510(K) SUMMARY

INMODE SR DEVICE

510(k) Number K131362

Applicant Name:

Company Name: InMode MD Ltd.
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OCT 08 2013

Contact Person:

Official Correspondent: Ahava Stein
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Date Prepared: May 6, 2013

Trade Name: InMode WMbody Device

Classification Name: CFR Classification section 878.4810; (Product code NUV, ISA)

Classification: Class II Medical Device

Predicate Device:

The InMode WMbody device is substantially equivalent to the following predicate devices.

Manufacturer	Device	510(k) No.
Viora Ltd.	Reaction System	K090221

Device Description:

The InMode WMbody device is designed to deliver mechanical vacuum skin massaging and non-thermal RF energy to the skin and subdermal fat. RF energy does not cause thermal damage to the treated skin and adipose tissue.

The device provides individual adjustment of non-thermal RF power and vacuum pulse duration to achieve maximum efficiency and safety for each patient. The ergonomic hand piece allows efficient treatment of large tissue surfaces.

The InMode WMbody device consists of an AC/DC power supply unit, RF generator, controller and user interface including a LCD screen and functional buttons. The 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 comprises a vacuum pump, vacuum chamber with two electrodes and a pressure sensor.

Following are the InMode WMbody device specifications:
RF Output Power: 10-50 Watt
RF Output Frequency: 1[MHz] ± 2%
Dimension: 36cm W x 36cm 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 WMbody device is intended for the treatment of the following medical conditions, using the WMbody applicator for delivering non-thermal RF combined with massage:

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

Performance Standards:

The InMode WMbody Device has been tested and 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:

A bench test was performed to measure the accuracy of the RF output parameters in the InMode WMbody device and compare them to the RF output measurements in the predicate device (Viora Reaction System). The results of the bench test demonstrate that the InMode WMbody device has the same RF output specifications as the predicate Viora Reaction System and therefore, is substantially equivalent to the predicate device.

Clinical Performance Data:

Not Applicable

Substantial Equivalence:

The indications for use and technological characteristics of the InMode WMbody device are substantially equivalent to the indications for use and technological characteristics of the Viora Reaction device.

The design and components in the InMode WMbody device, including the console (with power supply, RF generator, controller and display panel) and the hand piece applicator (with cable, connector to console and vacuum pump) are similar to the design and components found in the predicate Viora Reaction device. The performance specifications (including frequency, non-thermal RF electrical power, pulse duration and vacuum power) of the InMode WMbody device are substantially equivalent to those in the Viora Reaction device. The safety features and compliance with safety standards in the InMode WMbody device 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 WMbody device underwent performance testing, including software validation testing (provided in Section 16) and electrical and mechanical safety testing according to IEC 60601-1 and electromagnetic compatibility testing according to IEC 60601-1-2 (provided in Section 17). These performance tests demonstrated that the minor differences in the device software and specifications meet the system requirements and do not raise new safety or effectiveness concerns.

Consequently, it can be concluded that the InMode WMbody device is substantially equivalent to the predicate Viora Reaction device, cleared under 510(k) K090221, and therefore, may be legally marketed in the USA.

Conclusions:

Based on the performance testing and comparison to predicate devices, the InMode WMbody device is substantially equivalent to the Viora Reaction predicate device.

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

Inmode Md Ltd.
% Ms. Ahava Stein
Regulatory Manager
20 Hata'as Street, Suite 102
Kfar Saba, 44425 Israel

October 8, 2013

Re: K131362
Trade/Device Name: Inmode WMbody device
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: Class II
Product Code: NUV, ISA
Dated: August 8, 2013
Received: August 22, 2013

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 Small Manufacturers, International and Consumer Assistance 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 Small Manufacturers, International and Consumer Assistance 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,

Mark N. Melkerson -S

Mark N. Melkerson
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K131362

Device Name: InMode WMbody Device

Intended Use Statement:

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- Temporary reduction in the appearance of cellulite.

Prescription Use __√__ (Per 21 C.F.R. 801 Subpart D) OR Over-The-Counter Use___ (Optional Format Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Long H. Chen -A Digitally signed by Long H. Chen -A DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, cn=Long H. Chen -A, 0.9.2342.19200300.100.1.1=1300369056 Date: 2013.10.04 10:17:00 -04'00' for MXM

(Division Sign-Off)
Division of Surgical Devices
510(k) Number: K131362