June 13, 2024

InMode Ltd.
% Janice Hogan
Partner
Hogan Lovells US LLP
1735 Market Street, Floor 23
Philadelphia, Pennsylvania 19103

Re: K240017
Trade/Device Name: InMode System with the Morpheus8 90 Applicator
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: Class II
Product Code: GEI
Dated: NA
Received: May 16, 2024

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Long H. Chen -S

Digitally signed by Long H. Chen -S
Date: 2024.06.13 07:46:52 -04'00'

Long Chen, Ph.D.
Assistant Director
DHT4A: Division of General Surgery Devices
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Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K240017

Device Name

InMode System with the Morpheus8 90 Applicator

Indications for Use *(Describe)*

The InMode System with the Morpheus8 90 Applicator is intended for use in dermatological 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 90 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) #: K240017

510(k) Summary

Prepared on: 2024-06-11

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	InMode Ltd.
Applicant Address	Tabor Building, Shaar Yokneam POB 44 Yokneam Illit 2069200 Israel
Applicant Contact Telephone	+972-4-9097470
Applicant Contact	Mrs. Suhair Francis
Applicant Contact Email	Suhair.Francis-Najjar@inmodemd.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	InMode System with the Morpheus8 90 Applicator
Common Name	Electrosurgical cutting and coagulation device and accessories
Classification Name	Electrosurgical, Cutting & Coagulation & Accessories
Regulation Number	878.4400
Product Code	GEI

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K180189	InMode System with Fractora3D/3D-90 Applicators	GEI
K200947	InMode System with the Morpheus8 Applicators	GEI

Device Description Summary

21 CFR 807.92(a)(4)

The InMode System with the Morpheus8 90 Applicator 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 Fractora3D 90 Applicator (K180189), inclusive of minor software modifications. The InMode System with the Morpheus8 90 Applicator employs fractional RF multi-electrode technology for procedures requiring electrocoagulation and hemostasis. The Morpheus8 90 Applicator is 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 90 Applicator consists of an AC/DC power supply unit, RF generator, controller and user interface including LCD touch screen. The Morpheus8 90 Applicator is connected to the console via a cable and a foot switch activates the energy delivery to the applicator. The Morpheus8 90 Applicator comprises a handle and a detachable, sterilized, disposable, single-use 24 pin tip head accessory.

Following are the InMode System with the Morpheus8 90 Applicator 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

Intended Use/Indications for Use 21 CFR 807.92(a)(5)

The InMode System with the Morpheus8 90 Applicator is intended for use in dermatological 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 90 Applicator is limited to Skin Types I-IV.

Indications for Use Comparison 21 CFR 807.92(a)(5)

The device has similar indications for use as the predicate. Specifically, An additional change for this 510(k) submission consists of modified indications for use; the mention of "coagulation/contraction of soft tissue" is added to the indications. This change in the wording of the indications does not refer to a different intended use nor a different performance claim.

Technological Comparison 21 CFR 807.92(a)(6)

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 identical to the design and components found in the primary predicate device (K180189) except for minor design changes to the handle to improve ergonomics and manufacturing process. The safety features and compliance with safety standards in the InMode System with the Morpheus8 90 Applicator are identical to the safety features and compliance with safety standards found in the primary predicate device. (K180189). Patient contact materials are also identical.

Non-Clinical and/or Clinical Tests Summary & Conclusions 21 CFR 807.92(b)

The current system is a modification to InMode's system with the Fractora 3D 90 Applicator cleared for dermatological procedures for electrocoagulation and hemostasis (K180189).

The subject of the current 510(k) is to clear the Fractora 3D 90 for a treatment depth of up to 7mm. This change is implemented via software only.

No clinical data was submitted.

Performance testing which supported the primary predicate device (K180189), remains applicable, 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, bench testing, and ex-vivo tissue testing to evaluate the fractional coagulation necrosis pattern of target tissues formed by thermal effect. These performance tests demonstrated that the device's performance and specifications meet system requirements.

Further, ex-vivo testing was performed with the secondary predicate device K200947 up to a treatment depth of 7 mm. This testing is equally relevant to the current submission. Additional testing was provided in this submission comparing the thermal effect of the subject device to the primary predicate up to a treatment depth of 7 mm. Thus, the data and information provided demonstrates the subject device is substantially equivalent to and is as safe and as effective as the predicate device.