June 30, 2022

InMode Ltd.
% Amit Goren
Regulatory Consultant
A. Stein-Regulatory Affairs Consulting Ltd.
18 Hata'as Str., Sute 21
Kfar Saba, 4442518
Israel

Re: K221571
Trade/Device Name: InMode Multi-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, GEI, ONF, NUV, ISA, PBX
Dated: May 26, 2022
Received: May 31, 2022

Dear Amit Goren:

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 (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 located 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.

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 and Part 809 medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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

Jianting Wang
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K221571

Device Name
InMode Multi System

Indications for Use *(Describe)*

The InMode Multi System with the Diode laser Applicators is indicated for:

• Diolaze XL 810nm Applicator 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.
• Diolaze XL 755/810nm & 810/1064nm Applicators are intended for hair removal.
• VLaze Applicator is intended for the treatment of vascular lesions, including angiomas, hemangiomas, telangiectasia, port wine stains, leg veins and other benign vascular lesions.

The InMode Multi System with the IPL Applicator is indicated for:

• IPL Applicator with wavelengths (515-l200nm) is 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, poikilodenna of Civatte, superficial leg veins and venlous malformations.

The InMode Multi System with the non-invasive RF Applicators is indicated for:

• BodyFX (WMBody) and MiniFX Applicators are intended for the treatment of the following medical conditions: Relief of minor muscle aches and pains, relief of muscle spasm, temporary improvement of local blood circulation; and temporary reduction in the appearance of cellulite.
• PLUS/ PLUS90/PLUS-PLUS (FORMA) and i-Forma 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.
• FaceFX (WMFace) Applicator is intended for use in dermatologic procedures, for noninvasive treatment of mild to moderate facial wrinkles and rhytids.

The InMode Multi System with the Fractional RF Applicators is indicated for:

• FRACTORA 60 pin Applicator is intended for use in dermatological procedures requiring ablation and resurfacing of the skin.
• FRF 24 pin Applicator is intended for use in dermatologic and general surgical procedures for electrocoagulation and hemostasis.
• Fractora3D and Morpheus8 Applicators are intended for use in dermatologic and general surgical procedures for electrocoagulation and hemostasis. At higher energy levels greater than 62 mJ/pin, use 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

INMODE MULTI SYSTEM

510(k) Number K221571

Applicant Name:
Company Name: InMode Ltd.
Address: Tabor Building, Shaar Yokneam POB 44,
Yokneam Iillit, 2069200 Israel
Tel: +972-4-9097470
Fax: +972-4-9097471
E-mail: amit@asteinrac.com

Contact Person:
Official Correspondent: Amit Goren
Company Name: A. Stein – Regulatory Affairs Consulting Ltd.
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Kfar Saba 4442518, Israel
Tel: + 972-9-7670002
Fax: +972-9-7668534
E-mail: amit@asteinrac.com

Date Prepared: May 26, 2022

Trade Name: InMode Multi System

Classification Name:
Main system platform:

21 CFR 878.4810, Class II, GEX

System Applicators:

21 CFR 878.4810, Class II, GEX
21 CFR 878.4810, Class II, ONF
21 CFR 878.4810, Class II, NUV
21 CFR 878.4810, Class II, ISA

21 CFR 878.4400, Class II, GEI

21 CFR 878.4400, Class II, PBX

Classification: Class II Medical Device

Predicate Device:

The subject device is substantially equivalent to the following predicate device:

Subject Device Component	Regulation Number	Product Code	Primary/Secondary predicate device	Predicate device 510(K) number
Main platform/ Console	878.4810	GEX	Primary	K180719
Diolaze XL	878.4810	GEX	Secondary	K180719
VLaze	878.4810	GEX	Secondary	K173677
SR IPL	878.4810	ONF	Secondary	K123860
Fractional RF Applicators: FRACTORA 60 Pin, InMode FRF 24 Pin, Morpheus8, FRACTORA 3D Applicators	878.4810	GEI	Secondary	K200947, K180189, K151273, K102461
BodyFX (WMBody) Applicator	878.4810 890.5560	NUV, ISA	Secondary	K131362
MiniFX Applicator	878.4400 890.5560	GEI, ISA	Secondary	K160329
Forma (Plus), Plus90 and Plus (Plus-Plus) Applicators	878.4400 890.5560	PBX, ISA	Secondary	K172302
i-Forma Applicator	878.4400 890.5560	PBX, ISA	Secondary	K210492
WMFace Applicator	878.4400	GEI,	Secondary	K140926

Device Description:

The InMode Multi-System supports multiple technological applications and accessories intended for different clinical indications. The subject device is designed to exert finely controlled radiofrequency, laser or IPL energy utilizing different treatment applicators. The subject device comprises a system platform and compatible set of applicators. The system platform was originally FDA Cleared in K180719 and is manufactured by InMode Ltd.

The subject device platform sustains additional FDA Cleared applicators, all manufactured by InMode Ltd.

The below list comprises the set of applicators to be registered under the subject device:

- Laser Applicators:
  - Diolaze XL 810nm
  - Diolaze XL 755/810nm
  - Diolaze XL 810/1064nm
  - VLaze (Vasculaze)
- IPL Applicator:
  - SR IPL (Lumecca 580, Lumecca 515)
- Non-Invasive RF Applicators:
  - Forma (Plus)
  - Plus (Plus Plus)
  - Plus90
  - i-Forma
  - BodyFX™ (WMBody)
  - MiniFX™
  - WMFace
- Fractional RF Applicators:
  - Fractora
    - 24 pins tip (FRF)
    - 60 pins tip
  - Morpheus8™
    - 12 pins tip (Prime Tip)
    - 24 pins tip (Fractora 3D)
    - 40 pins tip (Body Tip)
    - T tip

The platform of the subject device has undergone some slight design modifications, mainly in software, to support the integration and operation of the abovementioned applicators.

Slight modifications were also performed on platform hardware for the same purpose.

Additionally, the user interface screen was slightly enlarged from 10" to 12".

The abovementioned modifications have no significant influence on device safety and efficacy.

Following are the InMode Multi System specifications:

Diode laser wavelength:	810±20 nm 755nm/810nm±20 nm 810nm/1064nm±20 nm
Fluence	5-40 J/cm^2
Vasculaze laser wavelength:	1064±20 nm
Fluence	100-300 J/cm^2
IPL wavelength:	515 – 1200nm (SR 515) 580 – 1200nm (SR 580)
Fluence	5-30 J/cm^2
RF Max Output Power:	65 Watt
RF Output Frequency:	1[MHz] ± 2%
Dimension:	46cm W x 46cm D x 100cm H [18.2'' W x 18.2'' D x 40'' H]
Weight:	32.0Kg [70.5lb]
Main Line Frequency (nominal):	50-60 Hz
Input Voltage (nominal):	100-240 VAC
Input Current (rms):	12A

Intended Use/Indication for Use:

The InMode Multi System with the Diode laser Applicators is indicated for:

- Diolaze XL 810nm Applicator 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.
- Diolaze XL 755/810nm & 810/1064nm Applicators are intended for hair removal.
- VLaze Applicator is intended for the treatment of vascular lesions, including angiomas, hemangiomas, telangiectasia, port wine stains, leg veins and other benign vascular lesions.

The InMode Multi System with the IPL Applicator is indicated for:

- IPL Applicator with wavelengths (515-l200nm) is 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, poikilodenna of Civatte, superficial leg veins and venlous malformations.

The InMode Multi System with the non-invasive RF Applicators is indicated for:

- BodyFX (WMBody) and MiniFX Applicators are intended for the treatment of the following medical conditions :Relief of minor muscle aches and pains, relief of muscle spasm, temporary improvement of local blood circulation; and temporary reduction in the appearance of cellulite.
- PLUS/ PLUS90/PLUS-PLUS (FORMA) and i-Forma 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.
- FaceFX (WMFace) Applicator is intended for use in dermatologic procedures, for noninvasive treatment of mild to moderate facial wrinkles and rhytids.

The InMode Multi System with the Fractional RF Applicators is indicated for:

- FRACTORA 60 pin Applicator is intended for use in dermatological procedures requiring ablation and resurfacing of the skin.
- FRF 24 pin Applicator is intended for use in dermatologic and general surgical procedures for electrocoagulation and hemostasis.
- Fractora3D and Morpheus8 Applicators are intended for use in dermatologic and general surgical procedures for electrocoagulation and hemostasis.
  At higher energy levels greater than 62 mJ/pin, use is limited to Skin Types I-IV.

Performance Standards:

The InMode Multi-System complies with the following recognized consensus standards:

[Rec. Number 19-4] ANSI AAMI ES 60601-1:2005/(R)2012 and A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012 (Consolidated Text) Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
[Rec. Number 5-89] IEC 60601-1-6 Edition 3.1 2013-10 Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
[Rec. Number 19-8] IEC 60601-1-2 Edition 4.0 2014-02 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests

[Rec. Number 6-389] 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
[Rec. Number 12-273] IEC 60825-1 Edition 2.0 2007-03 Safety of laser products - Part 1: Equipment classification, and requirements [Including: Technical Corrigendum 1 (2008), Interpretation Sheet 1 (2007), Interpretation Sheet 2 (2007)]
[Rec. Number 12-268] IEC 60601-2-22 Edition 3.1 2012-10 Medical electrical equipment - Part 2-22: Particular requirements for basic safety and essential performance of surgical, cosmetic, therapeutic and diagnostic laser equipment
[Rec. Number 12-242] IEC 60601-2-57 Edition 1.0 2011-01Medical Electrical Equipment - Part 2-57: Particular requirements for the basic safety and essential performance of non-laser light source equipment intended for therapeutic, diagnostic, monitoring and cosmetic/aesthetic use

All the requirements of these standards were met. No adaptations were made to any of the test methods recommended in the standard. There were no applied deviations from the standard.

Non-Clinical (Bench) Performance Data:

Not Applicable

Animal Performance Data / Histology Data:

Not Applicable

Clinical Performance Data:

Not Applicable

Biocompatibility

All of the modified device materials which come in direct contact with the patient skin are biocompatible and identical to the materials used in the manufacturing of the predicate devices.

Substantial Equivalence:

The following tables provide a comparison information for the InMode Multi-system and its primary predicate device; the InMode System and for the subject device applicators and their compatible secondary predicate devices:

System platform:

	InMode System ***Primary Predicate Device; InMode Ltd. K180719***	**InMode Multi-system** ***Modified device; InMode Ltd.***
Device Classification and Clinical Characteristics		
Product Code	GEX	idem
Class	Class II	idem
Manufacturer	InMode Ltd.	idem
Prescription or OTC	Prescription use only.	idem
Target Population	Adults requiring treatment as specified in the indications for use.	idem
Anatomical sites	Body parts requiring treatment as specified in the indications for use.	idem
Environment Used	Hospital or Clinic setting.	idem
Device Technological Characteristics		
Device description / Design	The InMode System is a line powered, computerized, software controlled, platform system. The system supports adjustable handpieces for several clinical indications.	idem

Device components	The InMode System consists of the following components: • Power supply unit, • Controller • LCD touch screen • Diode laser driver • Water cooling system • Designated diode laser applicators • Single applicator connector (for optical applicator) • Footswitch The InMode System platform was also utilized under different configurations, to support Laser, RF and IPL technology-based applicators as described in K173677, K123860, K160329, K131362, K172302, K102461, K180189, K151273 & K200947. The InMode System platform supporting RF applicators consist of the following components: • Power supply unit, • Controller • LCD touch screen • RF generator • Designated RF applicators • Two applicator connectors • Footswitch The InMode System platform supporting IPL applicators consist of the following components: • Power supply unit, • Controller • LCD touch screen • IPL driver • Water cooling system • Designated IPL applicators • Single applicator connector • Footswitch	The InMode Multi System consists of the following components: • Power supply unit, • Controller • LCD touch screen • Diode laser driver • IPL driver • RF generator • RF measuring circuit • Water cooling system • Designated diode laser, IPL, and RF applicators • Three applicator connectors (one frontside connector for optical applicator and two rear side connectors for RF applicators) • Footswitch

	InMode System ***Primary Predicate Device; InMode Ltd. K180719***	**InMode Multi-system** ***Modified device; InMode Ltd.***
Performance specifications	Input power: 100-240V, 50-60 Hz, 12A	idem
Physical specifications	Dimensions: 46cm W x 46cm D x 100cm H [18.2'' W x 18.2'' D x 40'' H] Weight: 30 Kg (70.4 lbs.)	idem
Operating parameters	Ambient Temperature Range: 15 – 30°C [59 – 86°F] Relative Humidity: 30% to 80%, non-condensing Atmospheric Pressure: 90 - 110kPa	idem
Transport & storage	Ambient Temperature Range: -20 – 65°C [-4 – 14°F] Relative Humidity: 0% to 80%, non-condensing Atmospheric Pressure: 50 - 110kPa	idem
Compatibility with Environment and Other Devices	InMode System is compliant with the IEC 60601-1-2 (EMC Safety) standard	idem
Electrical Safety	Power Requirements: 100-240 VAC 50-60 Hz The InMode System is compliant with the IEC 60601-1 standard.	idem
Mechanical Safety	The InMode System is compliant with the IEC 60601-1 standard.	idem
Chemical Safety	N/A	N/A
Thermal Safety	The InMode System is compliant with the IEC 60601-1 standard.	idem
Radiation Safety	The InMode System is compliant with the IEC 60601-1-2 (EMC Safety) standard.	idem

Laser and IPL devices:

	InMode System ***Secondary Predicate Devices; InMode Ltd.*** ***K180719 – DIOLAZE XL*** ***K173677 – Vlaze (Vasculaze)*** ***K123860 – SR IPL (Lumecca)***	**InMode Multi-system** ***Modified device; InMode Ltd.***
Device Classification and Clinical Characteristics		
Product Code	GEX, ONF	idem
Class	Class II	idem
Manufacturer	InMode Ltd.	idem
Prescription or OTC	Prescription use only	idem
Target Population	Adults requiring treatment as specified in the indications for use.	idem
Anatomical sites	Body parts requiring treatment as specified in the indications for use.	idem
Environment Used	Hospital or Clinic setting.	idem
Indications for use	**DIOLAZE XL:** The InMode Diolaze XL System with the Diolaze XL 810nm Hand piece 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 InMode Diolaze XL System with the Diolaze XL 755/810nm & 810/1064nm Handpieces is intended for hair removal. **VLaze (Vasculaze):** The InMode VLaze is intended for the treatment of vascular lesions, including angiomas, hemangiomas, telangiectasia, port wine stains, leg veins and other benign vascular lesions. **SR IPL (Lumecca):** The InMode SR IPL Device wavelengths (515-	idem

	InMode System ***Secondary Predicate Devices; InMode Ltd.*** ***K180719 – DIOLAZE XL*** ***K173677 – Vlaze (Vasculaze)*** ***K123860 – SR IPL (Lumecca)***	**InMode Multi-system** ***Modified device; InMode Ltd.***
	l200nm) 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, poikilodenna of Civatte, superficial leg veins and venlous malformations.	
Applicator Technological Characteristics		
Weight	**DIOLAZE XL:** 0.45 Kg [0.99 lb] **VLaze (Vasculaze):** 0.42 Kg [0.92 lb] **SR IPL (Lumecca):** 0.575 Kg [1.27 lb]	idem
Applicator cable length	170 cm L [110`` L]	idem
Wavelength	**DIOLAZE XL:** 810±20 nm 755/810±20 nm 810/1064±20 nm **VLaze (Vasculaze):** 1064±20 nm **SR IPL (Lumecca):** 515 – 1200nm (SR 515) 580 – 1200nm (SR 580)	idem
Fluence	**DIOLAZE XL:** 5 – 40 J/cm² **VLaze (Vasculaze):** 100 – 300 J/cm² **SR IPL (Lumecca):** 5 – 30 J/cm²	idem
Pulse width	**DIOLAZE XL**- 5-200 msec (pulse type : Short/Long)	idem

	InMode System ***Secondary Predicate Devices; InMode Ltd.*** ***K180719 – DIOLAZE XL*** ***K173677 – Vlaze (Vasculaze)*** ***K123860 – SR IPL (Lumecca)***	**InMode Multi-system** ***Modified device; InMode Ltd.***
	VLaze: 5-200 msec	
Light guide cooling	**DIOLAZE XL:** Strong: 7ºC, Normal: 12ºC **VLaze (Vasculaze):** Strong: 7ºC, Normal: 12ºC **SR IPL (Lumecca):** Strong - 15ºC, Normal - 22ºC	idem
Spot size	**DIOLAZE XL:** 11mm X 27.5mm **VLaze (Vasculaze):** 3mm X 4mm **SR IPL (Lumecca):** 10mm X 30mm	idem

Fractional RF Applicators:

	InMode System ***Secondary Predicate Devices; InMode Ltd.*** ***K102461 – FRACTORA 60 pin*** ***K151273 – InMode FRF 24 pin*** ***K180189 – Fractora3D*** ***K200947 – Morpheus8 (12, 24, 40 & T tip heads)***	**InMode Multi-system** ***Modified device; InMode Ltd.***
Device Classification and Clinical Characteristics		
Product Code	GEI	idem
Class	Class II	idem
Manufacturer	InMode Ltd.	idem
Prescription or OTC	Prescription use only	idem
Target Population	Adults requiring treatment as specified in the indications for use.	idem
Anatomical sites	Body parts requiring treatment as specified in the indications for use.	idem
Environment Used	Hospital or Clinic setting.	idem
Indications for use	**FRACTORA 60:** The InMode RF Multi-System with the FRACTORA 60 pin Applicator is	idem

	InMode System ***Secondary Predicate Devices; InMode Ltd.*** ***K102461 – FRACTORA 60 pin*** ***K151273 – InMode FRF 24 pin*** ***K180189 – Fractora3D*** ***K200947 – Morpheus8 (12, 24, 40 & T tip heads)***	**InMode Multi-system** ***Modified device; InMode Ltd.***
	intended for use in dermatological procedures requiring ablation and resurfacing of the skin. **InMode FRF 24:** The InMode RF Multi-System with the 24 pin Applicator is intended for use in dermatologic and general surgical procedures for electrocoagulation and hemostasis. At higher energy levels greater than 62 mJ/pin, use of the FRF applicator is limited to Skin Types I-IV. **FRACTORA 3D:** The InMode System with the Fractora3D Applicators is intended for use in dermatologic and general surgical procedures for electrocoagulation and hemostasis. At higher energy levels greater than 62 mJ/pin, use of the Fractora3D applicator is limited to Skin Types I-IV. **Morpheus8:** The InMode System with the Morpheus8 Applicators is intended for use in dermatological procedures for electrocoagulation and hemostasis. At higher energy levels greater than 62 mJ/pin, use of the Morpheus8 (Fractora) applicator is limited to Skin Types I-IV.	
Applicator Technological Characteristics		
Weight	**FRACTORA 60:** 0.1 Kg [0.22 lb.] **InMode FRF 24:** 0.1 Kg [0.22 lb.] **FRACTORA 3D:** 0.4 Kg [0.88 lb.] **Morpheus8:** 0.4 Kg [0.88 lb.]	idem
Pin length	**FRACTORA 60:** 200 microns **InMode FRF 24:** 2.5 mm **FRACTORA 3D:** 1-4 mm	idem

	InMode System ***Secondary Predicate Devices; InMode Ltd.*** ***K102461 – FRACTORA 60 pin*** ***K151273 – InMode FRF 24 pin*** ***K180189 – Fractora3D*** ***K200947 – Morpheus8 (12, 24, 40 & T tip heads)***	**InMode Multi-system** ***Modified device; InMode Ltd.***
	Morpheus8: 24, 40 pins: 7 mm (adjustable) 12 pins: 4 mm (adjustable) T tip: 0.5 mm (fixed)	
Maximum output power	**FRACTORA 60:** 65W **InMode FRF 24:** 65W **FRACTORA 3D:** 65W **Morpheus8:** 65W	idem
RF frequency	**FRACTORA 60:** 1 MHz **InMode FRF 24:** 1 MHz **FRACTORA 3D:** 1 MHz **Morpheus8:** 1 MHz	idem
Sterilization and reprocessing		
Sterilization	All tip heads are Gamma sterilized	idem
Reprocessing	All applicator handles are for multiple use All tip heads are for single use	idem

Non-invasive RF Applicators:

	InMode System ***Secondary Predicate Devices; InMode Ltd.*** ***K131362 – BodyFX (WMBody)*** ***K160329 – MiniFX*** ***K172302 – PLUS/PLUS90/PLUS-PLUS***	**InMode Multi-system** ***Modified device; InMode Ltd.***
Device Classification and Clinical Characteristics		
Product Code	PBX, ISA, NUV, GEI	idem
Class	Class II	idem
Manufacturer	InMode Ltd.	idem
Prescription or OTC	Prescription use only	idem

	InMode System ***Secondary Predicate Devices; InMode Ltd.*** ***K131362 – BodyFX (WMBody)*** ***K160329 – MiniFX*** ***K172302 – PLUS/PLUS90/PLUS-PLUS***	**InMode Multi-system** ***Modified device; InMode Ltd.***
Target Population	Adults requiring treatment as specified in the indications for use.	idem
Anatomical sites	Body parts requiring treatment as specified in the indications for use.	idem
Environment Used	Hospital or Clinic setting.	idem
Indications for use	**BodyFX:** The WMBody Applicator is intended for the treatment of the following medical conditions using non-thermal RF combined with massage: Relief of minor muscle aches and pains, relief of muscle spasm, temporary improvement of local blood circulation. Temporary reduction in the appearance of cellulite **MiniFX:** The MiniFX Applicator is intended for the treatment of the following medical conditions using non-thermal RF combined with massage: Relief of minor muscle aches and pains, relief of muscle spasm, temporary improvement of local blood circulation. Temporary reduction in the appearance of cellulite **PLUS/PLUS90/PLUS-PLUS/i-Forma:** The PLUS/PLUS90/PLUS-PLUS/i-Forma 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. **WMFace:** The WMFace Applicator is intended for use in dermatologic procedures, for noninvasive	idem

	InMode System ***Secondary Predicate Devices; InMode Ltd.*** ***K131362 – BodyFX (WMBody)*** ***K160329 – MiniFX*** ***K172302 – PLUS/PLUS90/PLUS-PLUS***	**InMode Multi-system** ***Modified device; InMode Ltd.***
	treatment of mild to moderate facial wrinkles and rhytids.	
Applicator Technological Characteristics		
Weight	**BodyFX:** 1 Kg [2.2 lb.] **MiniFX:** 0.75 Kg [1.6 lb.] **PLUS/PLUS90:** 0.11 Kg [0.24 lb.] **PLUS-PLUS:** 0.17 Kg [0.35 lb.] **i-Forma:** 0.35kg [0.77 Ib] **WMFace:** 1 Kg [2.2 lbs.]	idem
Maximum output power	**BodyFX:** 50W **MiniFX:** 25W **PLUS/PLUS90/PLUS-PLUS:** 50W **i-Forma:** 12W **WMFace:** 65W	idem
RF frequency	**BodyFX:** 1 MHz **MiniFX:** 1 MHz **PLUS/PLUS90/PLUS-PLUS:** 1 MHz **i-Forma:** 1 MHz **WMFace:** 1 MHz	idem
Vacuum	**BodyFX:** Automatically controlled, **MiniFX:** Automatically controlled, **PLUS/PLUS90/PLUS-PLUS/i-Forma/WMFace:** N/A	idem

Comparison Discussion:

To summarize, the indications for use and technological characteristics of the InMode Multi system (subject device) are substantially equivalent to the indications for use and technological characteristics of the InMode system (primary predicate device) and of the applicators predicate devices (secondary predicate devices).

The design of and components included in the InMode Multi system, including the main system platform are identical to the design and components found in the primary predicate device except for slight design modifications to support the utilization of all of the system

applicators, mainly in software design. The subject device applicators possess identical technological principals to that of the predicate devices' applicators. The subject device performance and safety are maintained due to the exact functionality and mechanism of operation to that of the predicate devices.

Both the subject and predicate devices present identical performance specifications (for the specified indications for use) and identical monitoring features (where applicable) in order to maintain the desired performance specifications. The safety features and compliance with safety standards of the InMode Multi system are identical to the safety features and compliance with safety standards of the predicate devices. Patient contacting materials are also identical. Any minor differences in the technological characteristics do not raise new safety or effectiveness concerns. Furthermore, the subject device underwent performance testing including software validation testing, electrical and mechanical safety testing, electromagnetic compatibility testing and specific testing for RF and laser technologies. User interface was slightly changed in order to support all applicators, and labeling was updated to allow appropriate use.

Consequently, it can be concluded that the InMode Multi system is substantially equivalent to the primary predicate; the InMode system (FDA-Cleared under 510(k) K180719) and to its complement secondary predicate devices (per system Applicator), and therefore may be legally marketed in the USA.