June 26, 2025

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

Re: K251632
Trade/Device Name: Optimas MAX System
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser Surgical Instrument For Use In General And Plastic Surgery And In Dermatology
Regulatory Class: Class II
Product Code: GEX, ONF, GEI, PBX
Dated: May 28, 2025
Received: May 28, 2025

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.

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,

TANISHA L. HITHE -S
Digitally signed by TANISHA L. HITHE -S
Date: 2025.06.26 19:59:23 -04'00'

Tanisha Hithe
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)*

K251632

Device Name

Optimas MAX System

Indications for Use *(Describe)*

The Optimas MAX System with the Diolaze XL MAX is intended for hair removal and permanent hair reduction defined as the stable, long-term reduction in hair counts at 6, 9, or 12 months following a treatment regime. The Fusion Light and the Fusion Dark are intended for hair removal.

The Optimas MAX System with the VasculazeMAX is intended for the treatment of vascular lesions, including angiomas, hemangiomas, telangiectasia, port wine stains, leg veins and other benign vascular lesions.

The Optimas MAX System with the Lumecca Peak Applicators are indicated for use for the following treatments:
• The treatment of benign pigmented epidermal lesions, including dyschromia, hyperpigmentation, melasma, ephelides (freckles);
• The treatment of benign cutaneous vascular lesions, including port wine stains, facial, truncal and leg telangiectasias, rosacea, erythema of rosacea, angiomas and spider angiomas, poikiloderma of Civatte, superficial leg veins and venous malformations.

The Optimas MAX System with the Plus and Forma Handpieces are indicated for the temporary relief of minor muscle aches and pain, temporary relief of muscle spasm, and temporary improvement of local blood circulation

The Optimas MAX System with the he 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.

K251632

510(k) SUMMARY
InMode Ltd.'s OptimasMAX 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: May 28, 2025

Name of Device

OptimasMAX 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: GEX, GEI, ONF, PBX

Predicate Devices

InMode Multi-System - K221571;

InMode System with the Morpheus8 Applicators - K231790.

Intended Use / Indications for Use

The Optimas MAX System with the Diolaze XL MAX is intended for hair removal and permanent hair reduction defined as the stable, long-term reduction in hair counts at 6, 9, or 12 months following a treatment regime. The Fusion Light and the Fusion Dark are intended for hair removal.

The Optimas MAX System with the VasculazeMAX is intended for the treatment of vascular lesions, including angiomas, hemangiomas, telangiectasia, port wine stains, leg veins and other benign vascular lesions.

The Optimas MAX System with the Lumecca Peak Applicators are indicated for use for the following treatments:

- The treatment of benign pigmented epidermal lesions, including dyschromia, hyperpigmentation, melasma, ephelides (freckles);

- The treatment of benign cutaneous vascular lesions, including port wine stains, facial, truncal and leg telangiectasias, rosacea, erythema of rosacea, angiomas and spider angiomas, poikiloderma of Civatte, superficial leg veins and venous malformations.

The Optimas MAX System with the Plus and Forma Handpieces are indicated for the temporary relief of minor muscle aches and pain, temporary relief of muscle spasm, and temporary improvement of local blood circulation

The Optimas MAX System with the he 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: Technological Characteristics

The Optimas MAX system is a computerized, versatile system that generates Laser, IPL, and RF energies for the treatment of several clinical indications. The device utilizes different applicators to achieve its mode of operation in accordance with the selected technology and clinical indication. The device system operates when any of the applicators are connected and enables individual adjustment of treatment parameters. The water-cooling system provides cooling for laser and IPL applicators and thermoelectric coolers (TECs). The cooling system includes a radiator, water pump, fan, water reservoir, deionizer, water filter, tissue contact temperature sensor, and water flow sensor.

The system is compatible with the following applicators:

- DIOLAZE XL 810, 810/1064 and 755/810 (previously cleared as DIOLAZE XL)
- LUMECCA 515 PEAK and LUMECCA 580 PEAK (previously cleared as LUMECCA)
- VASCULAZE 1064 (previously cleared as Vasculaze)
- FORMA (previously cleared as Forma (Plus))
- PLUS (previously cleared as Plus/Plus)
- MORPHEUS8
- MORPHEUS8 DEEP (previously cleared in K231790 as MORPHEUS8 Body)

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 primary difference between the subject Optimas MAX and the predicate Inmode Multi-System is the device has a new industrial design which has changed the console's color, placement of LCD touchscreen, and where connected handpieces are held on the console.

The operating system has also been upgraded from deprecated Windows CE to Linux. The specifications for the critical components of the system remain unchanged, aside for an increase in the IPL Charger max output voltage. Importantly, the system components, handpiece connectors, and the operating parameters of each handpiece remains unchanged. The subject Opimas MAX System is also compatible with a subset of the handpieces that were cleared for use with the predicate Inmode Multi-System. There are no changes to the Forma/Plus handpieces. The only change to the DiolazeXL, VasculazeMAX, and Lumecca handpieces is that the housing coloring (but not material) was changed from white to black and the marketed name of the handpieces have been updated. The Morpheus8 handpieces and associated tips have had a minor update to their shape and the selectable power levels have been restricted depending on treatment depth, operating mode, and selected tip.

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.

New electrical testing was performed, including testing per:

- IEC 60601-1: 2005/(R)2012 & A1:2012 C1: 2009/(R)2012
- IEC 60601-1-2: 2020-09 Consolidated Version
- IEC 60601-1-6: 2020-07 Consolidated Version
- IEC 60601-2-2: 2017-03
- IEC 60601-2-22: 2019-11
- IEC 60601-2-57: 2011-01
- IEC 60825: 2007-03

Conclusion

Consequently, it can be concluded that the OptimasMAX System is substantially equivalent to the predicate InMode Multi-System. - K221571; and InMode System with the Morpheus8 Applicators - K231790.