



Food and Drug Administration
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February 19, 2016

InMode MD Ltd.
% Ms. Ahava Stein
A.Stein- Regulatory Affairs Consulting Ltd.
20 Hata'as Str., Suite 102
Kfar Saba, 4442520 Israel

Re: K151793

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: January 17, 2016
Received: January 20, 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" (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.

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 -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

Indications for Use

510(k) Number (if known)

K151793

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.

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510(K) SUMMARY
INMODE RF SYSTEM

510(k) Number K151793

Applicant Name:

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Date Prepared: June 25, 2015

Trade Name: InMode RF System

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

Classification: Class II Medical Device

Predicate Device:

The InMode RF System is substantially equivalent to the following predicate device;

Manufacturer	Device	510(k) No.
ThermiGen Inc.	ThermiGen Symphony RF	K130689

Device Description:

The InMode RF System including the InMode RF Hand piece (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.

Following are the InMode RF System specifications:

RF Max Output Power: 20 Watt

RF Output Frequency: 1[MHz] \pm 2%

Dimension: 35cm W x 46cm D x 100cm H (14.2'' W x 18.2'' D x 40'' H)

Weight: 15 Kg (33 lbs)

Main Line Frequency (nominal): 50-60 Hz

Input Voltage (nominal): 100-240 VAC

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:

The InMode RF System 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:

A set of bench tests were performed to measure the accuracy and consistency of the device cut-off temperature outputs of the InMode RF Hand piece and compare them to the specific design requirements. The results of the bench tests demonstrate that the InMode RF System complies with the device design requirements; the cut off temperature measurements were validated and maintained constant as predetermined by the system operator.

Bench Top Tissue Performance Data / Histology Data:

The thermal effects of the InMode RF System on the target tissue were evaluated in an comparative *ex-vivo* study. The study was conducted on three different porcine tissue models (muscle, liver & fat) and included a single RF treatment followed by histology analysis (for the fat tissue specimens an additional TTC staining method was assessed). The *ex-vivo* study results demonstrated similar tissue/histological effects for the subject and predicate devices.

Clinical Performance Data:

Not Applicable

Substantial Equivalence:

Device Characteristic	InMode RF System K151793	ThermiGen Symphony RF K130689
Product Code, Class	GEI, Class II	GEI, Class II
IFU	The <i>InMode RF System</i> is indicated for use in dermatological and general surgical procedures for electrocoagulation and hemostasis.	The <i>Symphony RF System</i> and the probes that are used with it are indicated for use in dermatological and general surgical procedures for electrocoagulation and hemostasis.
RF Power	Up to 20 W	Up to 20 W
Internal Cut-Off	50-70oC	40-95oC
Treatment Time	15-120 sec	15-120 sec
RF Frequency	1 MHz	0.46 MHz
Tissue impedance	50 -300 Ohm	50 -300 Ohm

The indications for use and technological characteristics of the InMode RF System are substantially equivalent to the indications for use and technological characteristics of the ThermiGen Symphony RF System.

The design and components of the InMode RF System, including the console (with power supply, RF generator, controller and display panel) and the hand piece (with

cable, connector to console, handle and electrodes) are similar to the design and components found in the predicate ThermiGen Symphony RF System. The slight differences in the hand piece design do not raise new safety or effectiveness concerns. The performance specifications (including RF frequency, cut off temperature and pulse duration (treatment time)) of the InMode RF System were shown to be similar to those of the ThermiGen Symphony RF System. The safety features and compliance with safety standards in the InMode RF System 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 InMode RF System underwent performance testing, including software validation testing, electrical and mechanical safety testing according to IEC 60601-1 and IEC 60601-2-2, electromagnetic compatibility testing according to IEC 60601-1-2, bench testing and ex-vivo testing to evaluate the thermal effect of the device on the tissue. 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 RF System is substantially equivalent to the predicate ThermiGen Symphony RF System, cleared under 510(k) K130689, and therefore, may be legally marketed in the USA.

Conclusions:

Based on the performance testing, *ex-vivo* testing and comparison to predicate device, the InMode RF System is substantially equivalent to the ThermiGen Symphony RF System predicate device.