July 20, 2023

InMode Ltd.
℅ Janice Hogan
Partner
Hogan Lovells US LLP
1735 Market Street, Suite 2300
Philadelphia, Pennsylvania 19103

Re: K231790
Trade/Device Name: The InMode System with the Morpheus8 Applicators
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: Class II
Product Code: GEI
Dated: June 20, 2023
Received: June 20, 2023

Dear Janice Hogan:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Mark Trumbore -S

Digitally signed by Mark Trumbore -S
Date: 2023.07.20 10:51:15 -04'00'

Mark Trumbore, Ph.D.
Assistant Director
DHT4A: Division of General Surgery Devices
OHT4: Office of Surgical and Infection Control Devices
Office of Product Evaluation and Quality
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: 06/30/2023
See PRA Statement below

510(k) Number *(if known)*

Device Name

The InMode System with the Morpheus8 Applicators

Indications for Use *(Describe)*

The InMode System with the Morpheus8 Applicators is intended for use in dermatologic procedures where coagulation/contraction of soft tissue or hemostasis is needed.
At higher energy levels greater than 62 mJ/pin, the use of the Morpheus8 Applicator is limited to Skin Types I-IV.

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 WITH THE MORPHEUS8 APPLICATORS

Applicant Name:

Company Name: InMode MD Ltd.

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Tel: +972-4-9097470
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Contact Person:

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Date Prepared: July 20, 2023

Trade Name: InMode System with the Morpheus8 Applicators

Classification Name: CFR Classification section 878.4400; (Product code GEI)

Classification: Class II Medical Device

Predicate Device:

The InMode System with the Morpheus8 Applicators is substantially equivalent to the InMode System with the Morpheus8 Applicators (K200947)

Purpose of the Special 510(k) notice:

The InMode System with the Morpheus8 Applicators is a expansion of indications for the cleared InMode System with the Morpheus8 Applicators (K200947).

Intended Use:
The InMode System with the Morpheus8 Applicators is intended for use in dermatologic procedures where coagulation/contraction of soft tissue or hemostasis is needed.

At higher energy levels greater than 62 mJ/pin, the use of the Morpheus8 Applicator is limited to Skin Types I-IV.

Device Description:

The InMode System with the Morpheus8 Applicators is a RF technology based device intended for dermatological applications which require coagulation/contraction of soft tissue or hemostasis.

The device platform is identical to the one in FDA-Cleared InMode System with the Morpheus8 Applicators (K200947), inclusive of minor software modifications, cleared in K210492 and K221571. The InMode System with the Morpheus8 Applicators employs fractional RF multi-electrode technology for procedures requiring electrocoagulation and hemostasis. The Morpheus8 Applicators are designed to deliver radiofrequency energy to the skin in a fractional manner, via an array of multi-electrode pins. The device provides enhanced safety while minimizing possible side effects by monitoring RF parameters.

The InMode System with the Morpheus8 Applicators consists of an AC/DC power supply unit, RF generator, controller and user interface including LCD touch screen. The Morpheus8 Applicators are connected to the console via a cable and a foot switch activates the energy delivery to the applicator. The device has two Applicators which can be connected to the platform, one at the time. The Morpheus8 Applicator comprises a handle and detachable, sterilized, disposable, single-use 12, 24, and T tip head accessories. The Morpheus8 Body Applicator is identical except that the compatible tip head is a 40 pin tip head.

Following are the InMode System with the Morpheus8 Applicators specifications:

RF Max Output Power:	65 Watt
RF Output Frequency:	1 MHz
Dimension:	46cm W x 46cm D x 100cm H (18.2'' W x 18.2'' D x 40'' H)
Weight:	30 Kg (70.4 lbs.)
Main Line Frequency:	50-60 Hz
Input Voltage (nominal):	100-240 VAC

Performance Standards:

The InMode System with the Morpheus8 Applicators has been tested and complies with the following voluntary recognized standards:

- ANSI AAMI 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 60601-1-2 Edition 4.0 2014-02 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests.
- IEC 60601-2-2 Edition 6.0 2017-03 Medical electrical equipment - Part 2-2: Particular requirements for the basic safety and essential performance of high frequency surgical equipment and high frequency surgical accessories.

Non-Clinical (Bench) Performance Data:

No new bench performance data is submitted to support this submission. However, the following bench testing, submitted in K200947, is leveraged to support the expansion of Indications for Use and associated changes in labeling. The performance and safety of the InMode System with the Morpheus8 Applicators treatment in dermatological procedures was evaluated in an ex-vivo tissue study. The study was conducted on two different harvested porcine tissues, muscle and fat, utilizing the InMode System with the Morpheus8 applicator. Treatment was followed by biopsy sampling of slices and immediately stained to visualize the tissue coagulation necrosis pattern. The ex-vivo study results demonstrate that the Morpheus8 Applicators perform as intended for the specified indications.

Animal Performance Data / Histology Data:

No new animal performance data is submitted to support this submission.

Clinical Performance Data:

Not Applicable

Substantial Equivalence:

The indications for use and technological characteristics of the InMode System with the Morpheus8 Applicators are substantially equivalent to the indications for use and technological characteristics of the FDA-Cleared InMode System with the Morpheus8 Applicators (K200947).

The design and components in the InMode System, including the console (with power supply, RF generator, controller and display panel) and the Applicator (with cable, connector to console, handle and tip) are similar to the design and components found in the predicate. The safety features and compliance with safety standards in the InMode System with the Morpheus8 Applicators are identical to the safety features and compliance with safety standards found in the predicate device. Patient contact materials are also identical. Any minor modifications in the technological characteristics do not raise new safety or effectiveness concerns.

Furthermore, the previously cleared InMode System with the Morpheus8 Applicators underwent performance testing, including software validation testing, electrical and mechanical safety testing according to IEC 60601-1 and electromagnetic compatibility testing according to IEC 60601-1-2 and IEC 60601-2-2, comparative bench testing and *ex-vivo* tissue testing to evaluate the fractional coagulation necrosis pattern of target tissues, formed by thermal effect of the InMode System with the Morpheus8 Applicators in different tissue depths. These performance tests demonstrated that the device’s performance and specifications meet the system requirements. These performance tests are

equally relevant to the current submission.

Any change in the wording of the indications does not refer to a different intended use nor a different performance claim, and thus no additional performance testing is required.

Consequently, it can be concluded that the InMode System with the Morpheus8 Applicators is substantially equivalent to the predicate InMode System with the Morpheus8 Applicators, FDA-Cleared in K200947, and may, therefore. be legally marketed in the USA.