March 20, 2024

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

Re: K233642
Trade/Device Name: InMode RF System
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: Class II
Product Code: GEI
Dated: March 7, 2024
Received: March 7, 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,

Mark Trumbore -S Digitally signed by Mark Trumbore -S
Date: 2024.03.20 15:23:41 -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: 07/31/2026
*See PRA Statement below.*

Submission Number *(if known)*

K233642

Device Name

InMode RF System

Indications for Use *(Describe)*

The InMode RF System is indicated for use in dermatological and general surgical procedures where coagulation/contraction of soft tissue or hemostasis is needed.

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.**

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) #: K233642

# 510(k) Summary

Prepared on: 2024-03-19

## 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 | Francis-Najjar@inmodemd.com |

## Device Name

21 CFR 807.92(a)(2)

| | |
|---|---|
| Device Trade Name | InMode RF System |
| 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 |
|---|---|---|
| K182325 | InMode RF System | GEI |
| K231790 | InMode System with the Morpheus8 Applicators | GEI |

## Device Description Summary

21 CFR 807.92(a)(4)

The InMode RF System (InMode MD Ltd.) is a computerized system generating RF energy with integral temperature and impedance feedback mechanism for procedures requiring electrocoagulation/contraction of soft tissue and hemostasis. The InMode RF System constantly monitors the temperature and impedance of the target treatment tissue, automatically adjusting energy delivery to maintain effective and safe tissue heating.
The InMode RF System consists of an AC/DC power supply unit, RF generator, controller and user interface including touch screen. The RF handpiece is connected to the console via a cable and a foot switch activates the energy delivery to the hand piece. The handpiece is comprised of a disposable, single use plastic handle with internal and external electrodes.

## Intended Use/Indications for Use

21 CFR 807.92(a)(5)

The InMode RF System is indicated for use in dermatological and general surgical procedures where coagulation/contraction of soft tissue or hemostasis is needed.

## Indications for Use Comparison

21 CFR 807.92(a)(5)

The indications for use and technological characteristics of the InMode RF System are substantially equivalent to the indications for use and technological characteristics of the FDA-Cleared InMode RF System (K182325).

The indications for use are slightly different in that the indications for the modified system include now the mention of “coagulation/

contraction of soft tissue". This change is made for marketing purposes and does not involve any change to the intended user population, treatment area or other treatment parameters.

## Technological Comparison

21 CFR 807.92(a)(6)

The technological characteristics of the InMode RF System are substantially equivalent to the indications for use and technological characteristics of the FDA-Cleared InMode RF System (K182325).

The design and components in the InMode System, including the console (with power supply, RF generator, controller and display panel) and the handpieces (with cable, connector to console, handle and RF energy delivering electrodes) are similar to the design and components found in the predicate. The safety features and compliance with safety standards in the modified InMode RF System are identical to the safety features and compliance with safety standards found in the predicate device. Patient contact materials are also identical.

The cleared InMode RF System is compatible with the following handpieces: HP060909A; HP101306A; HP172206A; HP172246A; HP172248A. The modified InMode RF System includes the addition of two new handpieces: HP102206A and HP253966A. No changes are made to the already cleared system handpieces. The fundamental technology of the system is not altered. The new handpieces use the same technology and principles of operation and have the same power density and a similar geometry as the already cleared device. Any minor modifications in the technological characteristics do not raise new safety or effectiveness concerns.

The InMode RF System 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. Furthermore, the previously cleared system underwent comparative bench testing and ex-vivo tissue testing to evaluate the thermal effect of the InMode RF System. 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.

Consequently, it can be concluded that the InMode RF System is substantially equivalent to the predicate InMode RF System, FDA Cleared in K182325, and may, therefore be legally marketed in the USA.

## Non-Clinical and/or Clinical Tests Summary & Conclusions

21 CFR 807.92(b)

Ex vivo tissue study results demonstrate the safety and efficacy of thermal effects of the new handpieces on three different tissue types, muscle, liver, and fat.
A nonclinical performance test shows that RF frequency and output of the new handpieces is as predicted with respect to RF specifications (waveform, amplitude, frequency, crest factor).
A nonclinical power density demonstrates virtually identical RF power density for the predicate and subject handpieces based on measurements of tissue thermal response.