November 14, 2024

InMode Ltd.
Ahava Stein
Regulatory Consultant
Tabor Building, Shaar Yokneam
Yokneam, 2069200
Israel

Re: K242598
Trade/Device Name: DEFINE System (AG612444A)
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: Class II
Product Code: GEI, PBX, ISA, NUV
Dated: October 16, 2024
Received: October 16, 2024

Dear Ahava Stein:

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,

Long H. Chen -S

Digitally signed by Long H. Chen -S
Date: 2024.11.14 10:05:21 -05'00'

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)*

K242598

Device Name

DEFINE System (AG612444A)

Indications for Use *(Describe)*

The DEFINE System with the non-invasive applicators employs RF energy for various applications:

The DEFINE System with the Cheek and Chin Applicators is indicated for the temporary relief of minor muscle aches and pain, temporary relief of muscle spasm, and temporary improvement of local blood circulation.

The DEFINE System with the FORMA Applicator is intended for the relief of minor muscle aches and pain, relief of muscle spasm, and for the temporary improvement of local blood circulation.

The DEFINE System with the MiniFX Applicator is intended for the relief of minor muscle aches and pain, relief of muscle spasm, for the temporary improvement of local blood circulation and for the temporary reduction in the appearance of cellulite.

The DEFINE System with the Morpheus8 Applicator 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.**

**510(K) SUMMARY**

# DEFINE DEVICE

## 510(k) Number K242598

**Applicant Name:**
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**Date Prepared:** October 14, 2024

**Trade Name:** DEFINE

**Classification Name:** CFR Classification section 878.4400
Product Codes GEI, PBX, ISA and NUV

**Classification:** Class II Medical Device

**Predicate Device:**

The DEFINE System is substantially equivalent to the following predicate devices:

| Predicate | Manufacturer | Device Predicate | 510(k) No. |
|---|---|---|---|
| Main Predicate | InMode Ltd. | EmFace Device with Cheek & Chin Applicators | K191855 |
| Secondary Predicates | InMode Ltd. | FORMA Applicator | K210492 |
| | InMode Ltd. | MiniFX Applicator | K210492 |
| | InMode Ltd. | Morpheus8 Applicators | K210492 & K231790 |

*DEFINE Device 510(k)*

**Device Description:**

The DEFINE device is designed to deliver non-thermal RF energy to the skin and subdermal fat. The RF energy is transmitted to the Applicators and delivered to the treatment area throughout the set of RF electrodes positioned on the treatment units. The invested RF energy is transformed into local heating of the treatment area. Local heating of the skin and underlying tissue layers temporarily ease the symptoms of muscle aches, pain & spasm. It also contributes to the temporary improvement of local blood circulation.

The DEFINE device platform comprises a AC/DC power supply unit, main controller, two RF generators, distributor card and user interface including a touch screen. The system platform contains four designated connectors for the following applicators:

- Cheek Applicator (hands-free)
- Chin Applicator (hands-free)
- FORMA Applicator
- MiniFX
- MORPHEUS8 Applicator with the resurfacing, 12 and 24 pin tip heads

The DEFINE device RF Applicators are connected to the console via a cable. The delivery of the RF Energy is controlled by a "Start"/"Stop" button on the LCD screen or by a foot pedal. The DEFINE device incorporates a treatment deactivation button. Pressing the deactivation button by either the patient or caregiver would immediately halt the treatment and switch the device into a Pause mode until the operator re-enables it.

**Intended Use/Indication for Use:**

The DEFINE System with the non-invasive applicators employs RF energy for various applications:

The DEFINE System with the Cheek and Chin Applicators is indicated for the temporary relief of minor muscle aches and pain, temporary relief of muscle spasm, and temporary improvement of local blood circulation.

The DEFINE System with the FORMA Applicator is intended for the relief of minor muscle aches and pain, relief of muscle spasm, and for the temporary improvement of local blood circulation.

*DEFINE Device 510(k)*

The DEFINE System with the MiniFX Applicator is intended for the relief of minor muscle aches and pain, relief of muscle spasm, for the temporary improvement of local blood circulation and for the temporary reduction in the appearance of cellulite.

The DEFINE System with the Morpheus8 Applicator 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.

**Performance Standards:**

The DEFINE device complies with the following FDA recognized consensus standards:

- IEC 60601-1-2 Edition 4.1 2020-09 Consolidated Version - Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
- ANSI AAMI ES60601-1:2005/(R)2012 and A1:2012 C1:2009/(R)2012 and A2:2010/(R)2012 (Consolidated Text) [Incl. AMD2:2021] Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
- 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
- IEC 60601-1-6 Edition 3.2 2020-07 CONSOLIDATED VERSION Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
- ISO 10993-5 Third edition 2009-06-01 Biological evaluation of medical devices
- Part 5: Tests for in vitro cytotoxicity
- ISO 10993-10 Third Edition 2010-08-01 Biological evaluation of medical devices
- Part 10: Tests for irritation and skin sensitization
- IEC 62304 Edition 1.1 2015-06 CONSOLIDATED VERSION Medical device software - Software life cycle processes
- ISO 14971 Medical devices - Application of risk management to medical devices

**Non-Clinical (Bench) Performance Data:**

Following is a description of the non-clinical performance tests performed on the device and provided in the 510(k) submission:

- The modified device was tested for compliance with the electrical safety standard - IEC 60601-1.
- The modified device was tested for compliance with the EMD safety standard - IEC 60601-1-2.
- The modified device was tested for compliance with specific RF recognized consensus standard - IEC 60601-2-2.

- Validation of the device software was performed in accordance with clause 14 of IEC 60601-1 (third edition) Software requirements, IEC 62304:2004 to 62304:2006/A1:2016.

**Animal Performance Data / Histology Data:**

Not Applicable

**Clinical Performance Data:**

Not Applicable

**Substantial Equivalence:**

The DEFINE System is a modification of the EmFace System (a.k.a. Evoke System) previously cleared by the FDA (K191855), with the cheek and chin applicators. Therefore, the EmFace device (K191855) is the main predicate device. Additionally, the DEFINE System supports the following FDA-cleared RF Applicators:

- FORMA Applicator (K210492)
- MiniFX Applicator (K210492)
- Morpheus8 Applicators (K210492 and K231790)

Therefore, the FORMA Applicator (K210492), the MiniFX Applicator (K210492) and the Morpheus8 Applicators (K210492 and K231790) are the secondary predicate devices.

Table 1 presents the comparison of the DEFINE Device to the predicate EmFace device (K191855).

Table 2 presents the comparison of Cheek and Chin Applicators in the DEFINE device compared to those provided in the predicate EmFace device (K191855).

Comparison tables for the additional Applicators, including the FORMA Applicator, the MiniFX Applicator and the Morpheus8 Applicators are not provided as these Applicators are all identical to the secondary predicate FORMA Applicator (K210492), MiniFX Applicator (K210492) and Morpheus8 Applicators (K210492 and K231790) in intended use and all aspects of the technological characteristics. That is, absolutely no changes have been made to these applicators.

Table 1: Comparison of the DEFINE Device to the predicate EmFace device (K191855)

| | **EmFace Device (InMode Ltd.)**<br>***Main Predicate Device (K191855)*** | **DEFINE System (InMode Ltd.)**<br>***Modified device*** |
|---|---|---|
| **1) Device Classification and Clinical Characteristics** | | |
| **(a) Product Code** | PBX | GEI, PBX, ISA, NUV |
| **(b) Class** | Class II | idem |
| **(c) Intended Use** | See the Applicators Comparison Table (10.2.2) | idem |
| **(d) Manufacturer** | InMode Ltd. | idem |
| **(e) Prescription or OTC** | Prescription use only | idem |
| **(f) Target Population** | Adults requiring treatment as specified in the indications for use | idem |
| **(g) Anatomical sites** | Body parts requiring treatment as specified in the indications for use | idem |
| **(h) Environment Used** | Hospital or Clinic setting | idem |
| **2) Device Technological Characteristics** | | |
| **(a) Device description / Design** | The EmFace device with the Cheek and Chin Applicators is designed to deliver non-thermal RF energy to the skin and subdermal fat. | The DEFINE System with all Applicators is designed to deliver non-thermal RF energy to the skin and subdermal fat. |

*DEFINE Device 510(k)*

| | EmFace Device (InMode Ltd.)<br>*Main Predicate Device (K191855)* | DEFINE System (InMode Ltd.)<br>*Modified device* |
|---|---|---|
| **(b) Device components** | The EmFace Device platform consists of the following components:<br>• Console, including the following components:<br>- AC/DC Power Supply Unit<br>- Controller<br>- Distributor Card<br>- LCD touch screen color (10.1")<br>- 2 RF Generators<br>- 2 Applicator connectors (for Cheek and Chin Applicators)<br>- Deactivation Safety Switch<br>• Designated RF Applicators (see Table 10.2.2) | The Define System platform consists of the following components:<br>• Console, including the following components:<br>- AC/DC Power Supply Unit<br>- Controller<br>- Distributor Card<br>- LCD touch screen color (12")<br>- 2 RF Generators<br>- 4 Applicator connectors (one for Cheek and one for Chin Applicators, one for Morpheus8 or MiniFX Applicators, and one for FORMA Applicator)<br>- Deactivation Safety Switch<br>• Designated RF Applicators (see Table 10.2.2) |
| **(c) Performance specifications** | 100-240 VAC<br>50-60 Hz<br>4.0 A | idem |
| **(d) Physical specifications** | Dimensions: 40.7 cm W x 40.9 cm D x 102.5 cm H [16.1" W x 16.1" D x 40.3" H]<br>Weight: 20 Kg [44 lbs.] | Dimensions: idem<br>Weight: 33.0 Kg [72.753 lb] |
| **(e) Operating parameters** | Ambient Temperature Range: 15 – 35°C [59 – 95°F]<br>Relative Humidity: 30% to 80%, non-condensing<br>Atmospheric Pressure: 90 – 110 kPa | idem |
| **(f) Transport & storage** | Ambient Temperature Range: -20 – 65°C [-4 – 149°F]<br>Relative Humidity: 0% to 80%, non-condensing<br>Atmospheric Pressure: 50 – 110 kPa | idem |

*DEFINE Device 510(k)*

| | EmFace Device (InMode Ltd.)<br>*Main Predicate Device (K191855)* | DEFINE System (InMode Ltd.)<br>*Modified device* |
|---|---|---|
| **3) Safety and Adherence to Consensus Standards** | | |
| **(a) Compatibility with Environment and Other Devices** | The device is compliant with the IEC 60601-1-2 (EMC Safety) standard | idem |
| **(b) Electrical Safety** | Power Requirements:<br>100-240 VAC 50-60 Hz<br>The device is compliant with the IEC 60601-1 and IEC 60601-2-2 standards. | idem |
| **(c) Mechanical Safety** | The device is compliant with the IEC 60601-1 standard. | idem |
| **(d) Chemical Safety** | N/A | idem |
| **(e) Thermal Safety** | The device is compliant with the IEC 60601-1 standard. | idem |
| **(f) Radiation Safety** | The device is compliant with the IEC 60601-1-2 (EMC Safety) standard. | idem |

Table 2 – Comparison of Cheek and Chin Applicator in the DEFINE device compared to those provided in the predicate EmFace device (K191855)

| | **EmFace Device Cheek & Chin Applicators (InMode Ltd.)** *Main Predicate Device (K191855)* | **DEFINE System Cheek & Chin Applicators (InMode Ltd.)** *Modified device* |
|---|---|---|
| **1) Device Classification and Clinical Characteristics** | | |
| **(a) Product Code** | PBX | idem |
| **(b) Class** | Class II | idem |
| **(c) Manufacturer** | InMode Ltd. | idem |
| **(d) Prescription/OTC** | Prescription use only | idem |
| **(e) Target Population** | Adults requiring treatment as specified in the indications for use. | idem |
| **(f) Anatomical sites** | Body parts requiring treatment as specified in the indications for use. | idem |
| **(g) Environment Used** | Hospital or Clinic setting. | idem |
| **(h) Indications for use** | The Cheek and Chin Applicators are indicated for the temporary relief of minor muscle aches and pain, temporary relief of muscle spasm, and temporary improvement of local blood circulation. | idem |
| **2) Applicator Technological Characteristics** | | |
| **(a) Weight** | **Chin Applicator:** 0.5 Kg [1,1 lb]<br>**Cheek Applicator:** 0.9 Kg [2.0 lb] | idem |

| | EmFace Device Cheek & Chin Applicators (InMode Ltd.) *Main Predicate Device (K191855)* | DEFINE System Cheek & Chin Applicators (InMode Ltd.) *Modified device* |
|---|---|---|
| **(b) Applicator cable length** | 180 cm [71"] | 280 cm [100"] |
| **(c) RF Maximum Output Power** | 50 W | idem |
| **(d) Energy Output Levels** | Cheek Applicator: Up to 60 Energy Levels<br>Chin Applicator: Up to 40 Energy Levels | Cheek Applicator: Up to 60 Energy Levels<br>Chin Applicator: Up to 40 Energy Levels |
| **(e) Frequency** | 1 MHz | idem |
| **(f) RF Pulse Width** | 2 seconds | idem |
| **(g) Number of electrodes** | **Cheek Applicators:** 4 RF units, with 3 electrodes in each (total 12 electrodes on left cheek and 12 electrodes on right cheek)<br>**Chin Applicator:** 3 RF units with 2 electrodes in each (total 9 electrodes) | **Cheek Applicators:** idem<br><br>**Chin Applicator:** 2 RF units with 3 electrodes in each (total 6 electrodes) |
| **(h) Electrode dimensions** | Thickness of side electrode: 4 mm;<br>Thickness of middle electrode: 6 mm;<br>Length of electrode: 21 mm;<br>Centerline between electrodes: 9.5 mm | idem |
| **(i) Temperature sensor** | Thermistor embedded into the central electrode. | idem |
| **3) Applicator raw materials** | | |
| **(a) Applicator Housing** | PC Makrolon 2458 | Tritan MXF 121 |
| **(b) Cheek and Chin fixation mechanism** | **Adjustment straps and belts:** JF-DG007- Cool Grey 11C 90% Nylon and 10% Spandex Fabric with 1.2mm thickness | **Fixture:** Tritan MXF 121 |
| **(c) RF/Pin electrodes** | Gold coated stainless steel 304, insulated by Parylene C | idem |

*DEFINE Device 510(k)*

| | EmFace Device Cheek & Chin Applicators (InMode Ltd.)<br>*Main Predicate Device (K191855)* | DEFINE System Cheek & Chin Applicators (InMode Ltd.)<br>*Modified device* |
|---|---|---|
| **4) Sterilization and reprocessing** | | |
| **(a) Sterilization** | Not Applicable | idem |
| **(b) Reprocessing** | Applicator handle is for multiple use | idem |

**Conclusions:**

The DEFINE device has the same intended use and indication for use as the EmFace device with the Cheek and Chin Applicators (K191855) and the FORMA (K210492), MiniFX (K210492) and Morpheus8 (K210492 and 231790) Applicators. Furthermore, the technological characteristics are similar or even identical, including similar device components (i.e., main system platform containing the AC/DC power supply unit, main controller, two RF generators, distributor card and user interface including a touch screen), similar mechanism of action (heating skin and tissue layers using RF energy), similar treatment administration, similar energy regulation methods, biocompatibility of materials, validation of software component, and similar compliance with electrical, EMD and RF energy emitting device standards. The most important technological characteristic, i.e., using RF energy to deliver heat to the skin and tissue layers is the same in both devices.

The minor differences between the devices, mainly in the user interface to enable selecting the relevant Applicator, adding a temperature color scale to the temperatures and adding an indicator of the pressure for the Cheek Applicator contact with the skin, do not raise new types of questions about safety and effectiveness. Additional modifications to the Cheek and Chin Applicators included a more ergonomic design of positioning the applicators using a fixture rather than straps and belts, and modification of the patient contacting materials of the fixture (although the materials are still biocompatible). These modifications also do not raise new types of questions about safety and effectiveness

Furthermore, acceptable scientific methods were employed to evaluate the modified aspects of the device, including compliance with FDA recognized methods and standards to demonstrate RF safety and testing to validate the generated RF energy output in the DEFINE device is at least as safe and effective as the legally marketed, predicate EmFace device (K191855). Additionally, compliance with electrical and EMD safety standards, biocompatibility and validation of the device software have been provided in this 510(k) submission.

Consequently, the safety and effectiveness information provided in the 510(k) submission provides the supportive data necessary to demonstrate that the DEFINE device with the Cheek and Chin Applicators and the FORMA, MiniFX and Morpheus8 Applicators is substantially equivalent to the predicate EmFace device (K191855) and the FORMA (K210492), MiniFX (K210492) and Morpheus8 (K210492 and 231790) Applicators.