February 23, 2018

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

Re: K173677
Trade/Device Name: InMode VLaze
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: November 27, 2017
Received: November 30, 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.

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.

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K173677

Device Name
InMode VLaze

Indications for Use *(Describe)*
The InMode VLaze is intended for the treatment of vascular lesions, including angiomas, hemangiomas, telangiectasia, port wine stains, leg veins and other benign vascular lesions.

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 VLAZE DEVICE
510(k) Number K173677

Applicant Name:

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Date Prepared: February 4, 2018

Trade Name: InMode VLaze Device

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

Classification: Class II Medical Device

Predicate Device:

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

Manufacturer	Device	510(k) No.
Lumenis Ltd.	ET Lightsheer 1060	K133319
Quanta System SPA	EVO Platform	K160368
InMode MD Ltd.	InMode Diolaze XL	K170738

Device Description:

The InMode VLaze device is designed to deliver diode laser 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 VLaze device 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 VLaze device laser with linear scanning system, cooled sapphire output window (3 x 4mm^2), and electronic shutter.

The sapphire light guide is located on the front tip of the hand piece and delivers the laser beam energy to the treated tissue, while cooling the skin. The pair of thermoelectric coolers (TECs) located on both sides of the sapphire block provide cooling to a temperature of 7ºC. The hand piece contains a trigger button which starts the laser scan and radiation. Fluence is delivered within the limits of 40 to 300J/cm^2. The hand piece has a cable that is 170cm long and connects the hand piece to the console via a connector.

InMode VLaze Device Specifications:

Wavelengths	1060nm ± 15nm
Fluence	40 - 300 J/cm^2
Pulse width (duration)	5-100msec
Light guide cooling	Strong :7ºC, Normal:12 ºC
Spot size	3mm x 4mm
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 VLaze is intended for the treatment of vascular lesions, including angiomas, hemangiomas, telangiectasia, port wine stains, leg veins and other benign vascular lesions.

Performance Standards:

The InMode VLaze device was tested and complies with the voluntary performance standards listed below:

- IEC 60601-1: 2005 (Third Edition) + CORR.1 2006 + CORR.2 2007 + A1:2012 Medical Electrical Equipment - Part 1: General Requirements for Safety.
- IEC 60601-1-2, 2007 (Third Edition), Medical Electrical Equipment - Part 1-2: General Requirements for Safety - Collateral Standard: Electromagnetic Compatibility -- Requirements and Tests
- IEC 60825-1:2007 (Second Edition) - Safety of laser products, Part 1: Equipment classification and requirements.
- IEC 60601-2-22:2007 (Third Edition) + A1:2012 for use in conjunction with IEC 60601-1:2005 (Third Edition) + A1:2012 – Medical Electrical Equipment – Part 2-22: Particular requirements for basic safety and essential performance of surgical, cosmetic, therapeutic and diagnostic laser equipment.

Non-Clinical Performance Data:

The device laser performance specifications and system requirements were evaluated as part of the compliance tests to the IEC 60601-1, IEC 60601-2-22 and IEC 60825-1 standard requirements. The test results show that the device performance specifications meet the system requirements.

Clinical Performance Data:

Not Applicable

Substantial Equivalence:

The indications for use of the InMode VLaze device are substantially equivalent to the indications for use of the ET Lightsheer 1060 and of the EVO platform predicate devices. The design and components in the InMode VLaze device, including the console (with power supply, software, cooling system and touch screen user interface), the water-cooled hand piece (with cable and connector to console) and the foot switch are based on to the design and components found in the InMode Diolaze XL (same platform system) and are similar to the ET Lightsheer 1060 and EVO platform predicate devices. The performance specifications (including wavelength, pulse width, pulse repetition rate, spot size and cooling temperature) in the InMode VLaze device are similar to performance specifications of the ET Lightsheer 1060 and EVO platform predicate devices. The safety features in the InMode VLaze device are substantially equivalent to the safety features found in the predicate devices. Consequently, the InMode VLaze device is substantially equivalent to the ET Lightsheer 1060 predicate device cleared in 510(k) K133319, to the EVO platform predicate device, cleared in 510(k) K160368 and to the InMode Diolaze XL predicate device, cleared in 510(k) K170738and therefore, may be legally marketed in the USA.

Conclusions:

Based on the performance testing and comparison to predicate devices, the InMode VLaze device is substantially equivalent to the predicate devices listed above.