January 15, 2026

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

Re: K251254
Trade/Device Name: Ignite 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: April 23, 2025
Received: December 17, 2025

Dear Janice M. 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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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,

Colin K. Chen -S
Digitally signed by Colin K. Chen -S
Date: 2026.01.15 11:37:49 -05'00'

Colin K. Chen, Ph.D.
Acting 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)*

K251254

Device Name

Ignite RF System

Indications for Use *(Describe)*

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

Morpheus8: At higher energy levels greater than 62 mJ/pin, the use of the Morpheus8 Burst and Burst Deep 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.

K251254

510(k) SUMMARY

InMode Ltd.'s InMode RF System

Applicant Name and Contact Person

InMode Ltd.
Tabor Building, Shaar Yokneam POB 44
Yokneam Illit
2069200 Israel

Phone:+972-4-9097470
Email: Francis-Najjar@inmodemd.com
Contact Person: Mrs. Suhair Francis

Date Prepared: January 14, 2026

Name of Device

Ignite RF System

Name/Address of Sponsor

InMode Ltd.
Tabor Building, Shaar Yokneam POB 44
Yokneam Illit
2069200 Israel

Classification Name: Electrosurgical cutting and coagulation device and accessories

Regulation Number: 878.4400

Product Code: GEI

Predicate Devices

InMode RF system - K240780;

InMode System with the Morpheus8 Applicators - K231790.

Intended Use / Indications for Use

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

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

Technological Characteristics

The Ignite RF System is a computerized system generating RF energy for procedures requiring electrocoagulation/contraction of soft tissue and hemostasis.
The Ignite RF System consists of an AC/DC power supply unit, RF generator, controller and user interface including touch screen. The RF handpieces are connected to the console via a cable and a

foot switch activates the energy delivery to the handpiece. Multiple handpieces are available. The System is compatible with the following handpieces:

- Monopolar ("RFAL") handpieces: These handpieces are comprised of a disposable, single use plastic handle with active internal electrodes and external (return) electrodes. Both internal and external temperature are constantly monitored.
- Bipolar ("Quantum") handpieces: comprised of a disposable, single use plastic handle with active internal bipolar electrodes and no external electrodes. Control of the thermal effect is by selection of delivered amount of energy.
- Morpheus8 Burst/Burst Deep handpieces: the Morpheus8 Applicators are designed to deliver radiofrequency energy to the skin in a fractional manner, via an array of multi-electrode pins. The Morpheus8 Applicator comprises a handle and detachable, sterilized, disposable, single-use tip head accessories. Control of the thermal effect is by selection of delivered amount of energy.

Substantial Equivalence

Indications for Use Comparison

The indications for use of the RF Ignite System and handpieces are identical to the indications for use of the FDA-cleared predicate systems with respective handpieces.

Technological Comparison

The technological characteristics of the Ignite RF System and handpieces are substantially equivalent to the technological characteristics of the FDA-cleared predicate systems with respective handpieces (InMode RF system - K240780; InMode System with the Morpheus8 Applicators - K231790).

The design and components in the Ignite RF 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 also similar to the safety features and compliance with safety standards found in the predicate device. Patient contact materials are also identical. There are no new handpieces. The underlying technology of the system is not altered and any modifications in the technological characteristics, including the addition (for the Morpheus8 handpieces) of the new Burst and Scale Modes delivering several pulses at differing depths (2 mm apart) per needle activation, do not raise new safety or effectiveness concerns. As there were no changes to the patient contacting materials, no new biocompatibility testing was performed. Software and cybersecurity documentation and validation per FDA guidance was completed.

Non-Clinical and/or Clinical Tests Summary

The Ignite RF System underwent software validation testing to demonstrate that the system's new Burst and Scale Modes for the Morpheus8 handpieces function as expected.

Comparative ex vivo tissue study results demonstrate the safety and efficacy of thermal effects of the new operation modes. Specifically, to support the equivalence of the new modes, an ex vivo thermal safety study was conducted, with the objective to evaluate the coagulation necrosis pattern in muscle tissue formed using the Burst Mode, and to demonstrate that

treatment levels with 2 mm spacing are independent (i.e. the coagulation zones do not overlap). This testing demonstrates that there is no histological difference between performing treatments at several depths in quick succession (as is done in Burst Mode), or with a significant break in between (as has been previously cleared).

A multi-site clinical study was performed to establish the equivalence of the treatment modes. A split face/body model was used where one side of the subject was treated with one treatment mode and the other size was treated with the other mode. Eligible subjects received treatment to their abdomen, lower face (cheek area above the mandibular bone), or both, depending on eligibility and investigator discretion. A sufficient number of subjects were enrolled until there were 30 subjects for each treatment location. There were no subjects lost to follow up, and all subjects attended the immediate, 1 week, and 1 month follow ups.

Assessments included standardized photodocumentation of the treatments site and AE assessment by the investigators. Three independent evaluators, blinded to treatment mode, assessed standardized photographs taken at baseline, immediately post-treatment, 1 week, and 30 days. Occurrence of adverse events, their expectedness, relatedness, and severity was determined by majority rule.

In addition, subjects maintained a patient diary to record any adverse events (AEs) occurring between visits, including pain, numbness, tingling, redness (erythema), swelling (edema), burns (graded by degree of tissue involvement), blisters, pustules, scabs, bleeding, hyperpigmentation, hypopigmentation, pinpoint depressions, infection, erosions or ulcers, itch, and any other symptoms. For each event, subjects also documented severity, start and end date, and whether they used over-the-counter or prescription medications.

Pain/tolerability was also assessed immediately after treatment using an 11-point Visual Analog Scale (VAS; 0 = no pain, 10 = worst possible pain) for each treatment mode and anatomical region.

No serious adverse events occurred. Incidence, duration, and severity of AEs were as expected and comparable between Burst and Cycle modes. VAS pain scores were acceptable and not significantly higher for Burst mode, establishing equivalence between the modes.

These performance tests demonstrated that the device’s performance and specifications meet the system requirements.

Conclusion

Consequently, it can be concluded that the Ignite RF System is substantially equivalent to the predicate InMode Systems, FDA cleared in K231790 and K240780. The devices differ in regards to the addition of Burst mode. The company has conducted comparative ex-vivo and clinical testing to demonstrate equivalent treatment effects between the cleared Cycle mode and subject Burst mode and has validated the software modifications per FDA software and cybersecurity guidance. Accordingly, the subject device can be found substantially equivalent to its predicate devices.