



June 14, 2018

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

Re: K180719

Trade/Device Name: InMode Diolaze System
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: March 12, 2018
Received: March 19, 2018

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.

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 comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (<https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/>) and CDRH Learn (<http://www.fda.gov/Training/CDRHLearn>). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (<http://www.fda.gov/DICE>) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

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

Indications for Use

510(k) Number (if known)

K180719

Device Name

InMode Diolaze XL System

Indications for Use (Describe)

The InMode Diolaze XL System with the Diolaze XL 810nm Hand piece 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 regimen. The InMode Diolaze XL System with the Diolaze XL 755/810nm & 810/1064nm Hand pieces is intended for hair removal.

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 SYSTEM

510(k) Number K180719

Applicant Name:

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Date Prepared: March 12, 2018

Trade Name: InMode Diolaze XL System

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

Classification: Class II Medical Device

Predicate Device:

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

Manufacturer	Device	510(k) No.
Asceplion Laser Technologies GmbH	MedioStar NeXT Family (ALX)	K143519
InMode MD Ltd.	InMode Diolaze XL	K170738
Lutronics Corp.	Advantage	K141555

Device Description:

The InMode Diolaze XL multisystem (manufactured by InMode MD Ltd.) is a laser based technology platform system utilizing different hand pieces for laser hair removal procedures. The Diolaze XL system was already FDA cleared in K170738 along with its designated Diolaze 810nm hand piece.

The InMode Diolaze XL System 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 handpiece has integrated skin cooling to enhance safety and comfort of the treatment.

The InMode Diolaze XL System consists of an AC/DC power supply unit, a diode driver, water cooling system, controller and a touch screen user interface. The 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 System 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.

The InMode Diolaze XL System utilizes three add-ons diode laser hand pieces:

- Diolaze 810nm Hand piece (FDA cleared in K170738)
- Diolaze 755/810nm Hand piece
- Diolaze 810/1064nm Hand piece

Following are the InMode Diolaze XL System specifications:

Laser Output Parameters:

Wavelengths	810 nm 810/1064 nm 755/810 nm
Fluence	5-40 J/cm ²
Pulse width (duration)	5-200 ms (pulse type : Short/Long)
Light guide cooling	Strong: 7°C, Normal: 12°C
Spot size	11x 27.5 mm ²
Dimension:	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 with the Diolaze XL 810nm Hand piece 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.

The InMode Diolaze XL System with the Diolaze XL 755/810nm & 810/1064nm Hand pieces is intended for hair removal.

Performance Standards:

The InMode Diolaze XL System 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 System 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 60825-1. The results of these performance tests demonstrated that the InMode Diolaze XL System operates in accordance with the device design requirements and performs within the range of laser specifications as to that of the predicate devices and therefore, is substantially equivalent to the predicate devices. Additionally, the device SW was validated in accordance with the FDA recognized consensus standard IEC 62304:2004 to IEC 62304 – 2006/AC 2008.

Pre-Clinical Performance Data:

Not Applicable

Clinical Performance Data:

A proscription, open labeled, multicenter, single arm Clinical study was conducted to evaluate the efficacy and safety of the InMode Diolaze XL System with the Diolaze 755/810nm and 810/1064nm hand pieces. The study performed on 31 female subjects, aged between 18-65 years old, comprise three consecutive hair removal laser treatment, 4 weeks apart, and a follow up visit scheduled 3months from last laser treatment. The subjects were treated on their axilla, and groin areas with either the 755/810nm hand piece or the 810/1064nm hand piece. The treatment area was photographed following treatment and at follow up visit. Photography hair counts were performed by three independent, blinded evaluators and a statistical comparison was conducted between baseline hair counts and 3 months follow up hair counts. Study results revealed that a significant reduction in hair count was demonstrated for both hand pieces and at both treatment areas. An average hair reduction of 49.2% was reached. No adverse events were reported in the study.

Substantial Equivalence:

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

Technological Characteristic	InMode Diolaze XL System InMode MD Ltd.	InMode Diolaze XL System (InMode MD Ltd.) K170738	Advantage (Lutronics Corp.) K141555	MedioStar, ALX (Asceplion Laser Technologies GmbH) K143519
Product Code, Class	GEX, Class II	GEX, Class II	GEX, Class II	GEX, Class II
Indications for Use	The InMode Diolaze XL System with the Diolaze XL 810nm Hand piece 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. The InMode	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.	Is intended for hair removal, permanent hair reduction (defined as long term stable reduction in the number of hairs regrowing after the last treatment measured at 6,9 and 12 months	Hair removal and permanent hair reduction defined as reduced growth with or without maintenance when measured at 6, 9, or 12 months

Technological Characteristic	InMode Diolaze XL System InMode MD Ltd.	InMode Diolaze XL System (InMode MD Ltd.) K170738	Advantage (Lutronics Corp.) K141555	MedioStar, ALX (Asceplion Laser Technologies GmbH) K143519
	Diolaze XL System with the Diolaze XL 755/810nm & 810/1064nm Hand pieces is intended for hair removal.			
Target Population	Subjects seeking hair removal	Subjects seeking hair removal	Subjects seeking hair removal	Subjects seeking hair removal
Wavelength	810 nm 810/1064 nm 755/810 nm	810nm	1064 nm	755 nm, ALX (several hand pieces are available as an option that are 755-950nm))
Fluence	5-40 J/cm ²	5-40 J/cm ²	5-100 J/cm ²	Maximum fluence: 35 J/cm ²
Pulse duration	5-200 msec	5-200 msec	5-400 msec	Max pulse duration: 400 msec
Cooling temperature	Skin sapphire cooling	Skin sapphire cooling	Contact cooling chilled compression tip	Skin cooling: Contact skin cooling by cold aluminum probe (chilled compression tip). Integrated water compressor cooling system
Spot size	11x27.5mm ²	11x27.5mm ²	10x10mm ²	13x10mm ²

The indications for use of the InMode Diolaze XL System are substantially equivalent to the indications for use of predicate devices and are identical to the indications for use of the InMode Diolaze XL device (cleared as 510 (k) 170738). The design and components in the InMode Diolaze XL System, 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) 170738) and very similar to those of the predicate devices. The performance specifications (including wavelength, fluence, pulse width, spot size and cooling) in the InMode Diolaze XL System are very similar to the predicate devices. The safety features in the InMode Diolaze XL System are substantially equivalent to the safety features found in the predicate devices. Consequently, the InMode Diolaze XL System is substantially equivalent to the MedioStar NeXT Family (ALX) predicate device, cleared in 510(k) K143519, the InMode Diolaze XL System predicate device, cleared in 510(k) K170738,

and to the Advantage predicate device, cleared in 510 (k) K141555 and therefore, may be legally marketed in the USA.

Conclusions:

Based on the performance testing, clinical study and comparison to predicate devices, the InMode Diolaze XL System is as safe and effective as its predicate devices and consequently is substantially equivalent to the predicate devices listed above.