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

August 7, 2017

InMode MD Ltd.
% Amit Goren
Regulatory Manager
A. Stein- Regulatory Affairs Consulting Ltd.
20 Hata'as Str.
Suite 102
Kfar Saba, 44425 Israel

Re: K170738
Trade/Device Name: InMode Diolaze XL
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: GEX
Dated: July 4, 2017
Received: July 10, 2017

Dear Amit 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" (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,

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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K170738

Device Name
InMode Diolaze XL

Indications for Use *(Describe)*
The InMode Diolaze XL System is intended for hair removal and permanent hair reduction defined as stable, long-term reduction in hair counts at 6,9 or 12 months following a treatment regime.

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 DIOLAZE XL DEVICE

510(k) Number K170738

Applicant Name:

Company Name: InMode MD Ltd.
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E-mail: amit@asteinrac.com

Date Prepared: July 04, 2017

Trade Name: InMode Diolaze XL Device

Classification Name: CFR Classification section 878.4810; (Product code GEX)

Classification: Class II Medical Device

Predicate Device:

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

Manufacturer	Device	510(k) No.
Lumenis Ltd.	Lightsheer Desire (ET)	K151947

Device Description:

The InMode Diolaze XL device is designed to deliver optical energy to the skin via a pre-cooled sapphire block. The good optical contact between the sapphire block and skin is achieved by using water based gel. The device provides individual adjustment of light fluence and pulse duration to achieve maximum efficiency and safety for each patient. The hand piece has integrated skin cooling to enhance safety and comfort of the treatment.

The InMode Diolaze XL device consists of an AC/DC power supply unit, a diode driver, water cooling system, controller and a touch screen user interface. The 810nm diode laser 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 the InMode Diolaze XL with 20 diode laser bars stacked vertically. The diode is enclosed to the sapphire light guide. The diode laser produces up to 3000W peak optical power.

Following are the InMode Diolaze XL device specifications:

Laser Output Parameters:

Wavelength	810 nm
Fluence	5-40 J/cm^2
Pulse width (duration)	5-200 ms (pulse type : Short/Long)
Light guide cooling	Strong: 7ºC, Normal: 12ºC
Spot size	11mm x27.5 mm
Dimensions:	46cm W x 46cm D x 100cm H (18.2'' W x 18.2'' D x 40'' H)
Weight:	32 Kg (70.548 lbs)
Main Line Frequency (nominal):	50-60 Hz
Input Voltage (nominal):	100-240 VAC

Intended Use/Indication for Use:

The InMode Diolaze XL System is intended for hair removal and permanent hair reduction defined as the stable, long-term reduction in hair counts at 6, 9, or 12 months following a treatment regime.

Performance Standards:

The InMode Diolaze XL Device has been tested and complies with the following voluntary recognized standards:

- AAMI ANSI: ES 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 60601-1-2:2007-03(Modified), Medical Electrical Equipment Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests
- IEC 60601-2-22 Edition 3.1 2012-10, Medical electrical equipment - Part 2-22: Particular requirements for basic safety and essential performance of surgical, cosmetic, therapeutic and diagnostic laser equipment
- IEC 60825-1: Edition 2.0 2007-03, Safety of laser products - Part 1: Equipment classification and requirements [Including: Technical Corrigendum 1 (2008), Interpretation Sheet 1 (2007), Interpretation Sheet 2 (2007)].

Non-Clinical Performance Data:

The InMode Diolaze XL device laser output parameters were evaluated as part of the test performance evaluation conducted in adherence with the FDA recognized consensus standards 60601-1, 60601-1-2, 60601-2-22 and 60825. The results of these performance tests demonstrated that the InMode Diolaze XL device operates in accordance with the device design requirements and performs within the range of laser specifications as to that of the predicate device and therefore, is substantially equivalent to the predicate device.

Pre-Clinical Performance Data:

Not Applicable

Clinical Performance Data:

Not Applicable

Substantial Equivalence:

The following table presents a comparison between the subject device and its predicate device:

Technological Characteristic	**InMode Diolaze XL InMode MD Ltd.**	**LightSheer Desire, ET (Lumenis Ltd.) K151947**
Product Code, Class	GEX, Class II	GEX, Class II
Indications for Use	Hair removal and permanent hair reduction defined as the stable, long-term reduction in hair counts at 6, 9, or 12 months following a treatment regime.	Hair removal and permanent hair reduction defined as the stable, long-term reduction in hair regrowing when measured at 6, 9, or 12 months after the completion of treatment regime.
Target Population	Subjects seeking hair removal	Subjects seeking hair removal
Wavelength	808 nm	805 nm, ET (two handpiece options are available 790-830)
Fluence	5-40 J/cm^2	10-100 J/cm^2
Pulse duration	5-200 msec	5-400 msec
Cooling temperature	Skin sapphire cooling	Chilled sapphire tip water-cooled

The indications for use of the InMode Diolaze XL device are substantially equivalent to the indications for use of predicate device and are identical to the indications for use of the InMode Diolaze device (cleared as 510 (k) 142952). The design and components in the InMode Diolaze XL device, including the console (with power supply, software, cooling system and touch screen user interface), the water-cooled hand piece connected to the console via a cable and the foot switch are identical to the design and components found in the InMode Diolaze device (cleared as 510 (k) 142952) and very similar to those of the predicate device. The performance specifications (including wavelength, fluence, pulse width, pulse repetition rate, spot size and cooling) in the InMode Diolaze XL device are very similar to those at the predicate device. The safety features in the InMode Diolaze XL device are substantially equivalent to the safety features found in the predicate device. Consequently, the InMode Diolaze XL device is substantially equivalent to the Lightsheer Desire (ET) predicate device, cleared in 510(k) K151947, and therefore, may be legally marketed in the USA.

Conclusions:

Based on the performance testing and comparison to predicate device, the InMode Diolaze XL device is as safe and effective as the predicate device and consequently is substantially equivalent to the predicate device and can be sold in the US market.