FRF Applicator employs fractional RF multi-electrode technology for procedures requiring electrocoagulation and hemostasis. The FRF Applicator is 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 WMFace device with the FRF Applicator consists of an AC/DC power supply unit, RF generator, controller and user interface including a LCD screen and functional buttons. The FRF Applicator is 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 pin array tip.

Following are the InMode WMFace device with the FRF Applicator specifications:
FRF Applicator RF Max Output Power: 65 Watt
FRF Applicator RF Output Frequency: 1[MHz] ± 2%
Dimension: 46cm W x 46cm D x 100cm H (14.2'' W x 14.2'' 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 FRF Applicator 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 FRF Applicator 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.

Biocompatibility & Sterilization

All of the InMode FRF Applicator tip materials are biocompatible.
The InMode FRF Applicator tip is for single use and provided non-sterile to the user. The user must follow the sterilization procedures as specified in the user manual and sterilize the Applicator tip in approximation to the treatment.

Non-Clinical (Bench) Performance Data:

Performance bench tests were conducted to measure the accuracy and consistency of the RF output parameters of the InMode FRF Applicator 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 FRF Applicator 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 FRF Applicator and tissue healing processes were evaluated in a pre-clinical study. The study was conducted on swine 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 FRF Applicator 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 indications for use and technological characteristics of the InMode FRF Applicator are substantially equivalent to the indications for use and technological characteristics of the EndyMed Intensif Applicator.

The design and components in the InMode FRF 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 of the InMode FRF Applicator were shown to be similar and yielded RF energy per pin values in the range of the EndyMed Intensif Applicator specifications. The safety features and compliance with safety standards in the InMode FRF Applicator 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 FRF Applicator 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, performance bench testing and animal pre-clinical 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 FRF Applicator is substantially equivalent to the predicate EndyMed Intensif Applicator, cleared under 510(k) K130501, and therefore, may be legally marketed in the USA.

Conclusions:
Conclusively, based on the performance testing, pre-clinical testing and comparison to predicate device, the InMode FRF Applicator is substantially equivalent to the EndyMed Intensif Applicator predicate device.