



Food and Drug Administration
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August 19, 2016

InMode MD Ltd.
Dr. Amit Goren, Regulatory Manager
A. Stein-Regulatory Affairs Consulting Ltd.
20 Hata'as Str., Suite 102,
Kfar Saba, 44442520 Israel

Re: K160329
Trade/Device Name: InMode System MiniFX Handpiece
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: GEI
Dated: July 10, 2016
Received: July 14, 2016

Dear Dr. 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.

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,

Christopher J. Ronk -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)

K160329

Device Name

InMode System MiniFX Handpiece

Indications for Use (Describe)

The InMode System with the WMbody Handpiece and the MiniFX Handpiece is intended for the treatment of the following medical conditions using non thermal RF combined with massage:

- Relief of minor muscle aches and pain, relief of muscle spasm, temporary improvement of local blood circulation.
- Temporary reduction in the appearance of cellulite.

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 SYSTEM MINIFX HANDPIECE

510(k) Number K160329

Applicant Name:

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Date Prepared: August 17, 2016

Trade Name: InMode System MiniFX Handpiece

Classification Name: CFR Classification section 878.4400;
Primary product code: PBX
Secondary product code: GEI

Classification: Class II Medical Device

Predicate Device:

The InMode System with the MiniFX Handpiece is substantially equivalent to the following predicate device:

Device	Manufacturer	510(k) No.
InMode WMBody	InMode MD Ltd.	K131362

Device Description:

The InMode System with the MiniFX Handpiece is designed to deliver non-thermal RF energy and mechanical vacuum skin massaging to the skin and subdermal fat. The device provides individual adjustment of non-thermal RF power to achieve maximum efficiency and safety for each patient. The ergonomic MiniFX Handpiece allows efficient treatment of the indicated body areas.

The InMode System with the MiniFX Handpiece consists of an AC/DC power supply unit, RF generator, controller and user interface including a LCD screen and functional buttons. The handpiece is connected to the console via a cable and a foot switch activates the energy delivery to the handpiece. The handpiece comprises a vacuum pump, vacuum chamber with two bipolar RF electrodes including a pressure and temperature sensors.

The MiniFX Handpiece is operated while continuously moving it over the treatment area. This ensures a uniform non-thermal RF energy distribution on the entire treatment area. The MiniFX Handpiece is comprised of the hand piece handle, a cable 250 cm long, and a connector which connects to the rear connector of the InMode System (FDA cleared K131362).

Device Specifications:

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

RF Output Power: 10-25 Watt

Maximum Temperature (skin surface): 41°C \pm 2°C

Intended Use/Indication for Use:

The InMode System with the WMbody Handpiece and the MiniFX Handpiece is intended for the treatment of the following medical conditions using non thermal RF combined with massage:

- Relief of minor muscle aches and pain, relief of muscle spasm, temporary improvement of local blood circulation.
- Temporary reduction in the appearance of cellulite.

Performance Standards:

The InMode System MiniFX Handpiece complies with the following voluntary recognized standards:

- IEC 60601-1, Medical Electrical Equipment - Part 1: General Requirements for Safety, 1988; Amendment 1, 1991-11, Amendment 2, 1995
- IEC 60601-1-2, (Second Edition, 2001), Medical Electrical Equipment - Part 1-2: General Requirements for Safety - Collateral Standard: Electromagnetic Compatibility -- Requirements and Tests

- IEC 60601-2-2 (2006): Medical Electrical Equipment - Part 2: Particular requirements for the safety of high frequency surgical equipment.

Non-Clinical (Bench) Performance Data:

Bench tests were conducted to evaluate the performance of the InMode MiniFX Handpiece. RF power output and temperature profile changes at different power settings were measured. The results of the bench test demonstrated that the InMode MiniFX Handpiece has the same RF output specifications as the predicate device. The temperature measurement test results indicated that when the device is operated in accordance with its instructions for use and in all treatment modes, a maximal temperature of 41°C is reached and maintained over 20 minutes. Therefore, the results of the bench tests demonstrated substantial equivalence of the new InMode System MiniFX Handpiece compared to the predicate InMode WMBody device.

Pre-Clinical (Animal Study) Performance Data:

Not Applicable

Clinical Performance Data:

Not Applicable

Cleaning, Sterilization, Shelf life and Biocompatibility:

The InMode MiniFX is a non-sterile, reusable device, intended for multiple patients. The device cleaning instructions are based on the cleaning instructions of the predicate device due to the fact that the MiniFX handpiece is made from the same materials as the predicate device handpiece materials and the handpiece design is similar to the predicate hand piece design. The shelf life expectancy of the device handpiece is 2 years, similarly to the predicate device. 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 System with the MiniFX Handpiece are substantially equivalent to the indications for use and technological characteristics of the predicate device.

The design and components of the InMode System with the MiniFX Handpiece, including the console and its components (i.e., power supply, RF generator, controller and display panel) and the handpiece applicators (including the cable and connector to console) are similar to the design and components found at the predicate device. The performance specifications (i.e., RF frequency, RF electrical power and mechanical vacuum massaging) of the InMode System with the MiniFX Handpiece are substantially equivalent to the performance specifications in the predicate device. The safety features and compliance with safety standards of the InMode System with the MiniFX Handpiece are similar to the safety features and compliance with safety standards of the

predicate device. Patient contact materials are identical. The minor differences in the technological characteristics do not raise new safety or effectiveness concerns and are demonstrated to be substantially equivalent through relevant performance tests, including temperature and RF output power testing. Furthermore, the new InMode System with the MiniFX Handpiece underwent additional performance tests, including software validation testing, electrical and mechanical safety testing according to IEC 60601-1, electromagnetic compatibility testing according to IEC 60601-1-2 and high frequency of surgical equipment according to IEC 60601-2-2. 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 System MiniFX Handpiece is substantially equivalent to the predicate InMode WMbody device, FDA cleared under 510(k) K131362 and therefore can be sold in the USA.