U.S. FOOD & DRUG ADMINISTRATION

July 2, 2020

InMode Ltd.
% Amit Goren
Regulatory Manager
A. Stein - Regulatory Affairs Consulting Ltd.
20 Hata'as Str., Suite 102
Kfar Saba, Israel 4442520

Re: K200947/S001
Trade/Device Name: InMode System with the Morhpeus8 Applicators
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting and Coagulation Device and Accessories
Regulatory Class: Class II
Product Code: GEI
Dated: June 10, 2020
Received: June 12, 2020

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.

U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
www.fda.gov

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 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,

Long H. Chen -S

Digitally signed by Long H. Chen -S
Date: 2020.07.02 14:37:41 -04'00'

Long Chen, 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K200947

Device Name
InMode System with the Morpheus8 Applicators

Indications for Use *(Describe)*
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.

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) SUMMARY

INMODE SYSTEM WITH THE MORPHEUS8 APPLICATORS

510(k) Number K200947

Applicant Name:

Company Name: InMode MD Ltd.
Address: Tabor Building, Shaar Yokneam
Yokneam 20692
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.
Address: 20 Hata'as Str., Suite 102
Kfar Saba 44425
Israel
Tel: +972-9-7670002
Fax: +972-9-7668534
E-mail: amit@asteinrac.com

Date Prepared: July 02, 2020

Trade Name: InMode System with the Morpheus8 Applicators

Classification Name: CFR Classification section 878.4400; (Product code GEI)

Classification: Class II Medical Device

Predicate Device:

The InMode System with the Morpheus8 Applicators is substantially equivalent to the following predicate device;

Manufacturer	Device	510(k) No.
InMode Ltd.	InMode System with the Morpheus8 Applicators	K192695

Device Description:

The InMode System with the Morpheus8 Applicators is a computerized, programmed, RF technology based device intended for dermatological applications which requires skin electrocoagulation and hemostasis.

The device platform is basically constituted on the same system platform as FDA-Cleared InMode System with the Morpheus8 Applicators (K192695). The InMode System with the Morpheus8 Applicators employs fractional RF multi-electrode technology for procedures requiring electrocoagulation and hemostasis. The Morpheus8 Applicators are designed to deliver radiofrequency energy to the skin in a fractional manner, via an array of multi-electrode pins. The Device provides enhanced safety while minimizing possible side effects by monitoring RF parameters.

The InMode System with the Morpheus8 Applicators consists of an AC/DC power supply unit, RF generator, controller and user interface including LCD touch screen. The Morpheus8 Applicators are connected to the console via a cable and a foot switch activates the energy delivery to the applicator. The Morpheus8 Applicator comprises handle and detachable, sterilized, disposable, single use 12, 24, 40 pin and T tip head accessory.

Following are the InMode System with the Morpheus8 Applicators specifications:

RF Max Output Power:	65 Watt
RF Output Frequency:	1[MHz]
Dimension:	46cm W x 46cm D x 100cm H (18.2'' W x 18.2'' D x 40'' H)
Weight:	30 Kg (70.4 lbs.)
Main Line Frequency (nominal):	50-60 Hz
Input Voltage (nominal):	100-240 VAC

Intended Use/Indication for Use:

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.

Performance Standards:

The InMode System with the Morpheus8 Applicators has been tested and complies with the following voluntary recognized standards:

- 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.

- 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.

- 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.

Non-Clinical (Bench) Performance Data:

The performance and safety of the InMode System with the Morpheus8 Applicators treatment in dermatological procedures requiring electrocoagulation and hemostasis in deeper tissues of up to 5, 6 and 7 mm was evaluated in an *ex-vivo* tissue study. The study was conducted on a porcine animal model and included a single treatment of two different harvested porcine tissues: muscle and fat utilizing the InMode System with the Morpheus8 applicator 40 pin tip head. Treatment was followed by biopsy sampling of slices trimmed along the pin's penetration path and collection immediately stained by TTC staining to visualize the tissue coagulation necrosis pattern. The *ex-vivo* study results show that the Morpheus8 Applicators is safe for use and effective in achieving the specified indications of dermatological and general electrocoagulation and hemostasis.

Animal Performance Data / Histology Data:

Not Applicable

Clinical Performance Data:

Not Applicable

Substantial Equivalence:

A comparison table is provided below comparing the intended use and basic technological characteristics of the subject device to the intended use and basic technological characteristics of the predicate device.

Technological Characteristic	InMode System with the Morpheus8 Applicators InMode Ltd. K200947 (Subject Device)	InMode System with the Morpheus8 Applicators InMode Ltd. K192695 (Predicate Device)
Product Code, Class	GEI Class II	GEI Class II
Indications for Use	The InMode System with the Morpheus8 Applicators is intended for use in dermatological and general surgical procedures for electrocoagulation and hemostasis. At higher energy levels greater than 62 mJ/pin, use of these Applicators is limited to Skin Types I-IV.	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 these Applicators is limited to Skin Types I-IV.
Anatomical Sites	Body parts requiring treatment as specified in the indication for use	idem
Target Population	Adults requiring treatment as specified in the indication for use	idem
Environment Used	Hospital or Clinic setting	idem
Energy Used / Delivered	RF energy	idem
Design:	Fractional RF: Use of RF energy delivered through a matrix of multiple pin electrodes allocated on the applicator tip	idem
- Mechanism of Action	Treatment is based on fractional RF technology for localized dermis and	idem

Technological Characteristic	InMode System with the Morpheus8 Applicators InMode Ltd. K200947 (Subject Device)	InMode System with the Morpheus8 Applicators InMode Ltd. K192695 (Predicate Device)
	sub dermis coagulation triggering slow collagen regeneration and fibroblast cells' proliferation.	
- Components	The InMode Morpheus8 Applicators are add-on applicators to the FDA cleared InMode System (K192695). The system consists of the following components: - Console, including a power supply, RF generator, controller, and touch screen control and display panel. - Applicator connected to the console via a cable, with tip including 12, 24, 40 & T tip heads. - Footswitch	idem
- System Dimensions	46cm W x 46cm D x 100cm H [18.2'' W x 18.2'' D x 40'' H]	idem
- Weight Platform weight Applicator weight	30 Kg (70.4 lbs.) Applicator – 0.4 Kg (0.88 lbs.) Tip – 0.02 Kg	idem
Number of pins	12, 24 and 40 pins	idem
Maximal Treatment depth	0.5mm (for T tip head) 4.0mm (for 12 pin tip head) 7.0mm (for 24 and 40 pin tip heads)	0.5mm (for T tip head) 4.0mm (for 12 pin tip head) 4.0mm (for 24 and 40 pin tip heads)

Technological Characteristic	**InMode System with the Morpheus8 Applicators InMode Ltd. K200947 (Subject Device)**	**InMode System with the Morpheus8 Applicators InMode Ltd. K192695 (Predicate Device)**
RF energy level	5-30 (for 24 tip head up to 1 mm) 5-30 (for T tip head and for 12 tip head) 5-60 (for 24 and 40 in the range of 2-7mm)	5-30 (for 24 tip head up to 1 mm) 5-30 (for T tip head and for 12 tip head up to 1 mm) 5-60 (for 12 tip head in the range of 2-4mm) 5-60 (for 24 and 40 in the range of 2-4mm)
Cable Dimensions:	270 cm	idem
Performance	Frequency: 1 MHz Maximal RF output power: 65W Maximal pulse duration: up to 74msec	idem
Standards Met	AAMI/ANSI ES 60601-1 IEC 60601-1-2 IEC 60601-2-2	idem
Biocompatibility	All materials are biocompatible	idem
Compatibility with Environment and Other Devices	InMode System with the Morpheus8 Applicators is compliant with the IEC 60601-1-2 (EMC Safety) standard	idem
Sterility	The 12, 24, 40 and T tip head are Gamma sterilized and for single use. The Morpheus8 Applicator handle is for multiple use	idem
Electrical Safety	Power Requirements:	idem

Technological Characteristic	InMode System with the Morpheus8 Applicators InMode Ltd. K200947 (Subject Device)	InMode System with the Morpheus8 Applicators InMode Ltd. K192695 (Predicate Device)
	100-240 VAC 50-60 Hz The InMode System with the Morpheus8 Applicators is compliant with the IEC 60601-1 standard.	
Mechanical Safety	The InMode System with the Morpheus8 Applicator is compliant with the IEC 60601-1 standard.	idem
Chemical Safety	Not Applicable	Not Applicable
Thermal Safety	The InMode System with the Morpheus8 Applicators is compliant with the IEC 60601-1 standard.	idem
Radiation Safety	The InMode System with the Morpheus8 Applicators is compliant with the IEC 60601-1-2 (EMC Safety) standard.	idem

The indications for use and technological characteristics of the InMode System with the Morpheus8 Applicators are substantially equivalent to the indications for use and technological characteristics of the FDA-Cleared InMode System with the Morpheus8 Applicators (K192695).

The design and components in the InMode System, including the console (with power supply, RF generator, controller and display panel) and the Applicator (with cable, connector to console, handle and tip) are similar to the design and components found in the predicate. The performance specifications (including RF frequency, pulse duration and RF energy per pin) of the subject device were shown to be identical and yielded the same RF energy per pin values to those of the predicate device. The safety features and compliance with safety standards in the InMode System with the Morpheus8 Applicators are identical to the safety features and compliance with safety standards found in the predicate device. Patient contact materials are also identical. Any minor differences in the technological characteristics do not raise new safety or effectiveness

concerns. Furthermore, the new InMode System with the Morpheus8 Applicators 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, comparative bench testing and *ex-vivo* tissue testing to evaluate and compare the fractional coagulation necrosis pattern of target tissues, formed by thermal effect of the InMode System with the Morpheus8 Applicators 24 and 40 pin tip heads in different tissue depths. These performance tests demonstrated that the minor differences in the device design and specifications meet the system requirements and do not raise new safety or effectiveness concerns.

Consequently, it can be concluded that the InMode System with the Morpheus8 Applicators are substantially equivalent to the predicate InMode System with the Morpheus8 Applicators, FDA-Cleared in 510(k) K192695, and therefore, may be legally marketed in the USA.

From: Sumpter, Melanie * [Melanie.Sumpter@fda.hhs.gov]
Sent: 4/8/2020 9:17:14 PM
To: amit@asteinrac.com
Subject: K200947 Acknowledgement Notification
Attachments: K200947 letters.pdf

U.S. FOOD & DRUG ADMINISTRATION

Acknowledgment Letter

4/8/2020

Amit Goren, Regulatory Manager
A. Stein - Regulatory Affairs Consulting Ltd.
20 Hata'as Str., Suite 102
Kfar Saba 4442520
ISRAEL

Dear Amit Goren:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has received your submission. This submission has been assigned the unique document control number below. All future correspondence regarding this submission should be identified prominently with the number assigned and should be submitted to the Document Control Center at the above letterhead address. Failure to do so may result in processing delays. If you believe the information identified below is incorrect, please notify the Program Operations Staff at (301) 796-5640.

Submission Number: K200947
Received: 4/8/2020
Applicant: InMode Ltd.
Device: InMode System with the Morhpeus8 Applicators

We will notify you when the review of this document has been completed or if any additional information is required. If you are submitting new information about a submission for which we have already made a final decision, please note that your submission will not be re-opened. For information about CDRH review regulations and policies, please refer to http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/default.htm.

Sincerely yours,

Center for Devices and Radiological Health

Appendix 3.0: Revised Operator Manual (Red-lined and Clean Versions)

MORPHEUS8

Operator Manual

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MORPHEUS8

Operator Manual

Morpheus8 (Fractora) Applicator

Version: DO607530D

INMODE

Operator Manual: Morpheus8 Applicator

DO607530D

InMode Ltd

Tavor House. POB 533, Industrial Park South,

Yokneam, 2069206. Israel

Tel: +972-4-9096313

Fax: +972-4-9096310

Table of Contents

1 Section 1: Introduction

1.1 Before You Start

The manual and the equipment described are for use only by qualified medical professionals trained in the particular technique to be performed.

Federal (USA) law restricts sale of this device by or on the order of a physician.

Read this manual to become familiar with all safety requirements and operating procedures before attempting to operate the System.

1.2 System Overview

The InMode Platform with Morpheus8 Applicators employs bi-polar Radio-frequency (RF) technology for various aesthetic applications. The Morpheus8 Applicators are used with InMode platform. The device provides individual adjustment of treatment parameters to achieve maximum efficiency and safety for each patient and applications.

1.3 Conventions Used in the Manual

The following conventions in the form of notes and warnings are used in this manual:

WARNING! This information is extremely important!

ATTENTION! Consult Accompanying Document.

NOTE! Provides general information that is important to keep in mind.

1.4 Explanation of the Symbols used on the System

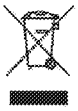
Symbol	Description
	CSA marking (212603 CSA master contract number)
	Do not discard in trash. Electronic equipment should be disposed of in an appropriate manner
	Fuse
	Type BF Equipment
	HF Isolated Patient Circuit
	Follow the operating instructions
	Caution: Federal law restricts this device to sale by or on the order of a Physician
	Do not reuse/single use only. This symbol is used for disposable one-time-use products.
	This equipment intentionally supplies non-ionizing RF energy
	Sterilized by Radiation

Table 1-1: Device Symbols

2 Section 2: Safety

This chapter describes safety issues regarding the use and maintenance of the Morpheus8 Applicator, with a special emphasis on electrical safety.

The system is designed for safe and reliable treatment when used in accordance with proper operation and maintenance procedures. Only trained, qualified practitioners can use the system. The operator and all other personnel operating or maintaining the system should be familiar with the safety information provided in this section.

The primary consideration should be to maximize safety for both treating attendant and patient.

⚠ Read this chapter to be familiar with all its safety requirements and operating procedures prior to system operation.

⚠ RF energy can cause injury if used improperly.

⚠ High voltage is present inside the System.

⚠ Always be aware of the possible dangers and take proper safeguards as described in the manual.

2.1 The Patient

- Well-trained staff is key for assuring patient safety. A patient history report should be completed prior to scheduling. Patients should be fully informed of the treatment details, the likely results and any risks associated with the treatment.
- Jewelry and metal accessories that are within the activation range of the Applicator should be removed to avoid accidental RF conduction.
- Patients will not be in contact with any metal or other alternate pathway to ground whilst the System is in use.

2.2 Treating Attendant

- Only authorized individuals with appropriate training and knowledge should operate, assist in the operation of, or provide maintenance to the device with Morpheus8 Applicator.

- Personnel should not operate the System until they have been fully educated in its use. Make sure that all treatment personnel are familiar with the System controls and know how to shut down the System instantly.
- There are no user-serviceable parts in the System, and all service and repair must be performed only by the factory or authorized field service technicians.

2.3 Cautions

The following cautions should be heeded for safe System use:

- Do not touch the System's inner parts.
- Service is supplied by company authorized personal only.
- To avoid damage, do not allow the Applicator to come in contact with hard materials.

2.4 Electrical and Mechanical Safety

- Keep all covers and panels of the System closed. Removing the covers creates a safety hazard.
- Keep hands away from the applicator during the System start-up.
- Perform maintenance procedures when the System is shut down and disconnected from the power.
- The System is grounded through the grounding conductor in the power cable. This protective grounding is essential for safe operation.
- Move the System slowly and carefully. The System weighs approximately 15kg (33 lb.) and may cause injury if proper care is not used when moving it.
- Provide as much distance as possible between the System, RF Applicator and other electronic equipment as the activated RF generator may cause interference between them.

2.5 Fire Hazards

- Do not use the System in the presence of explosive or flammable materials.
- Materials conducting RF energy may cause temperature rise of the absorbing material. Do not use the System in the presence of explosive or flammable materials conductive to RF.

- Do not use flammable substances when preparing the skin for treatment. Be especially careful with the use of oxygen.
- Keep drapes and towels moist to prevent them from igniting and burning. Use nonflammable prepping solutions.
- If alcohol is used for cleaning and disinfecting, it must be allowed to dry thoroughly before the System is used.

2.6 Safety Features of the System

The System incorporates the following safety features. All personnel operating the System should be familiar with these features.

- The System has unique password to avoid device operation by non-authorized personnel.
- The power electronics cannot be activated unless the applicator and Footswitch have been connected to the System
- An audible tone indicates energy activation.
- During activation, the System performs a self-test of the hardware.
- Hardware is tested every 10ms to ensure proper operation of electrical circuit.
- During activation, the System performs a self-test of the hardware.
- Hardware is tested every 10ms to ensure proper operation of electrical circuit.
- The System starts at a low setting.

2.7 Safe use of the Active Accessories

- Examine the connection of the Applicator through the connectors to the System before using. Ensure that the accessory functions as intended. Improper connection may result in arcs and sparks, accessory malfunction, or unintended treatment effects.
- Do not wrap the Applicator cords around metal objects. It may induce current that could lead to electrical shocks, fire or injury to the patient or personnel.
- When using the Morpheus8 applicators, ensure that all electrodes are in full contact with the skin. Bad coupling of electrodes with the skin results in a specific warning sound, a message on the screen, and disabling of RF.

- The tips are for single use only. Do not try to reuse them. Re-use of the tips may cause for unintended cross contaminations and infections, create loss of integrity that may affect the performance and make the Device non-functional.

⚠ Do not connect a wet accessory to the System.

⚠ Do not immerse the applicator under water at any time.

⚠ The Morpheus8 12, 24, 40 & T Tip heads arrive sterilized in gamma rays and cannot be autoclaved.

⚠ The Morpheus8 Tips are for single use only!

2.8 Warnings

⚠ This equipment is for use only by qualified medical professionals trained in the particular technique to be performed.

⚠ Only Applicator manufactured or approved by InMode Ltd. should be used with InMode System with Morpheus8 Applicator.

⚠ Connect the power cord to a properly polarized and grounded power source with the frequency and voltage characteristics that match those listed on the back of the unit.

⚠ Connect the System power cord to a properly grounded receptacle. Do not use power plug adapters.

⚠ Always turn off and unplug the device before cleaning.

⚠ The patient should not come into contact with metal parts which are earthed or which have an appreciable capacitance to earth. The use of antistatic sheeting is recommended for this purpose. Treatment bed or chair should not be electric.

⚠ Use the lowest output setting necessary to achieve the desired treatment effect. The higher RF is applied, the greater the possibility of unintended thermal damage.

⚠ Failure of the equipment could result in an unintended increase of output power.

⚠ The cables of the Applicator should be positioned in such a way that contact with the PATIENT or other leads is avoided.

⚠ Fire / Explosion Hazard - The following substances will contribute to increased fire and explosion hazards in the operating room:

- Flammable substances (such as alcohol-based skin prepping agents and tinctures).
- Naturally occurring flammable gases which may accumulate in body cavities such as the bowel.
- Oxygen enriched atmospheres.
- Oxidizing agents (such as nitrous oxide [N2O] atmospheres).

– Endogenous gases.

⚠ The RF energy and heating associated with the System can provide an ignition source. Observe fire precautions at all times. When using InMode System with Morpheus8 Applicator in the same room with any of these substances or gases, prevent their accumulation or pooling within the area where Morpheus8 procedures are performed.

⚠ The operation of the InMode System with Morpheus8 Applicator may adversely influence the operation of other electronic EQUIPMENT.

⚠ To avoid the RISK of electric shock, this equipment must only be connected to a SUPPLY MAINS with protective earth.

⚠ Do not use Morpheus8 on patients with pacemakers or internal defibrillators.

2.9 Device Labels

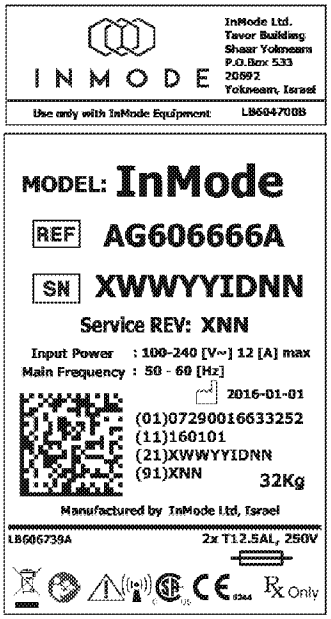


Figure 2-1: InMode Device label

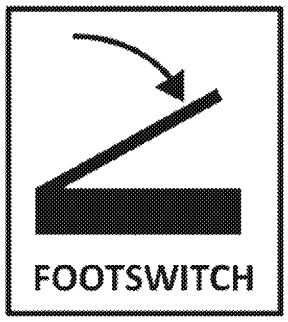


Figure 2-2: Footswitch Label

2.10 Applicator Labels

As required by national and international regulatory agencies, appropriate warning and information labels have been attached in specific locations on the instrument as identified below.

The following device labels are located on the InMode System with Morpheus8 Applicator device console and the Applicator:

The Applicator certifications and identification labels are attached to connectors on the Applicators. It states that the product conforms to the performance standards, and indicates the manufacturer's name, date of manufacturing, model and serial number of the Applicator. The following labels are located on the Applicator: Manufacturer identification labeling is placed on the Applicator:

Figure 2-3: Morpheus8 Applicator Identification Labels

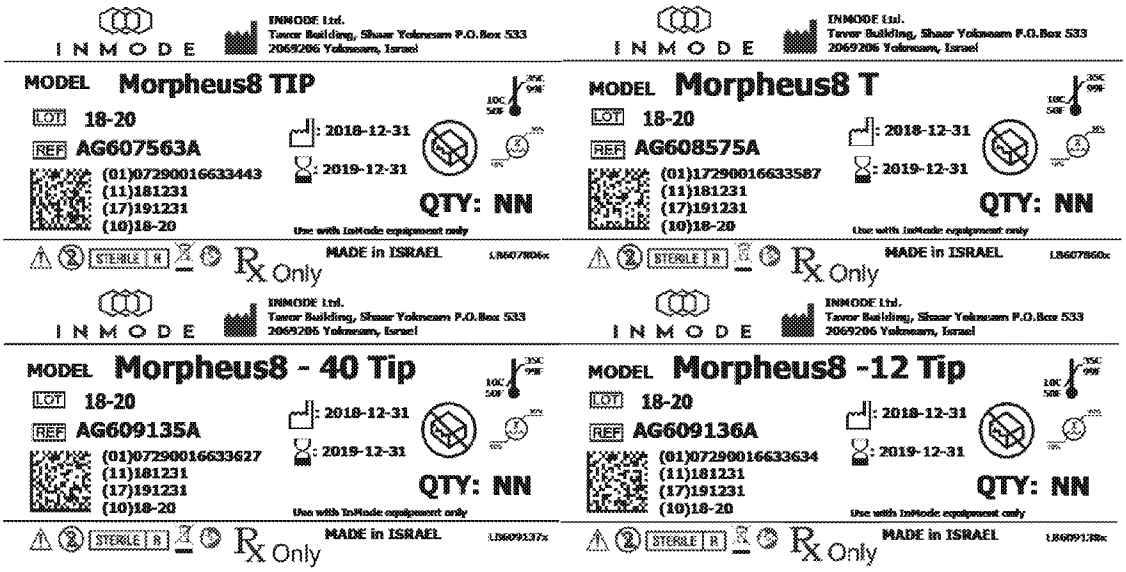


Figure 2-4: : Morpheus8 (24 Pin) Tip (Upper Left), Morpheus8 T Tip, Morpheus8 Body (40 Pin) Tip (Lower Left), Morpheus8 Prime (12 Pin) Tip (Lower Right)

2.11 Equipment Classification

The following is a list of the different equipment used and their classifications.

- Electric shock protection: Class I, Type BF for the RF Applicator.
- Protection against ingress of liquids: Ordinary equipment.
- Not suitable for use in presence of flammable substance.
- Power receptacle must include protective earth and must be checked before connecting the System.

The InMode Systems with the Morpheus8 Applicators is classified as Class II device defined by the FDA CDRH and complies with 21 CFR subparts E.

3 Section 3: System Installation

3.1 Electrical Requirements

- The System will require a separate line supply of single phase (100Vac; 15A) or (115Vac; 15A) or (230Vac; 15A) or (240Vac; 15A) 50-60Hz. Zmax = 0.03Ω.
- Power receptacles must be within 15 feet of the System site.
- The System should not share a power line with other equipment.
- Power receptacle must include protective earth and must be checked before connecting the System.

⚠ For continued protection against fire, replace the fuse only with one of the same types and rating.

⚠ Proper grounding is essential for safe operation.

3.2 Environmental Requirements

- Corrosive materials can damage electronic parts; therefore, the System should operate in a non-corrosive atmosphere.
- For optimal operation of the System, maintain room temperature between 20º-27ºC (68º-79ºF) and relative humidity of less than 80%.

3.3 Equipment List

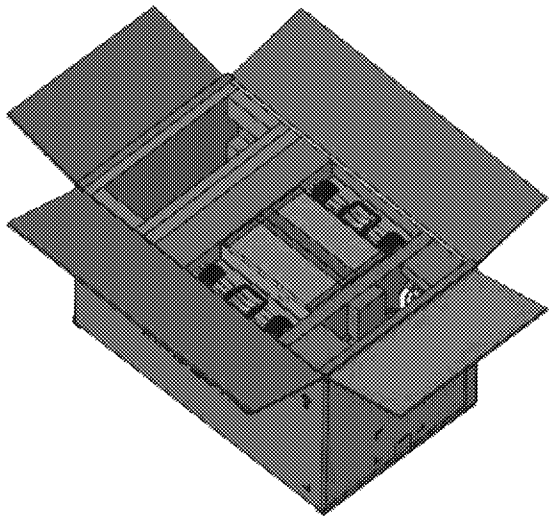
The System includes the following:

- System platform
- Applicator Handle & Detachable Tips
- Applicators cradles
- Footswitch
- Operator manual
- Power cord

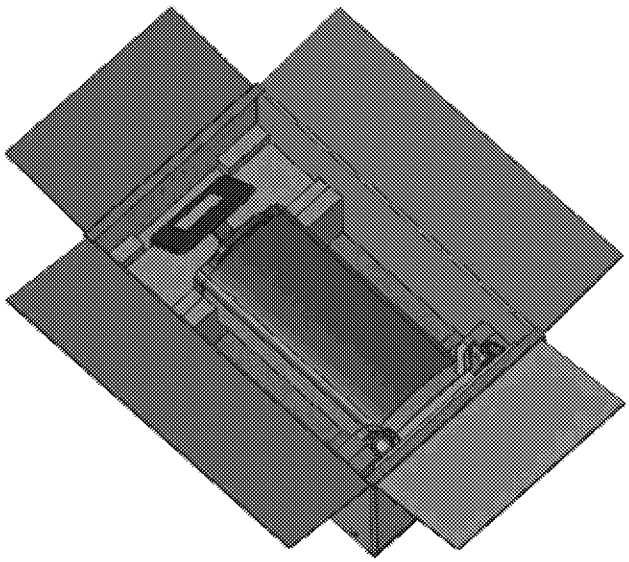
3.4 Unpacking

In order to unpack the device:

1. Remove the paper strip and open the box



2. Remove accessories and foams around the device.



3. Take device out of the box using top and bottom handles.

3.5 Installation

The System is designed for installation in a clinic environment. To install the System, perform the following tasks:

- Check the System and all its components for damage.
- Connect cradle to the device.
- Connect Applicator to the connector and place into the cradle.
- Connect the Footswitch.
- Connect the power cord to the System inlet.
- Plug the System Power Cord into an appropriate electrical outlet.

3.6 Moving the System

- Turn the System off.
- Disconnect the Power Cord.
- Disconnect the Applicator.
- Disconnect the Footswitch.
- Release the Wheel Brakes.
- Slowly push or pull the System using the handle.
- When moving the System to another facility, lift the System to the vehicle and lay it carefully on its side.

Never lift, pull or push the System using the operating panel.

Always use the handles when moving the System.

Upon unpacking, check the System for mechanical damage (e.g., cracks in the cable insulation).

3.7 System Disposal

To comply with European Commission Directive 2002/96/EC on Waste Electrical and Electronic Equipment (WEEE) and other country and state regulations, please DO NOT dispose of this equipment in any location other than designated locations.

4 Section 4: Device Description

4.1 Rear Panel

	**Power Cord Inlet** 100-240V~, 15A, 50-60Hz.
	**Fuse Holder** Rating is T 12.5A, 250V. Replace fuses if needed, only with fuses having exactly the same rating.
	**Software Flash Memory Plug** The software plug is a flash memory with the machine software. The software plug should be screwed to the connectors. To tighten and/or loosen the screws use fingertips only. Do not use screwdriver as it can damage the connectors.
	**Footswitch Connector** Footswitch is connected to the inlet. Footswitch activates RF energy if the System is in Ready mode. Place the Footswitch on the floor near the treatment area.

4.2 Operator Control Panel

The Operator Control Panel is located on the upper side of the System. The Operator Control Panel consists of On-Off switch, four function keys, an information screen and hand piece connectors (Figure 4.1).

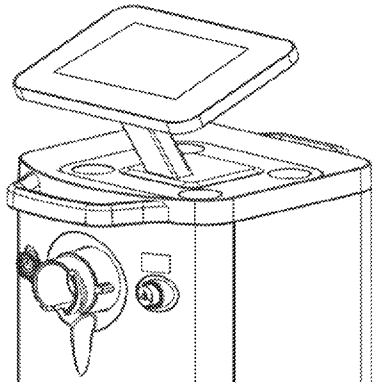


Figure 4-1: Operator Control Panel

Power On-Off Switch	Power switch turns System On and Off.
Hand piece connector	RF power cannot be activated if Applicator is not connected to the connector.
LCD Screen	LCD screen shows information about machine status, treatment parameter. Touch screen allows to user change treatment parameters and device mode

4.3 Software Screens

The Progress screen appears after the On-Off switch is turned on.

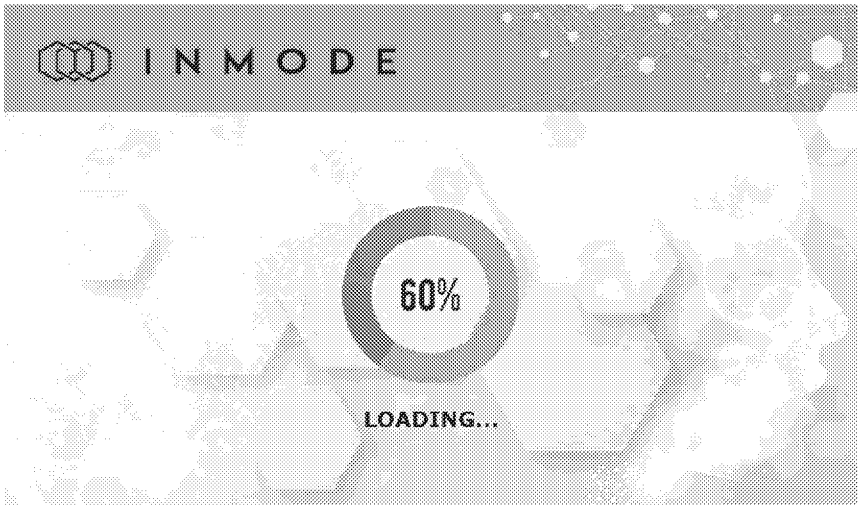


Figure 4-2: Progress Screen

*The SW version number will be displayed according to the software version.

After entering the individual code on the Login Screen, non-authorized use of the device is prevented.

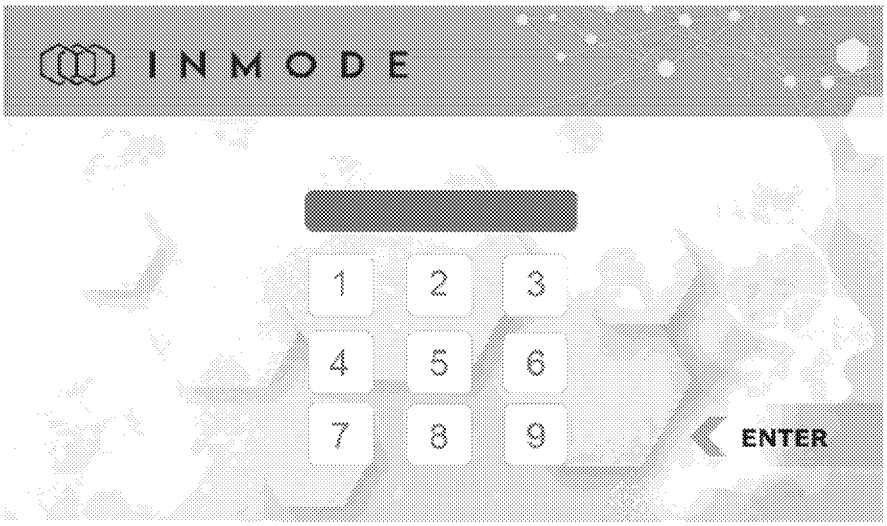


Figure 4-3: Login Screen

Software is loaded from the plug and self-test of the System modules is performed. After the end of the self-test the Menu Screen appears.

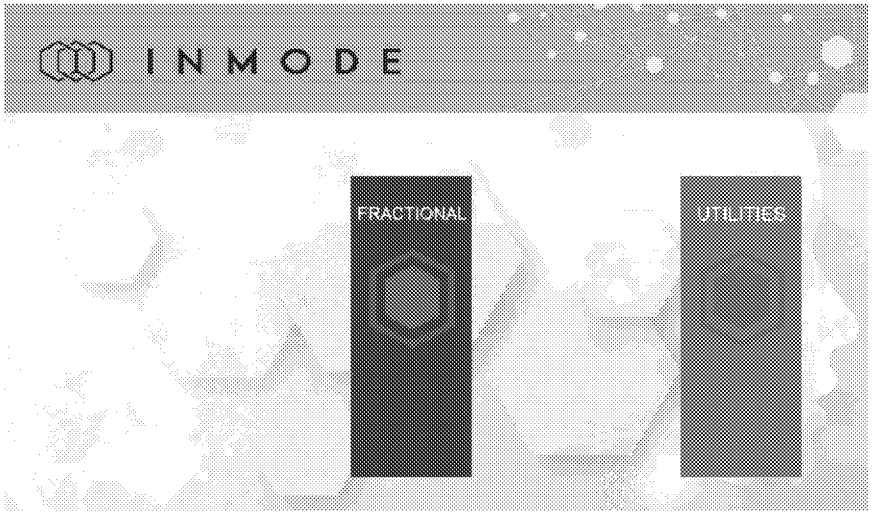


Figure 4-4: Menu Screen

The Menu Screen allows the selection of the connected Applicator, or entry to the Utilities Screen.

Figure 4-5: Utilities Screen

The Utility Screen contains:

Volume	This function allows the user to adjust the System volume.
Change Password	Change the password by entering the old password and then entering another 4-digit password.
Calibration	N/A
Main Menu	Return to the Main Menu to select an applicator.

After returning to the Menu Screen and choosing the application on the Menu Screen, the corresponding Treatment Screen appears.

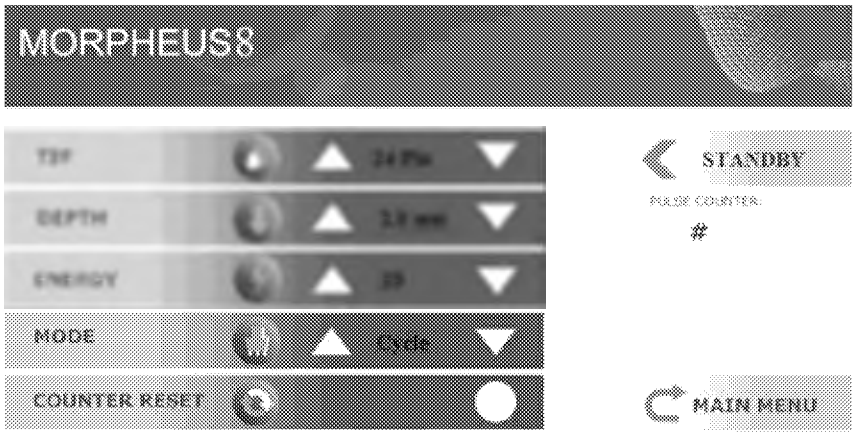


Figure 4-6: Morpheus8 Treatment Screen

Tip	Allows selecting the Tip. Available Tips are: T, 12 Pin, 24 Pin tip and 40 Pin.
Depth	Allows selecting the pins length and penetration depth according to dermis thickness in treated area to provide effective sub-dermal treatment. Available depths for Morpheus 8 are: For the Morpheus8 Prime (12 pins) Tip: 1 to 4mm (In increments of 1mm) For the Morpheus8 (24 pin) Tip 1 to 7mm (In increments of 1mm) For the Morpheus8 Body (40 pins) Tip 2 to 7mm (In increments of 1mm) When connecting the Morpheus8 T Tip, depth control is disabled and the pin length is fixed (0.5mm).
Energy	Delivered energy is changed from level 5 to 60 energy levels and the System starts up at the minimal energy setting.
Mode	Selects between Cycle mode when needle goes out and in at each pulse and Fixed mode which is solely used for T tip.
Counter Reset	Counter can be reset.
Pulse Counter	Shows number of pulses delivered on one zone and total number of pulses from the beginning of the treatment.
System Mode	The System has three treatment modes: Standby, Ready, and Active. Standby mode allows the user to set treatment parameters. Activation of energy is not allowed in Standby mode. In Ready mode, the system is waiting for a signal from the foot switch to activate the energy. Any attempt to change the treatment settings switches the system to Standby mode. When the signal from the footswitch is indicated, the system switches to Active mode. Any attempt to change the treatment settings switches the system to Standby mode.
Main Menu	Return to the Main Menu to select another applicator and change the applicator if needed.

4.4 Sound Indicator

Periodic beeping signal is emitted when RF energy is delivered.

4.5 Applicator

Morpheus8 Applicator (Figure 4.7) comprise motor with actuator pushing needle electrodes out to pre-determined depth of up to 7mm. The tip (Figure 4.8) is connected or disconnected with the Applicator.

Figure 4-7: Morpheus8 Applicator

Tip	See below table for Tip specifications.
Handle	The Applicator handle is made of plastic and has an ergonomic design for easy treatment, with high visibility of the treated area.
Cable	The Cable has a length of 270cm.
Connector	The Connector is connected to the front panel of the System.

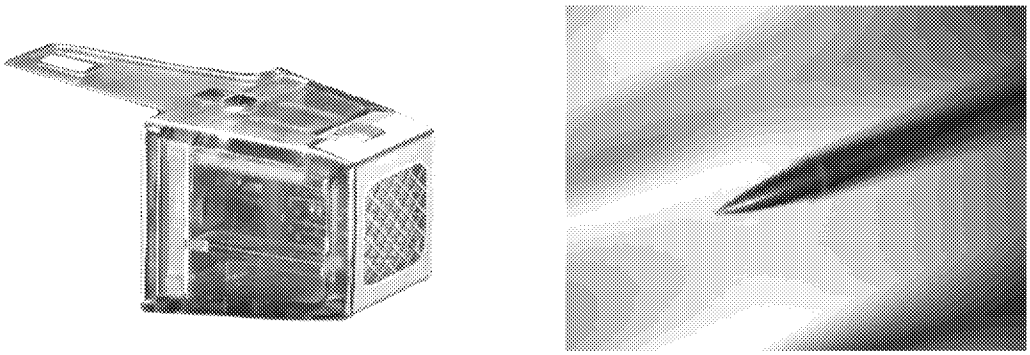


Figure 4-8: Morpheus8 Tip (Left) and Coated Needle (Right)

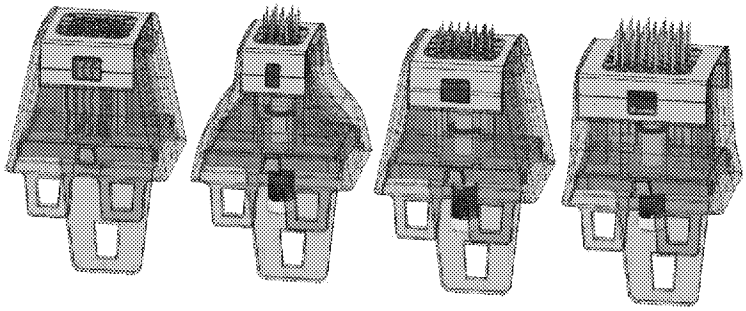


Figure 4-9: Morpheus8 T Tip (Left), Morpheus8 Prime (12 Pins) Tip (Center-Left), Morpheus8 (24 Pins) Tip (Center-Right), Morpheus8 Body (40 Pins) Tip (Right)

⚠ Morpheus8 Tips are for single-use only!

The table below summarizes the specifications of the various Morpheus8 tips:

Tip Name	Pins number	Depth mm	Energy Levels	Cycle Mode	Fixed Mode
Morpheus8 – Body	40	2, 3, 4, 5, 6, 7	5-60	Yes	NA
Morpheus8 -	24	1, 2, 3, 4, 5, 6, 7	5-60 (1mm-5-30)	Yes	NA
Morpheus8 – Prime	12	1, 2, 3, 4	5-30	Yes	NA
Morpheus8 T	24	0.5 Fixed	5-30	NA	Yes

5 Section 5: System Operation

This section of the manual explains how to start the device, operate it, and turn it off.

Prior to using or connecting the Applicator, inspect the System and Applicator for possible mechanical damage.

5.1 Device Start-Up

1. Connect the Applicator to the Applicator connector socket on the System.
2. Press the On-Off button on the control panel to turn the device on. The System loads the software and enters the Login Screen.
3. Enter password to get access to the device. If password is correct the System enters Menu Screen.
4. The System loads the software and enters a self-test mode. If any problem is detected during the test the error message will appear (See Troubleshooting Section in this manual). If the test is passed correctly then the System automatically enters the Menu Screen.
5. Select the application from the Menu Screen and System will enter the Treatment Screen.
6. Verify on the screen that the Software version is properly displayed and the connected Applicator type is recognized correctly.
7. Select the treatment parameters using Up and Down keys.
8. Press the Standby icon that will change to Ready.
9. To start treatment, press the Footswitch for RF applicators.
10. Apply Applicator to the treated area, ensuring a full contact with pressure.

5.2 System Shutdown

- To shut down the System turn the On-Off switch off.
- Turn the Main Power switch off at the end of the day.

6 Section 6: Morpheus8 Treatment Information

6.1 Sub-dermal Fractional Treatment

The Morpheus8 Applicators are designed for delivering RF energy to the dermal and sub-subdermal tissue in a fractional manner with the energy applied to <5% of the total coverage area. The energy is delivered to the skin through bipolar arrays of coated needles and results in localized heating and coagulation of the tissue that is in direct contact with the needle tip. The Morpheus8 Applicator is a versatile fractional technology to treat different body areas.

6.2 Indications for Use

The Morpheus8 Applicators are intended for use in dermatological procedures for electrocoagulation and hemostasis.

At higher energy levels greater than 62 mJ/pin, use of the Morrpheus8 (Fractora) Applicator is limited to Skin Types I-IV.

6.3 Contraindications

- Pacemaker or internal defibrillator, or other metallic or electronic implant anywhere in the body. The Hand piece should be used at least 1cm away from cochlear implants in the ear.
- Permanent implant in the treated area such as metal plates, screws and metal piercing or silicon, unless deep enough in the periosteal plane.
- Intra-dermal or superficial sub-dermal areas injected with Botox®/HA/collagen/fat injections or other augmentation methods with bio-material, before the product has been dissipated (up to 6 months), except Botox after binding to the facial muscles (3-7 days). It is possible to treat sooner over injectable products placed in the deep, periosteal plane, as soon as the area has healed (1-3 weeks).
- Current or history of skin cancer, or any other type of cancer, or pre-malignant moles.
- Pregnancy and nursing.
- Severe concurrent conditions, such as cardiac disorders or sensory disturbances.
- Impaired immune system due to immunosuppressive diseases such as AIDS and HIV, or use of immunosuppressive medications.

- Patients with history of diseases stimulated by heat, such as recurrent Herpes Simplex in the treatment area, may be treated only following a prophylactic regime.
- Poorly controlled endocrine disorders, such as diabetes or thyroid dysfunction and hormonal virilization.
- Any active skin condition in the treatment area, such as sores, psoriasis, eczema, and rash.
- History of skin disorders, keloids, abnormal wound healing, as well as very dry and fragile skin.
- History of bleeding coagulopathies or use of anticoagulants in the last 10 days
- Any facial surgery performed within a year prior to treatment.
- Facial dermabrasion, facial resurfacing, or deep chemical peeling within the last three months, if face is treated.
- Having received treatment with light, laser, RF, or other devices in the treated area within 2-3 weeks for non-ablative procedures, and 6-12 weeks for ablative fractional laser resurfacing (according to treatment severity) prior to treatment, except special recommendations.
- Use of Isotretinoin (Accutane®) within 6 months prior to treatment.
- Use of non-steroidal anti-inflammatory drugs (NSAIDS, e.g., ibuprofen-containing agents) one week before and after each treatment session, as per the practitioner's discretion.
- Treating over tattoo or permanent makeup to be kept.
- Treating over the lips.
- Skin type VI and dark VI patients treat with caution.
- Treating over hair bearing surfaces.
- Irritable skin like excessively tanned skin from sun, tanning beds or tanning creams and sprays within the last two weeks.
- As per the practitioner's discretion, refrain from treating any condition that might make it unsafe for the patient.

6.4 Possible Adverse Side Effects

- Possible adverse effects include but are not limited by: discomfort or pain, excessive skin redness (erythema) and/or swelling (edema), damage to natural skin texture (crust, blister, and burn), change of pigmentation (hyper- and hypo-pigmentation), and scarring.
- Erythema lasting not longer than 24h and edema for 1-3 weeks is a typical skin reaction to the treatment.
- Crusting from the ablated dots will exfoliate naturally after 1-3 weeks.
- The patient must understand the importance of pre-treatment and post-treatment instructions and that failure to comply with these instructions may increase the probability of complications.

6.5 Pre-treatment Recommendations

During the patient's first visit the treating attendant should:

- Complete or update the patient's medical and physical history.
- Exclude from treatment anyone with the listed contraindications.
- Determine why the patient is seeking treatment and what his/her expectations are.
- Determine accurately the patients Fitzpatrick skin type.
- Inform the patient about treatment arrangement, typical treatment results and possible side effects and discomfort.
- Instruct the patient about the safety warnings.
- Advise the patient to avoid skin irritation or intentional skin tanning. Sunscreen is advisable when outdoors during daylight hours
- Asian patients and those with skin types IV-VI should be treated gradually by bleaching products 6 weeks prior treatment and stop at least 48 hours prior Morpheus8 treatment to minimize risk of post inflammatory hyper-pigmentation.
- Prophylactic antiviral therapy should be prescribed for patients with history of cold sores (Herpes Simplex) when treating around the mouth.
- Stop anticoagulants 7-10 days prior to treatment, if medically permitted.
- Clean the treatment area.

- Apply anesthesia:
  - Topical anesthetic can be applied as needed prior to treatment.
- Cooling methods, such as air cooling, sterile ice-packs, or sterile latex gloves filled with ice, help patient comfort during and after treatment.

The patient should shave the area to be treated. Long and dense hairs prevent electrode contact with the skin's surface.

The operator shall inspect the hand pieces functionality prior to use, by attaching the disposable tip, pressing the footswitch and observing the pins to come out and returning back.

In case of engine failure when the pins of the hand pieces do not retract out of the skin, detach the disposable tip from the hand piece and release the spring mechanism manually.

6.6 Handling Instructions Prior to Use

The Applicator should be thoroughly cleaned before and after use by applying 70% alcohol-absorbed pad for at least 30 sec.

Before each use thoroughly inspect the Applicator for visible damage and cleanliness.

Inspect all components of the Hand piece for visible damage.

The Morpheus8 tips arrive sterile and are for single use only!

6.7 Test Spots

A small test spot should be performed in a non-conspicuous area of the treatment site, prior to the first complete session. Test spot is performed to establish the following requirements:

- Confirm the patient's suitability for treatment:
  - For skin types I – III wait 10-15 minutes before assessing the skin response.
  - For skin types V-VI wait 2-3 days if energy level <30 is used and 7-10 days if energy level >30 is used.
- Establish and confirm treatment parameters: if the desired end-point of erythema and edema – in a tip-shaped pattern – has not been achieved within 10-15 minutes, increase the RF energy. If the response is excessive, decrease the parameters.

6.8 Treatment Recommendations

1. Apply the necessary means of anesthesia. If topical, make sure that it is cleaned off the face before treatment and the skin is dried with alcohol 70%.
2. Ensure that skin is clean and dried with alcohol 70%.
3. Take an alcohol cleaned and dry tip and connect it to the Applicator in the groove.
4. Connect Applicator to the System.
5. Follow Device Start-Up Procedure from System Operation section.
6. Select tip and set treatment parameters.
7. Make sure that the treatment settings correlate to the treated tissue depth.
8. Always start with a low energy level, test patient comfort and observe the skin's response before increasing the energy. Tips, depth and energy levels may vary according to physician discretion, based on patient response.
9. On sensitive thin skin area apply lower parameters.
10. Dark skin (V-VI) treat with restricted energy, starting at the minimal suggested energy level or lower, adding 5 levels each visit (every 3-4 weeks).
11. Apply the Applicator to the treated area ensuring a contact with pressure to minimize discomfort, and press footswitch to deliver RF energy.
12. Move Applicator to the adjacent area and activate RF again.

13. Move to adjacent areas with no overlapping of side-electrodes (30-50% overlap).

14. The endpoint is substantial erythema and edema, visible ablative craters, and burnt tissue smell often accompanied by tingling heat sensation.

The below list summarizes the Treatment recommendations per each tip type:

Tip name	Treatment areas
Morpheus8 Prime (12 pin) Tip	Dermal and subdermal treatment of small areas difficult to maneuver
Morpheus8 T Tip	Superficial (epidermal) treatment
Morpheus8 (24 pin) Tip	Dermal and subdermal treatment
Morpheus8 Body (40 pin) Tip	Dermal and sub-dermal treatment of large body areas
Typical number of treatments is 1 to 6 and depends on used energy and treatment goal	
Typical down time is 1 to 6 days and depends on used energy and number of passes	

6.9 Treatment Schedule

The number of treatment sessions depends on the individual patient and treatment aggressiveness and may vary from 1-6 sessions, depending on used energy and treatment goal, as well as patient tolerance and skin response. Treatments are typically repeated every 3-6 weeks.

It is recommended to schedule a follow-up session 2-3 days after the treatment to ensure safe healing process.

Typical down time is 1 to 6 days and depends on used energy.

Treatment should be concluded when the results are satisfactory to the patient or according to the physician's discretion. Generally, 3-6 sessions are needed for mild to moderate depth settings. It is not typical to perform more than five consecutive sessions; however, more sessions can be performed as per physician discretion. In some instances, 1-2 sessions may be sufficient.

6.10 Post-treatment Recommendations

After each treatment session, the physician should advise the patient on proper care.

- Cool the skin for 10-20 min.
- Emollient cream or occlusive dressing could be applied to the treatment area.
- Alternatively, prophylactic antibiotic treatment may be prescribed for 1-3 days post treatment. Patient is to contact the physician if there is any indication of infection, excessive swelling, redness, undue pain, or any other unusual or untoward symptom.
- Tiny scabs may appear after 1-3 days and stay for several days following the treatment. The scabs should not be touched or scratched even if they itch and should be allowed to flake off naturally.
- Blisters may be treated with a prescribed antibiotic ointment or burn treatment cream as per physician's discretion.
- During the first two days following treatment the skin should be kept clean to avoid contamination or infection; any mechanical or thermal damage to the area must be avoided.
- Prophylactic antiviral therapy should be continued for patients with history of cold sores (Herpes Simplex) when treating around the mouth.
- Moisturizer may be applied 24-72 hours after each treatment and then should be applied regularly throughout the course of the treatment. Make-up may be applied only 24-72 hours after each treatment session. Generally, 24 hours after treatment, patients may use regular soaps, but not scrub soaps or exfoliates.
- The patient should use a high-factor sunscreen (at least 30 SPF) and protect the treated area from over-exposure to sunlight for at least one month after the treatment, starting 24-72 hours post treatment. Excessive tanning of any sort (sun exposure, tanning beds, and artificial tanning lotions) is not allowed in the treated areas during the entire course of the treatment.
- For Asian patients and skin types IV and V, a prescription or compounded bleaching regimen may be prescribed by the physician for 6-12 weeks, 2-3 times a week following the healing of treatment area (typically 7 days) to minimize risk of post inflammatory hyper-pigmentation. It should be stopped 48-72 hours before another Morpheus8 session.

7 Section 7: Troubleshooting

The InMode System with Morpheus8 Applicator provides monitoring of all critical parameters to ensure safety of patient and user. If any of the following faults are detected system automatically goes to STAND BY mode.

7.1 Description of Faults with All Applicator

Problem	Description and Checks
System does not turn on	▪ Check power cord connection. ▪ Check that On/Off switch on front panel is on. ▪ Check fuses on back panel of the System. ▪ Call Technical Service if problem persists.
System shuts down by itself	▪ Check power cord connection. ▪ Check fuses on back panel of the System. ▪ Call Technical Service if problem persists.
Checksum	▪ The software was not loaded properly from software plug. ▪ Check the plug connection and reboot the System. ▪ Call Technical Service if the problem persists.
Fault H8002 - Applicator is not connected	▪ Check the connection of the Applicator. ▪ Replace the Applicator. ▪ Call Technical Service if the problem persists.
Fault H8005, H800F, H8010 – System Memory Fault	Call Technical Service if the problem persists.
Fault H800E- System Incompatible Software Version	Call Technical Service if the problem persists.
Fault H800F- System Memory Fault	Call Technical Service if the problem persists.
Faults H8003, H8006, H8007 - RF Related Faults	Call Technical Service if the problem persists.

8 Section 8: System Specifications

Input Power		
Main Line Frequency (nominal)	50-60Hz	
Input Voltage (nominal)	100-240VAC	
Input Current (rms)	12A	
Operating Parameters		
Ambient Temperature Range	15 – 30°C [59 – 86°F]	
Relative Humidity	30% to 80%, non-condensing	
Atmospheric Pressure	90 - 110kPa	
Warm-up Time	If transported or stored at temperatures outside the operating temperature range, allow one hour for the device to reach room temperature before use.	
Transport and Storage		
Ambient Temperature Range	-20– 65°C [-4 – 149°F]	
Relative Humidity	0% to 80%, non-condensing	
Atmospheric Pressure	50 to 110kPa	
Dimensions		
System	46cm W x 46cm D x 100cm H	[18.2'' W x 18.2'' D x 40'' H]
Applicator Cable	270cm L	[100`` L]
Weight		
System	32.000kg	[70.548lb]
Morpheus8 Applicator	0.400kg	[1.268lb]
Morpheus8 Output Parameters		
Maximum Output Power	65[W]	
Frequency	1MHz	
Crest Factor (Rated Load)	1.4± 2%	

8.1 Output Power Curves

The curves that follow depict the changes for each RF mode at specific power settings.

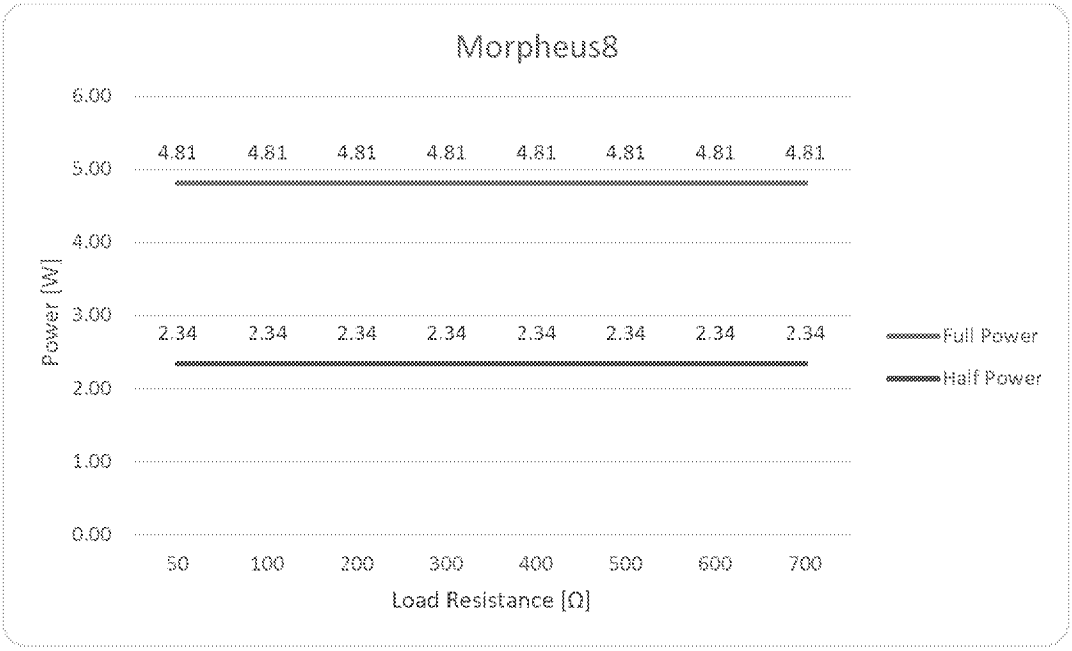


Figure 8-1: Morpheus Output Power versus Impedance

8.2 EMC Safety

The device has been tested and found to comply with the limits for the medical devices to the IEC 60601-1-2. These limits are designed to provide reasonable protection against harmful interference in a typical clinical installation. This device generates uses and can radiate radio frequency energy. If not installed and used in accordance with the instructions, may cause harmful interference to other devices in the vicinity. However, there is no guarantee that the interference to other devices, which can be determined by turning the device off and on, is caused by this instrument.

The user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving device.
- Increase the separation between the devices.
- Connect the device into an outlet on a circuit different from that which was previously used.

- Consult InMode service personnel for help.

Interference to the device may be caused by portable and mobile RF communication equipment. In case of an interruption, beware of such a device in the vicinity.

- Use of the System with any accessory, transducer or cable other than those specified may result in increased EMISSIONS or decreased IMMUNITY than those specified.

- The System should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the System should be observed to verify normal operation in the configuration in which it will be used.

Guidance and manufacturer's declaration – electromagnetic emissions		
The InMode System with Morpheus8Hand pieces is intended for use in the electromagnetic environment specified below. The customer or the user of the InMode System with Morpheus8Hand pieces should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment – guidance**
RF emissions CISPR 11	Group 1	The InMode System with Morpheus8 Hand pieces uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class A	The InMode System with Morpheus8 Hand pieces is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Complies	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

Guidance and manufacturer's declaration – electromagnetic immunity

The InMode System with Morpheus8Hand pieces is intended for use in the electromagnetic environment specified below. The customer or the user of the InMode System with Morpheus8Hand pieces should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Electrostatic discharge (ESD) IEC 61000-4-2	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	± 2 kV for power supply lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV differential mode ± 2 kV common mode	± 1 kV differential mode ± 2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5 % U_T (>95 % dip in U_T) for 0,5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles <5 % U_T (>95 % dip in U_T) for 5sec	>95 % dip for 10 ms 60 % dip for 100 ms 30 % dip for 500 ms 95 % dip for 5000 ms	Mains power quality should be that of a typical commercial or hospital environment. If the user of the InMode System with Morpheus8 Hand pieces requires continued operation during power mains interruptions, it is recommended that the InMode System with Morpheus8Hand pieces be powered from an uninterruptible power supply.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

NOTE - U_T is the AC mains voltage prior to application of the test level.

Guidance and manufacturer's declaration – electromagnetic immunity

The InMode System with Morpheus8Hand pieces is intended for use in the electromagnetic environment specified below. The customer or the user of the InMode System with Morpheus8Hand pieces should assure that it is used in such an environment.

IMMUNITY Test	IEC 60601 Test Level	Compliance Level	Electromagnetic environment – guidance
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3 Vrms 150 kHz to 80 MHz 3 V/m 80 MHz to 2,5 GHz	[3] V [3] V/m	Portable and mobile RF communications equipment should be used no closer to any part of the device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = \left[\frac{3,5}{V_1}\right]\sqrt{P} = \left[\frac{3,5}{3}\right]\sqrt{65} = \mathbf{9.4}\ [m]$ $80\ MHz\ to\ 800\ MHz$ $d = \left[\frac{7}{E_1}\right]\sqrt{P} = \left[\frac{7}{3}\right]\sqrt{65} = \mathbf{18.81}\ [m]$ $80\ MHz\ to\ 2{,}5\ GHz$ Where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and *d* is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol: 

NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the InMode System with Morpheus8Hand pieces is used exceeds the applicable RF compliance level above, the InMode System with Morpheus8Hand pieces should be observed to verify normal operation. If abnormal performance is observed, additional

measures may be necessary, such as re-orienting or relocating the InMode System with Morpheus8Hand pieces.

b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Recommended separation distances between portable and mobile RF communications equipment and the InMode System with Morpheus8Hand pieces System

The InMode System with Morpheus8Hand pieces System is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the InMode System with Morpheus8Hand pieces can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the InMode System with Morpheus8Hand pieces as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter [W]	Separation distance according to frequency of transmitter [m]		
	150 kHz to 80 MHz $d = \left[\frac{3,5}{V_1}\right]\sqrt{P}$	80 MHz to 800 MHz $d = \left[\frac{3,5}{E_1}\right]\sqrt{P}$	800 MHz to 2,5 GHz $d = \left[\frac{7}{E_1}\right]\sqrt{P}$
0,01	0.117	0.117	0.233
0,1	0.369	0.369	0.738
1	1.167	1.167	2.333
10	3.689	3.689	7.379
100	11.667	11.667	23.333

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

IEC 60601-1-2 Edition 4.0 (2014)

Environment of intended uses:

Professional Healthcare Facility Environment

Summary of Test Results

Test	Standard	Class/ Severity level	Test result
Documentation (IEC 60601-1-2 sections 4 and 5)			
General requirements for EMC	section 4.1.1.	---	Complies
External labels	section 5.1	---	Complies
Conformity of Users' Manual	section 5.2.1	---	Complies
Accuracy of Technical Descri.	section 5.2.2	---	Complies
Emission (IEC 60601-1-2 section 7 and IEC 60601-2-2 section 202.6.1)			
Conducted emission Freq. range:150 kHz - 30 MHz	sec. 7.1 & CISPR 11	Group 1 Class A on 230, 120 & 100 VAC mains	Complies
Radiated emission Freq. range: 30 - 1000 MHz	sec. 7.1 & CISPR 11	Group 1 Class A	Complies
Harmonic current emission test	sec. 7.2.1 & IEC 61000-3-2	AC mains (EUT with HP BodyTite, PLUS90, PLUSPLUS and BodyFX)	Complies
		AC mains (EUT with HP FaceTite and Fractora)	N/A
Voltage changes, Voltage fluctuations and Flicker test	sec. 7.2.2 & IEC 61000-3-3	AC mains	Complies
Immunity (IEC 60601-1-2 section 8 and IEC 60601-2-2 section 202.6.2)			
Immunity from Electrostatic discharge (ESD)	IEC 61000-4-2	8 kV contact discharges & 15 kV air discharges	Complies
Immunity from radiated electromagnetic fields	IEC 61000-4-3	3.0 V/m; 80 MHz ÷ 2.7 GHz, 80% AM, 1 kHz	Complies
Immunity from Proximity field from wireless communications equipment	IEC 61000-4-3	List of frequencies, from 9 V/m up to 28 V/m, PM (18 Hz or 217 Hz), FM 1 kHz	Complies
Immunity from Electrical Fast transient (EFT)	IEC 61000-4-4	± 2.0 kV on AC mains, Tr/Th – 5/50 ns, 100 kHz	Complies
Immunity from Surge	IEC 61000-4-5	±1.0 kV DM / ±2.0 kV CM on AC mains; Tr/Th – 1.2/50 (8/20) µs	Complies
Immunity from conducted disturbances induced by radio-frequency fields	IEC 61000-4-6	3.0; 6.0 V_{RMS} on AC mains & HP cables; 0.15÷ 80 MHz, 80% AM, 1 kHz	Complies
Immunity from Voltage dips, short interruptions and voltage variations	IEC 61000-4-11	On 230 & 100 VAC mains: 0 % - 0.5 cycle & 1 cycle; 70% - 25 cycles; 0% - 250 cycles	Complies

June 7, 2020</br></br> We have reviewed your submission. Please see attached.

If you have any questions, please contact the lead reviewer assigned to your submission, Mykhaylo Nosovskyy.

 *** This is a system-generated email notification ***

DO NOT DATE THIS DOCUMENT

K200947
InMode Ltd.
Trade/Device Name: InMode System with the Morhpeus8 Applicators
Contact Name: Amit Goren

This document is being communicated via e-mail as an attachment. The date on which FDA sent this e-mail is the official date of this correspondence.

We have reviewed your submission K200947 and have determined that additional information is required. Your file is being placed on hold pending a complete response to the attached deficiencies.

Please submit your response, referencing the submission number K200947 to:

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Control Center - WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Please refer to the eCopy guidance at https://www.fda.gov/media/83522/download for current information on eCopy requirements.

Your response is due within 180 days from the date of this request, which is the hold date plus 180 days. If a complete response is not received in CDRH's Document Control Center by this date, we will consider this submission to be withdrawn, and we will delete it from our review system.

You may not market this device until you have received a letter from FDA allowing you to do so. If you market the device without FDA clearance, you will be in violation of the Federal Food, Drug, and Cosmetic Act.

If you would like a meeting or teleconference with the review team and management to discuss your planned approach for responding to the attached deficiencies, please submit your request for feedback as a Submission Issue Q-Submission (Q-Sub). Please note that a Submission Issue Q-Sub does not take the place of a formal response to this email notification. As noted above, FDA will consider this submission to be withdrawn if FDA does not receive, in a submission to the Document Control Center, a complete response to all of the attached deficiencies within 180 calendar days of the date of this request.

This request for additional information has undergone supervisory review to ensure that the deficiencies cited are least burdensome and relevant to the marketing decision. Please see the revised guidance "Developing and Responding to Deficiencies in Accordance with the Least Burdensome Provisions" issued

on September 29, 2017 (https://www.fda.gov/media/71735/download) for clarification regarding major and minor deficiencies.

MAJOR DEFICIENCY LIST

(b)(4)

(b)(4)

FDA is offering a teleconference within 10 calendar days from the date on this letter to address any clarification questions you may have pertaining to the deficiencies. If you are interested in a teleconference, please provide (1) proposed dates and (2) a list of your clarification questions via email at least 48 hours before the teleconference to the lead reviewer assigned to your submission. We would like to emphasize that the purpose of the meeting is to address specific clarification questions. The teleconference is not intended for review of new information, test methods or data; these types of questions could be better addressed via a Submission Issue Q-Submission (Q-Sub). For additional information regarding Q-Subs, please refer to the Guidance for Industry and FDA Staff on Medical Devices: Requests for Feedback and Meetings for Medical Device Submissions at https://www.fda.gov/media/114034/download.

Least Burdensome (LB) Flag

The LB flag is an approach to allow 510(k) submitters the opportunity for the informal review by or on behalf of Division management of an issue raised in an FDA request for additional information (i.e., a deficiency letter). The goal of the LB flag is to quickly address FDA requests that submitters do not believe are least burdensome or when submitters believe they are being held to a different standard than their legally marketed predicate device. The LB flag is not intended to clarify deficiencies, is not an appeal under 21 CFR 10.75, and is not intended to provide a review of a proposed response to deficiencies.

If you would like to throw the LB flag, FDA has several criteria that should be met before you submit your request:

- You should have tried to address your concern by discussing it with Division management before attempting to throw the LB flag. This discussion with Division management may take place as part of a teleconference (such as the voluntary teleconference held within 10 days following transmission of an Additional Information letter to clarify deficiencies), email, or a Q-Submission Submission Issue Request.
- Your flag should generally be limited to two topic areas. Topic areas are common premarket review deficiency categories that apply to many device types across multiple reviewing Divisions. Examples of topic areas include biocompatibility, sterility, reprocessing, software, electromagnetic compatibility, wireless, electrical safety, clinical, and non-clinical performance testing.
- If you would like to discuss issues pertaining to more than two topic areas, you should contact 510K_Program@fda.hhs.gov for more information.
- You should throw the LB flag within 60 calendar days of the date that FDA sent the deficiency letter.

Upon meeting the criteria, you should send a short email (e.g., 1-2 page) that includes: 1) a summary of the deficiencies under disagreement, 2) a summary of relevant communications with Division management, and 3) a proposed path forward. The LB flag should be sent to the lead reviewer and their Assistance Director. You should also copy 510K_Program@fda.hhs.gov on your LB flag email request. Within two business days of your email, your request will be acknowledged by the reviewing Division. If you do not meet the criteria for the LB flag, you will be notified in this acknowledgement email.

Your LB flag should contain sufficient information to determine whether the deficiency letter was not least burdensome, or you are being held to a different standard than your predicate device. FDA may request a phone call with you to discuss your concern further and intends to communicate feedback from Division management on LB flags through email no later than 21 calendar days of their receipt. Please note that the LB flag does not change the deadline for your response to the Document Control Center. If you have any questions, please contact 510K_Program@fda.hhs.gov.

U.S. FOOD & DRUG ADMINISTRATION

Food and Drug Administration
CDRH/OPEQ/OHTIV/DHTIVA
WO66 RM4676
10903 New Hampshire Ave
Silver Spring, MD 20993-0002
301-796-3745

Premarket Notification 510(k) Review

Date: June 7, 2020

Reviewer: Mykhaylo Nosovskyy

Subject: Traditional 510(k)# K200947

Applicant: InMode Ltd.	**Device Trade Name:** InMode System with the Morhpeus8 Applicators
Contact Name: Amit Goren	**Contact Title:** Regulatory Manager
Correspondent Firm: A. Stein - Regulatory Affairs Consulting Ltd.	**Phone:** 972 (9) 767-0002 **Email:** amit@asteinrac.com
Received Date: April 8, 2020	**Due Date:** July 7, 2020
Pro Code(s): GEI **Class:** II **Reg #:** 878.4400	**Reg Name:** Electrosurgical Cutting And Coagulation Device And Accessories

Predicate Devices:

Submission #	Pro Code	Device Trade Name	Applicant
K192695	GEI	InMode System with the Morpheus8 (Fractora) Applicators	Inmode MD Ltd.

Recommendation

(b)(5)

Review Team

Lead Reviewer	Mykhaylo Nosovskyy (CDRH/OPEQ/OHTIV/DHTIVA)

(b)(5)

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U.S. FOOD & DRUG ADMINISTRATION

Food and Drug Administration
CDRH/OPEQ/OHTIV/DHTIVA
WO66 RM4676
10903 New Hampshire Ave
Silver Spring, MD 20993-0002
301-796-3745

Premarket Notification 510(k) Review

Date: July 1, 2020

Reviewer: Mykhaylo Nosovskyy

Subject: Traditional 510(k)# K200947/S001

Applicant: InMode Ltd.	**Device Trade Name:** InMode System with the Morhpeus8 Applicators
Contact Name: Amit Goren	**Contact Title:** Regulatory Manager
Correspondent Firm: A. Stein - Regulatory Affairs Consulting Ltd.	**Phone:** 972 (9) 767-0002 **Email:** amit@asteinrac.com
Received Date: June 12, 2020	**Due Date:** July 12, 2020
Pro Code(s): GEI **Class:** II **Reg #:** 878.4400	**Reg Name:** Electrosurgical Cutting And Coagulation Device And Accessories

Predicate Devices:

Submission #	Pro Code	Device Trade Name	Applicant
K192695	GEI	InMode System with the Morpheus8 (Fractora) Applicators	Inmode MD Ltd.

Recommendation

I recommend that the InMode System with the Morhpeus8 Applicators is/are Substantially Equivalent (SESE)

(b)(5)

Review Team

Lead Reviewer	Mykhaylo Nosovskyy (CDRH/OPEQ/OHTIV/DHTIVA)

(b)(5)

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(b)(5)

From: Lively, Harmony * [Harmony.Lively@fda.hhs.gov]
Sent: 6/12/2020 9:27:12 PM
To: amit@asteinrac.com
Subject: K200947/S001- Acknowledgment Notification
Attachments: K200947.S001- Letter.pdf

Harmony E. Lively
Records Management Specialist 1
CDRH Document Control Center

Acknowledgment Letter

6/12/2020

Amit Goren, Regulatory Manager
A. Stein - Regulatory Affairs Consulting Ltd.
20 Hata'as Str., Suite 102
Kfar Saba 4442520
ISRAEL

Dear Amit Goren:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has received your submission. This submission has been assigned the unique document control number below. All future correspondence regarding this submission should be identified prominently with the number assigned and should be submitted to the Document Control Center at the above letterhead address. Failure to do so may result in processing delays. If you believe the information identified below is incorrect, please notify the Program Operations Staff at (301) 796-5640.

Submission Number: K200947/S001
Received: 6/12/2020
Applicant: InMode Ltd.
Device: InMode System with the Morhpeus8 Applicators

We will notify you when the review of this document has been completed or if any additional information is required. If you are submitting new information about a submission for which we have already made a final decision, please note that your submission will not be re-opened. For information about CDRH review regulations and policies, please refer to http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/default.htm.

Sincerely yours,

Center for Devices and Radiological Health

Contains Nonbinding Recommendations

Print Form

510(k) Acceptance Checklist

Not for use with Third Party 510(k)s

Choose Submission Type: ☒ **Traditional** ☐ **Abbreviated** ☐ **Special**

(Should be completed within 15 days of DCC receipt)

The following information is not intended to serve as a comprehensive review.
FDA recommends that the submitter include this completed checklist as part of the submission.

510(k) #: K200947 Date Received by DCC: Apr 8, 2020

Lead Reviewer: Mykhaylo Nosovskyy

Center: CDRH Office: OHT 4 Division: DHT4A

Decision:

◉ Accept. If Accept, notify submitter.

○ Refuse to Accept. If Refuse to Accept, notify submitter electronically and include a copy of this checklist.

Is an Addendum attached?: ○ Yes ◉ No Click paperclip icon on the left panel if Addendum is attached.

Note: If an element is left blank on the checklist, it does not mean the checklist is incomplete; it means the reviewer did not assess the element during the RTA review and that the element will be assessed during substantive review.

IMPORTANT - Many checklist elements include additional details regarding information to address the element that can be seen by hovering over the element (Example - Element 4 in Section A of the checklist).

Preliminary Questions **Answers in the shaded blocks indicate consultation with a Center advisor is needed. (Boxes checked in this section represent FDA's preliminary assessment of these questions at the time of administrative review.)**	**Yes**	**No**	**N/A**
1 Is the product a device (per section 201(h) of the FD&C Act) or a combination product (per 21 CFR 3.2(e)) with a device constituent part subject to review in a 510(k)? If it appears not to be a device (per section 201(h) of the FD&C Act) or such a combination product (per 21 CFR 3.2(e)), or you are unsure, consult with the CDRH Product Jurisdiction Officer or the CBER Product Jurisdiction Officer to determine the appropriate action, and inform management. *Provide a summary of the Product Jurisdiction Officer's determination/recommendation/action in the comment section below.* If the product does not appear to be a device or such a combination product, mark "No."	☒	☐	
Comments:			
2 Is the submission with the appropriate Center? If the product is a device or a combination product with a device constituent part, is it subject to review by the Center in which the submission was received? If you believe the submission is not with the appropriate Center or you are unsure, consult with the CDRH Product Jurisdiction Officer or CBER Product Jurisdiction Officer to determine the appropriate action and inform your management. *Provide a summary of the Product Jurisdiction Officer's determination/recommendation/action in the comment section below.* If submission should not be reviewed by your Center mark "No."	☒	☐	
Comments:			

3 If a Request for Designation (RFD) was submitted for the device or combination product with a device constituent part and assigned to your center, identify the RFD # and confirm the following: **a) Is the device or combination product the same (e.g., design, formulation) as that presented in the RFD submission?** **b) Are the indications for use for the device or combination product identified in the 510(k) the same as those identified in the RFD submission?** If you believe the product or the indications presented in the 510(k) have changed from the RFD, or you are unsure, consult with the CDRH Product Jurisdiction Officer or the CBER Product Jurisdiction Officer to determine the appropriate action and inform your management. *Provide a summary of Product Jurisdiction Officer's determination/recommendation/action in the comment section below.* If the answer to either question above is no, mark "No." If there was no RFD, mark "N/A."	☐	☐	☒
Comments:			
4 Is the submission for a combination product that contains as a constituent part a drug that has the same active moiety as an approved drug with exclusivity as described in 21 USC 503(g)(5)(C)(ii)-(v) (section 503(g)(5)(C)(ii)-(v) of the FD&C Act)? If "Yes," then contact the CDRH Product Jurisdiction Officer or CBER Product Jurisdiction Officer to determine the appropriate action and inform your management. *Provide the summary of the Product Jurisdiction Officer's determination/recommendation/action in the comment section below.*	☐	☐	☒
Comments:			
5 Is this device type eligible for a 510(k) submission? If a 510(k) does not appear to be appropriate (e.g., Class III type and PMA required, or Class I or II type and 510(k)-exempt), consult with the appropriate CDRH or CBER staff during the acceptance review, provide a summary of the discussion with them, and indicate their recommendation/action in the comment section below. If 510(k) is not the appropriate regulatory submission, mark "No."	☒	☐	
Comments:			
6 Is there a pending PMA for the same device with the same indications for use? If "Yes," consult your management and CDRH Office of Product Evaluation and Quality/Office of Regulatory Programs/Division of Regulatory Programs 1 (Submission Support) (OPEQ/ORP/DRP1) or appropriate CBER staff to determine the appropriate action.	☐	☒	
Comments:			
7 If clinical studies have been submitted, is the submitter the subject of an Application Integrity Policy (AIP)? If "Yes," consult with the CDRH Office of Product Evaluation and Quality/ Office of Clinical Evidence and Analysis/Division of Clinical Science and Quality (OPEQ/OCEA/DCEA1) or CBER Office of Compliance and Biologics Quality/Division of Inspections and Surveillance/Bioresearch Monitoring Branch (OCBQ/DIS/BMB) to determine the appropriate action, provide a summary of the discussion with them, and indicate their recommendation/action. If no clinical studies have been submitted, mark "N/A." Check on the AIP list at https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/application-integrity-policy/application-integrity-policy-list.	☐	☐	☒
Comments:			

- If the answer to 1 or 2 appears to be "No," then stop review of the 510(k) and contact the CDRH Product Jurisdiction Officer or CBER Product Jurisdiction Officer.
- If the answer to 3a or 3b appears to be "No," then stop the review and contact the CDRH Product Jurisdiction Officer or CBER Product Jurisdiction Officer.
- If the answer to 4 is "Yes," then contact the CDRH Product Jurisdiction Officer or CBER Product Jurisdiction Officer, provide a summary of the discussion with them, and indicate their recommendation/action.
- If the answer to 5 is "No," the lead reviewer should consult management and other Center resources to determine the appropriate action.
- If the answer to 6 is "Yes," then stop review of the 510(k), contact the CDRH/OPEQ/ORP/DRP1, or appropriate CBER staff.
- If the answer to 7 is "Yes," then contact CDRH/OPEQ/OCEA/DCEA1 or CBER/OCBQ/DIS/BMB, provide a summary of the discussion with DCEA1 or BMB Staff, and indicate their recommendation/action.

Organizational Elements

Failure to include these items should not result in an RTA designation.

*Submitters including the checklist with their submission should identify the page numbers where requested information located. Use the comments section for an element if additional space is needed to identify the location of supporting information.	Yes	No	*Page #
1) Submission contains a Table of Contents	☒	☐	
2) Each section is labeled (e.g., headings or tabs designating Device Description section, Labeling section, etc.)	☒	☐	
3) All pages of the submission are numbered. *All pages should be numbered in such a manner that information can be referenced by page number. This may be done either by consecutively numbering the entire submission, or numbering the pages within a section (e.g., 12-1, 12-2…).*	☒	☐	
4) Type of 510(k) is identified (i.e., Traditional, Abbreviated, or Special). *If type of 510(k) is not designated, review as a Traditional 510(k).*	☒	☐	
Comments: Traditional			

Elements of a Complete Submission (RTA Items)

(21 CFR 807.87 unless otherwise indicated)

Submission should be designated RTA if not addressed.

- Any "No" answer will result in a "Refuse to Accept" decision; however, FDA staff has discretion to determine whether missing items are needed to ensure that the submission is administratively complete to allow the submission to be accepted or to request missing checklist items interactively from submitters during RTA review.
- Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission.

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. *Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.	Yes	No	N/A	Comment	*Page #
A. Administrative					
1) All content used to support the submission is written in English (including translations of test reports, literature articles, etc.)	☒	☐		☐	
2) Submission identifies the following (FDA recommends use of the CDRH Premarket Review Submission Cover Sheet form (Form 3514, available at https://www.fda.gov/media/72421/download)):				☐	
a) Device trade/proprietary name	☒	☐			
b) Device class and panel OR Classification regulation OR Statement that device has not been classified with rationale for that conclusion	☒	☐			
3) Submission contains an Indication for Use Statement with Rx and/or OTC designated (see also 21 CFR 801.109, and FDA's guidance "Alternative to Certain Prescription Devices Labeling Requirements," available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/alternative-certain-prescription-device-labeling-requirements.) *See recommended* format (https://www.fda.gov/media/86323/download).	☒	☐		☐	
4) Submission contains a 510(k) Summary or 510(k) Statement.	☒	☐		☐	
5) Submission contains a Truthful and Accuracy Statement per 21 CFR 807.87(l) *See recommended format (https://www.fda.gov/medical-devices/premarket-notification-510k/premarket-notification-truthful-and-accurate-statement).*	☒	☐		☐	
6) Submission is a Class III 510(k) device.	☐		☒	☐	
7) Submission contains clinical data	☐		☒	☐	
8) The submission identifies prior submissions for the same device included in the current submission (e.g., submission numbers for a prior not substantially equivalent [NSE] determination, prior deleted or withdrawn 510(k), Q-Submission, IDE, PMA, etc.). **OR** States that there were no prior submissions for the subject device.	☒	☐		☐	
a) If there were prior submissions, the submitter has identified where in the current submission any issues related to a determination of substantial equivalence from prior submissions for this device are addressed.	☐	☐	☒		
9) The submission utilizes voluntary consensus standard(s) (See section 514(c) of the FD&C Act). *This includes both FDA-recognized and non-recognized consensus standards.*	☒		☐	☐	
a) The submission cites FDA-recognized voluntary consensus standard(s).	☒		☐		
i) The submission includes a Declaration of Conformity (DOC) as outlined in FDA's guidance "Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices," available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/appropriate-use-voluntary-consensus-standards-premarket-submissions-medical-devices. **OR** If citing general use of a standard as noted in FDA's guidance "Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices," the basis of such use is included along with the underlying information or data that supports how the standard was used.	☒	☐			

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. *Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.	Yes	No	N/A	Comment	*Page #
b) The submission cites non-FDA-recognized voluntary consensus standard(s).	☐		☒		
Combination Product Provisions - Per 503(g) of the FD&C Act. Select "N/A" if the product is not a combination product. 21 CFR 3.2(e). The remaining criteria in this section will be omitted from the checklist if "N/A" is selected. If you are unsure if the product is a combination product, consult with the CDRH Product Jurisdiction Officer or CBER Product Jurisdiction Officer.			☒		
B. Device Description					
12) The device has a device-specific guidance document, special controls, and/or requirements in a device-specific classification regulation regarding the device description that is applicable to the subject device.	☒		☐	☐	
a) The submission addresses device description recommendations outlined in the device-specific guidance. **OR** The submission provides an alternative approach intended to address the applicable statutory and/or regulatory criteria.	☒	☐	☐		
b) The submission includes device description information that addresses relevant mitigation measures set forth in the special controls or device-specific classification regulation applicable to the device. **OR** The submission uses alternative mitigation measures and provides rationale why the alternative measures provide an equivalent assurance of safety and effectiveness.	☐	☐	☒		
13) Descriptive information is present and consistent within the submission (e.g., the device description section is consistent with the device description in the labeling).	☒	☐		☐	
14) The submission includes descriptive information for the device, including the following:				☐	
a) A description of the principle of operation or mechanism of action for achieving the intended effect.	☒	☐			
b) A description of proposed conditions of use, such as surgical technique for implants; anatomical location of use; user interface; how the device interacts with other devices; and/or how the device interacts with the patient.	☒	☐	☐		
c) A list and description of each device for which clearance is requested.	☒	☐	☐		
d) Submission contains representative engineering drawing(s), schematics, illustrations, photos and/or figures of the device. **OR** Submission includes a statement that engineering drawings, schematics, etc. are not applicable to the device (e.g., device is a reagent and figures are not pertinent to describe the device).	☒	☐			
15) Device is intended to be marketed with accessories and/or as part of a system.	☒		☐	☐	
a) Submission includes a list of all accessories to be marketed with the subject device.	☒	☐			
b) Submission includes a description (as detailed in item 14(a), 14(b) and 14(d) above) of each accessory.	☒	☐	☐		

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. *Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.	Yes	No	N/A	Comment	*Page #
c) A 510(k) number is provided for each accessory that received a prior 510(k) clearance. **AND** A statement is provided that identifies accessories that have not received prior 510(k) clearance.	☒	☐			
C. Substantial Equivalence Discussion					
16) Submitter has identified a predicate device(s), including the following information:				☐	
a) Predicate device identifier provided (e.g., 510(k) number, De Novo number, reclassified PMA number, classification regulation reference, if exempt (e.g., 21 CFR 872.3710), or statement that the predicate is a preamendment device). For predicates that are preamendments devices, information is provided to document preamendments status. *Information regarding documenting preamendment status is available online (https://www.fda.gov/medical-devices/quality-and-compliance-medical-devices/preamendment-status).*	☒	☐			
b) The identified predicate(s) is consistent throughout the submission (e.g., the predicate(s) identified in the Substantial Equivalence section is the same as that listed in the 510(k) Summary (if applicable) and that used in comparative performance testing).	☒	☐			
17) Submission includes a comparison of the following for the predicate(s) and subject device and a discussion why any differences between the subject and predicate(s) do not impact safety and effectiveness [see section 513(i)(1)(A) of the FD&C Act and 21 CFR 807.87(f)] *See the FDA guidance document "The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)]," available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/510k-program-evaluating-substantial-equivalence-premarket-notifications-510k for more information on comparing intended use and technological characteristics.*				☐	
a) Indications for Use	☒	☐			
b) Technology, including technical specifications, features, materials, and principles of operation	☒	☐			
D. Proposed Labeling (see also 21 CFR part 801 and 809 as applicable)					
18) Submission includes proposed package labels and labeling (e.g., instructions for use, package insert, operator's manual).	☒	☐		☐	
a) Indications for use are stated in labeling and are identical to Indications for Use form and 510(k) Summary (if 510(k) Summary provided).	☒	☐			
b) Labeling includes: - Statements of conditions, purposes or uses for which the device is intended (e.g., hazards, warnings, precautions, contraindications) (21 CFR 801.5) **AND** - Includes adequate directions for use (see 21 CFR 801.5) **OR** - Submission states that device qualifies for exemption per 21 CFR 801 Subpart D	☒	☐			
19) Labeling includes name and place of business of the manufacturer, packer, or distributor (21 CFR 801.1).	☒	☐		☐	

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. *Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.	Yes	No	N/A	Comment	*Page #
20) Labeling includes the prescription statement [see 21 CFR 801.109(b)(1)] or Rx Only symbol (see also Section 502(a) of the FD&C Act and FDA's guidance "Alternative to Certain Prescription Device Labeling Requirements," available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/alternative-certain-prescription-device-labeling-requirements.	☒	☐	☐	☐	
21) The device has a device-specific guidance document, special controls, and/or requirements in a device-specific classification regulation regarding labeling that is applicable to the subject device.	☒		☐		
a) The submission addresses labeling recommendations outlined in the device-specific guidance. **OR** The submission provides an alternative approach intended to address the applicable statutory and/or regulatory criteria.	☒	☐	☐		
b) The submission includes labeling information that addresses relevant mitigation measures set forth in the special controls or device-specific classification regulation applicable to the device. **OR** The submission uses alternative mitigation measures and provides rationale why the alternative measures provide an equivalent assurance of safety and effectiveness.	☐	☐	☒		
22) If the device is an in vitro diagnostic device, provided labeling includes all applicable information required per 21 CFR 809.10.	☐	☐	☒	☐	
E. Sterilization					
If an *in vitro* diagnostic (IVD) device and sterilization is not applicable, select "N/A." The criteria in this section will be omitted from the checklist if "N/A" is selected.			☐		
☒ Provided sterile, intended to be single-use					
☐ Requires processing during its use-life					
☒ Non-sterile when used (and no processing required)					
☐ Information regarding the sterility status of the device is not provided. (If this box is checked, please also check one of the two boxes below.)					
☐ Sterility status not needed for this device (e.g., software-only device)					
☐ Sterility status needed or need unclear					
This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination. *Please refer to the FDA guidance document "Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling," available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/reprocessing-medical-devices-health-care-settings-validation-methods-and-labeling, for additional information.*					
F. Shelf Life					
27) Proposed shelf life/expiration date stated **OR** Statement that shelf-life is not applicable because of low likelihood of time-dependent product degradation	☒	☐	☐	☐	

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. *Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.	Yes	No	N/A	Comment	*Page #
28) For a sterile device, submission includes summary of methods used to establish that device packaging will maintain a sterile barrier for the entirety of the proposed shelf life.	☒	☐	☐	☐	
29) Submission includes summary of methods used to establish that device performance is maintained for the entirety of the proposed shelf-life (e.g., mechanical properties, coating integrity, pH, osmolality, etc.). **OR** Statement why performance data is not needed to establish maintenance of device performance characteristics over the shelf-life period.	☒	☐		☐	
G. Biocompatibility					
If an vitro diagnostic (IVD) device, select "N/A." The criteria in this section will be omitted from the checklist if "N/A" is selected.			☐		
Submission states that there: (one of the below must be checked)		☐		☐	
☒ Are direct or indirect tissue-contacting components.					
☐ Are no direct or indirect tissue-contacting components.					
☐ Information regarding tissue contact status of the device is not provided (if this box checked, please also check one of the two boxes below).					
☐ Tissue contact information not needed for this device (e.g., software-only device)					
☐ Tissue contact information needed or need unclear					
This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination.					
30) Submission includes a list identifying each of tissue-contacting device component (e.g., implant, delivery catheter) and associated materials of construction for each component, including identification of color additives, if present.	☒	☐		☐	
31) Submission identifies contact classification (e.g., surface-contacting, less then 24 hour duration) for each tissue-contacting device component (e.g., implant, delivery catheter)	☒	☐		☐	

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. *Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.	Yes	No	N/A	Comment	*Page #
32) For a biocompatibility assessment of tissue-contacting components, submission includes: – Each relevant endpoint for the device (as identified in device-specific guidance, or Attachment A of the FDA guidance document entitled "Use of International Standard ISO 10993-1, `Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process,'" available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/use-international-standard-iso-10993-1-biological-evaluation-medical-devices-part-1-evaluation-and), has been addressed. - For any testing performed, test protocol (including identification and description of test article including whether the test article is the device in its final finished form using the recommended approach in Attachment F of "Use of International Standard ISO 10993-1, `Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process,'" methods, and pass/fail criteria), and analysis of results (including tables with data points and statistical analyses, where appropriate), as described in Attachment E of the guidance document entitled "Use of International Standard ISO 10993-1, `Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process'" provided for each completed test. **OR** A statement that biocompatibility testing is not needed with a rationale that considers all relevant endpoints (e.g., materials and manufacturing/processing are identical to the predicate).	☒	☐		☐	
H. Software					
Submission states that the device: (one of the below must be checked)		☐		☐	
☒ Does contain software/firmware					
☐ Does not contain software/firmware					
☐ Information on whether device contains software/firmware is not provided. (If this box is checked, please also check one of the two boxes below.)					
☐ Software/firmware information not needed for this device (e.g., surgical suture, condom)					
☐ Software/firmware information is needed or need unclear					
This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination.					
33) Submission includes a statement of software level of concern and rationale for the software level of concern.	☒	☐		☐	
34) All applicable software documentation provided based on level of concern identified by the submitter, as described in "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices," available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-content-premarket-submissions-software-contained-medical-devices, or the submission includes information to establish that the submitter has otherwise met the applicable statutory or regulatory criteria through an alternative approach (i.e., the submitter has identified an alternate approach with a rationale).	☒	☐		☐	
I. Cybersecurity					
Submission states that the device: *(one of the below must be checked)*		☐		☐	

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. *Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.	Yes	No	N/A	Comment	*Page #
☒ Does contain any external wired and/or wireless communication interfaces (Wired: USB, ethernet, SD, CD, RGA, etc. or Wireless: Wi-Fi, Bluetooth, RF, inductive, Cloud, etc.)					
☐ Does not contain external interfaces as described above					
☐ Information on whether device has external interfaces is not provided. (If this box is checked, please also check one of the two boxes below.)					
☐ Cybersecurity information not needed for this device (e.g., surgical suture, condom)					
☐ Cybersecurity information is needed or need unclear					
This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination.					
35) All applicable documentation identified by the submitter, as described in "Guidance for the Content of Premarket Submissions for Management of Cybersecurity in Medical Devices," available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/content-premarket-submissions-management-cybersecurity-medical-devices-0. **OR** Submission includes information to establish that the submitter has otherwise met the applicable statutory or regulatory criteria through an alternative approach (i.e., the submitter has identified an alternate approach with a rationale).	☒	☐		☐	
J. Electrical Safety and EMC					
Electrical Safety Submission states that the device: *(one of the below must be checked)*		☐		☐	
☒ Does require electrical safety evaluation					
☐ Does not require electrical safety evaluation					
☐ Information on whether device requires electrical safety evaluation is not provided. (If this box is checked, please also check one of the two boxes below.)					
☐ Electrical safety information not needed for this device (e.g., surgical suture, condom)					
☐ Electrical safety information is needed or need unclear					
This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination.					
36) Submission includes evaluation of electrical safety (e.g., per IEC 60601-1, or equivalent FDA-recognized standard, and if applicable, a device-specific standard), **OR** Submission includes electrical safety evaluation using methods or standards that are not FDA-recognized and submission includes information to establish that the submitter has otherwise met the applicable statutory or regulatory criteria through this alternative approach (i.e., the submitter has identified alternate methods or standards with a rationale).	☒	☐		☐	
EMC Submission states that the device: (one of the below must be checked)		☐		☐	
☒ Does require EMC evaluation					
☐ Does not require EMC evaluation					

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. *Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.	Yes	No	N/A	Comment	*Page #
☐ Information on whether device requires EMC evaluation is not provided. (If this box is checked, please also check one of the two boxes below.)					
☐ EMC information not needed for this device (e.g., surgical suture, condom)					
☐ EMC information is needed or need unclear					
This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination.					
37) Submission includes evaluation of electromagnetic compatibility (e.g., per IEC 60601-1-2 or equivalent FDA-recognized standard and if applicable, the device-specific standard) **OR** Submission includes electromagnetic compatibility evaluation using methods or standards that are not FDA-recognized and submission includes information to establish that the submitter has otherwise met the applicable statutory or regulatory criteria through this alternative approach (i.e., the submitter has identified alternate methods or standards with a rationale).	☒	☐		☐	
K. Performance Data - General					
If an in vitro diagnostic (IVD) device, select "N/A." The criteria in this section will be omitted from checklist if "N/A" is selected. Performance data criteria relating to IVD devices is addressed in Section K.			☐		
38) Summaries of the non-clinical laboratory studies and full test reports* are provided. *Summary and full test report content recommendations can be found in FDA's guidance "Recommended Content and Format of Non-Clinical Bench Performance Testing Information in Premarket Submissions," available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/recommended-content-and-format-non-clinical-bench-performance-testing-information-premarket. If a submitter chooses to declare conformity to a voluntary consensus standard that FDA has recognized, submission of a full test report may not be necessary. Refer to 9a. See FDA's guidance "Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices," available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/appropriate-use-voluntary-consensus-standards-premarket-submissions-medical-devices.	☒	☐	☐	☐	
a) Submission includes an explanation of how the data generated from each test supports a finding of substantial equivalence (e.g., comparison to predicate device testing, dimensional analysis, etc.).	☒	☐			
39) The device has a device-specific guidance document, special controls, and/or requirements in a device-specific classification regulation regarding performance data that is applicable to the subject device.	☒		☐	☐	
a) The submission addresses performance data recommendations outlined in the device-specific guidance. **OR** The submission provides an alternative approach intended to address the applicable statutory and/or regulatory criteria.	☒	☐	☐		

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. *Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.	Yes	No	N/A	Comment	*Page #
b) The submission includes performance data that addresses relevant mitigation measures set forth in the special controls or device-specific classification regulation applicable to the device. **OR** The submission uses alternative mitigation measures and provides rationale why the alternative measures provide an equivalent assurance of safety and effectiveness.	☐	☐	☒		
40) If literature is referenced in the submission, submission includes:			☒		
41) For each completed animal study, the submission provides the following:			☒	☐	
L. Performance Characteristics - In Vitro Diagnostic Devices Only **(Also see 21 CFR 809.10(b)(12))**					
Submission states that the device: (one of the below must be checked)				☐	
☐ is an in vitro diagnostic device.					
☒ is not an in vitro diagnostic device.					
If "is not" is selected, the performance data-related criteria below are omitted from the checklist.					

Digital Signature Concurrence Table

Reviewer Sign-Off	Mykhaylo B. Nosovskyy -S 2020.04.22 02:47:41 -04'00'
Management Sign-Off (digital signature optional)*	

* Management review of checklist and concurrence with with decision required.

April 22, 2020</br></br>

Acceptance Review Notification - Accepted

An administrative acceptance review was conducted on your premarket notification (510(k)) K200947, and it was found to contain all of the necessary elements and information needed to proceed with the substantive review. We will contact you should we require any additional information during the course of the substantive review. The lead reviewer assigned to your submission is Mykhaylo Nosovskyy.

 *** This is a system-generated email notification ***

U.S. FOOD & DRUG ADMINISTRATION

July 2, 2020

InMode Ltd.
% Amit Goren
Regulatory Manager
A. Stein - Regulatory Affairs Consulting Ltd.
20 Hata'as Str., Suite 102
Kfar Saba, Israel 4442520

Re: K200947/S001
Trade/Device Name: InMode System with the Morhpeus8 Applicators
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting and Coagulation Device and Accessories
Regulatory Class: Class II
Product Code: GEI
Dated: June 10, 2020
Received: June 12, 2020

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.

U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
www.fda.gov

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 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,

Long H. Chen -S

Digitally signed by Long H. Chen -S
Date: 2020.07.02 14:37:41 -04'00'

Long Chen, 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

K200947
InMode Ltd.
Trade/Device Name: InMode System with the Morhpeus8 Applicators
Contact Name: Amit Goren

This document is being communicated via e-mail as an attachment. The date on which FDA sent this e-mail is the official date of this correspondence.

We have reviewed your submission K200947 and have determined that additional information is required. Your file is being placed on hold pending a complete response to the attached deficiencies.

Please submit your response, referencing the submission number K200947 to:

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Control Center - WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Please refer to the eCopy guidance at https://www.fda.gov/media/83522/download for current information on eCopy requirements.

Your response is due within 180 days from the date of this request, which is the hold date plus 180 days. If a complete response is not received in CDRH's Document Control Center by this date, we will consider this submission to be withdrawn, and we will delete it from our review system.

You may not market this device until you have received a letter from FDA allowing you to do so. If you market the device without FDA clearance, you will be in violation of the Federal Food, Drug, and Cosmetic Act.

If you would like a meeting or teleconference with the review team and management to discuss your planned approach for responding to the attached deficiencies, please submit your request for feedback as a Submission Issue Q-Submission (Q-Sub). Please note that a Submission Issue Q-Sub does not take the place of a formal response to this email notification. As noted above, FDA will consider this submission to be withdrawn if FDA does not receive, in a submission to the Document Control Center, a complete response to all of the attached deficiencies within 180 calendar days of the date of this request.

This request for additional information has undergone supervisory review to ensure that the deficiencies cited are least burdensome and relevant to the marketing decision. Please see the revised guidance "Developing and Responding to Deficiencies in Accordance with the Least Burdensome Provisions" issued

on September 29, 2017 (https://www.fda.gov/media/71735/download) for clarification regarding major and minor deficiencies.

MAJOR DEFICIENCY LIST

(b)(4)

(b)(4)

FDA is offering a teleconference within 10 calendar days from the date on this letter to address any clarification questions you may have pertaining to the deficiencies. If you are interested in a teleconference, please provide (1) proposed dates and (2) a list of your clarification questions via email at least 48 hours

before the teleconference to the lead reviewer assigned to your submission. We would like to emphasize that the purpose of the meeting is to address specific clarification questions. The teleconference is not intended for review of new information, test methods or data; these types of questions could be better addressed via a Submission Issue Q-Submission (Q-Sub). For additional information regarding Q-Subs, please refer to the Guidance for Industry and FDA Staff on Medical Devices: Requests for Feedback and Meetings for Medical Device Submissions at https://www.fda.gov/media/114034/download.

Least Burdensome (LB) Flag

The LB flag is an approach to allow 510(k) submitters the opportunity for the informal review by or on behalf of Division management of an issue raised in an FDA request for additional information (i.e., a deficiency letter). The goal of the LB flag is to quickly address FDA requests that submitters do not believe are least burdensome or when submitters believe they are being held to a different standard than their legally marketed predicate device. The LB flag is not intended to clarify deficiencies, is not an appeal under 21 CFR 10.75, and is not intended to provide a review of a proposed response to deficiencies.

If you would like to throw the LB flag, FDA has several criteria that should be met before you submit your request:

- You should have tried to address your concern by discussing it with Division management before attempting to throw the LB flag. This discussion with Division management may take place as part of a teleconference (such as the voluntary teleconference held within 10 days following transmission of an Additional Information letter to clarify deficiencies), email, or a Q-Submission Submission Issue Request.
- Your flag should generally be limited to two topic areas. Topic areas are common premarket review deficiency categories that apply to many device types across multiple reviewing Divisions. Examples of topic areas include biocompatibility, sterility, reprocessing, software, electromagnetic compatibility, wireless, electrical safety, clinical, and non-clinical performance testing.
- If you would like to discuss issues pertaining to more than two topic areas, you should contact 510K_Program@fda.hhs.gov for more information.
- You should throw the LB flag within 60 calendar days of the date that FDA sent the deficiency letter.

Upon meeting the criteria, you should send a short email (e.g., 1-2 page) that includes: 1) a summary of the deficiencies under disagreement, 2) a summary of relevant communications with Division management, and 3) a proposed path forward. The LB flag should be sent to the lead reviewer and their Assistance Director. You should also copy 510K_Program@fda.hhs.gov on your LB flag email request. Within two business days of your email, your request will be acknowledged by the reviewing Division. If you do not meet the criteria for the LB flag, you will be notified in this acknowledgement email.

Your LB flag should contain sufficient information to determine whether the deficiency letter was not least burdensome, or you are being held to a different standard than your predicate device. FDA may request a phone call with you to discuss your concern further and intends to communicate feedback from Division management on LB flags through email no later than 21 calendar days of their receipt. Please note that the LB flag does not change the deadline for your response to the Document Control Center. If you have any questions, please contact 510K_Program@fda.hhs.gov.

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June 10, 2020

510(k) Document Mail Center (WO66-0609)
Office of Device Evaluation
Center for Devices and Radiological Health
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002
U.S.A.

Re: K200947 AINN Response letter for the InMode System with the Morhpeus8 Applicators

Dear Mykhaylo Nosovskyy,

Further to your K200947 AINN hold letter, dated June 07, 2020, enclosed please find our responses. The enclosed response is arranged such that the questions from your e-mail letter are printed in bold lettering with our responses following in regular print.

The e-copy is an exact duplicate of the paper copy.

I trust that the information included in this supplement, will be adequate to allow for its prompt review. If you have any questions or comments, please don't hesitate to contact me at the following telephone no. +972-9-767002, fax no. +972-9-7668534 or by e-mail to amit@asteinrac.com.

Thank you for your cooperation and understanding.

Sincerely yours,

(b)(6)

Amit Goren, PhD,
Senior Regulatory Affairs Consultant,
A. Stein – Regulatory Affairs Consulting Ltd.,
for InMode Ltd.

MAJOR DEFICIENCY LIST

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List of Appendices:

Appendix 1.0: Revised 510(K) Summary

Appendix 2.0: Revised Indication For Use Statement (Form FDA 3881)

Appendix 3.0: Revised Operator Manual (Red-lined and Clean Versions)

Appendix 4.0: Revised Brochure

Appendix 1.0: Revised 510(K) Summary

510(K) SUMMARY

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Appendix 2.0: Revised Indication For Use Statement (Form FDA 3881)

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

(b)(4)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

Appendix 3.0: Revised Operator Manual (Red-lined and Clean Versions)

MORPHEUS8

Operator Manual

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INMODE

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MORPHEUS8

Operator Manual

Morpheus8 (Fractora) Applicator

Version: DO607530D

INMODE

Operator Manual: Morpheus8 Applicator

DO607530D

InMode Ltd

Tavor House. POB 533, Industrial Park South,

Yokneam, 2069206. Israel

Tel: +972-4-9096313

Fax: +972-4-9096310

Table of Contents

1 Section 1: Introduction

1.1 Before You Start

The manual and the equipment described are for use only by qualified medical professionals trained in the particular technique to be performed.

Federal (USA) law restricts sale of this device by or on the order of a physician.

Read this manual to become familiar with all safety requirements and operating procedures before attempting to operate the System.

1.2 System Overview

The InMode Platform with Morpheus8 Applicators employs bi-polar Radio-frequency (RF) technology for various aesthetic applications. The Morpheus8 Applicators are used with InMode platform. The device provides individual adjustment of treatment parameters to achieve maximum efficiency and safety for each patient and applications.

1.3 Conventions Used in the Manual

The following conventions in the form of notes and warnings are used in this manual:

WARNING! This information is extremely important!

ATTENTION! Consult Accompanying Document.

NOTE! Provides general information that is important to keep in mind.

1.4 Explanation of the Symbols used on the System

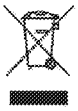
Symbol	Description
	CSA marking (212603 CSA master contract number)
	Do not discard in trash. Electronic equipment should be disposed of in an appropriate manner
	Fuse
	Type BF Equipment
	HF Isolated Patient Circuit
	Follow the operating instructions
	Caution: Federal law restricts this device to sale by or on the order of a Physician
	Do not reuse/single use only. This symbol is used for disposable one-time-use products.
	This equipment intentionally supplies non-ionizing RF energy
	Sterilized by Radiation

Table 1-1: Device Symbols

2 Section 2: Safety

This chapter describes safety issues regarding the use and maintenance of the Morpheus8 Applicator, with a special emphasis on electrical safety.

The system is designed for safe and reliable treatment when used in accordance with proper operation and maintenance procedures. Only trained, qualified practitioners can use the system. The operator and all other personnel operating or maintaining the system should be familiar with the safety information provided in this section.

The primary consideration should be to maximize safety for both treating attendant and patient.

⚠ Read this chapter to be familiar with all its safety requirements and operating procedures prior to system operation.

⚠ RF energy can cause injury if used improperly.

⚠ High voltage is present inside the System.

⚠ Always be aware of the possible dangers and take proper safeguards as described in the manual.

2.1 The Patient

- Well-trained staff is key for assuring patient safety. A patient history report should be completed prior to scheduling. Patients should be fully informed of the treatment details, the likely results and any risks associated with the treatment.
- Jewelry and metal accessories that are within the activation range of the Applicator should be removed to avoid accidental RF conduction.
- Patients will not be in contact with any metal or other alternate pathway to ground whilst the System is in use.

2.2 Treating Attendant

- Only authorized individuals with appropriate training and knowledge should operate, assist in the operation of, or provide maintenance to the device with Morpheus8 Applicator.

- Personnel should not operate the System until they have been fully educated in its use. Make sure that all treatment personnel are familiar with the System controls and know how to shut down the System instantly.
- There are no user-serviceable parts in the System, and all service and repair must be performed only by the factory or authorized field service technicians.

2.3 Cautions

The following cautions should be heeded for safe System use:

- Do not touch the System's inner parts.
- Service is supplied by company authorized personal only.
- To avoid damage, do not allow the Applicator to come in contact with hard materials.

2.4 Electrical and Mechanical Safety

- Keep all covers and panels of the System closed. Removing the covers creates a safety hazard.
- Keep hands away from the applicator during the System start-up.
- Perform maintenance procedures when the System is shut down and disconnected from the power.
- The System is grounded through the grounding conductor in the power cable. This protective grounding is essential for safe operation.
- Move the System slowly and carefully. The System weighs approximately 15kg (33 lb.) and may cause injury if proper care is not used when moving it.
- Provide as much distance as possible between the System, RF Applicator and other electronic equipment as the activated RF generator may cause interference between them.

2.5 Fire Hazards

- Do not use the System in the presence of explosive or flammable materials.
- Materials conducting RF energy may cause temperature rise of the absorbing material. Do not use the System in the presence of explosive or flammable materials conductive to RF.

- Do not use flammable substances when preparing the skin for treatment. Be especially careful with the use of oxygen.
- Keep drapes and towels moist to prevent them from igniting and burning. Use nonflammable prepping solutions.
- If alcohol is used for cleaning and disinfecting, it must be allowed to dry thoroughly before the System is used.

2.6 Safety Features of the System

The System incorporates the following safety features. All personnel operating the System should be familiar with these features.

- The System has unique password to avoid device operation by non-authorized personnel.
- The power electronics cannot be activated unless the applicator and Footswitch have been connected to the System
- An audible tone indicates energy activation.
- During activation, the System performs a self-test of the hardware.
- Hardware is tested every 10ms to ensure proper operation of electrical circuit.
- During activation, the System performs a self-test of the hardware.
- Hardware is tested every 10ms to ensure proper operation of electrical circuit.
- The System starts at a low setting.

2.7 Safe use of the Active Accessories

- Examine the connection of the Applicator through the connectors to the System before using. Ensure that the accessory functions as intended. Improper connection may result in arcs and sparks, accessory malfunction, or unintended treatment effects.
- Do not wrap the Applicator cords around metal objects. It may induce current that could lead to electrical shocks, fire or injury to the patient or personnel.
- When using the Morpheus8 applicators, ensure that all electrodes are in full contact with the skin. Bad coupling of electrodes with the skin results in a specific warning sound, a message on the screen, and disabling of RF.

- The tips are for single use only. Do not try to reuse them. Re-use of the tips may cause for unintended cross contaminations and infections, create loss of integrity that may affect the performance and make the Device non-functional.

⚠ Do not connect a wet accessory to the System.

⚠ Do not immerse the applicator under water at any time.

⚠ The Morpheus8 12, 24, 40 & T Tip heads arrive sterilized in gamma rays and cannot be autoclaved.

⚠ The Morpheus8 Tips are for single use only!

2.8 Warnings

⚠ This equipment is for use only by qualified medical professionals trained in the particular technique to be performed.

⚠ Only Applicator manufactured or approved by InMode Ltd. should be used with InMode System with Morpheus8 Applicator.

⚠ Connect the power cord to a properly polarized and grounded power source with the frequency and voltage characteristics that match those listed on the back of the unit.

⚠ Connect the System power cord to a properly grounded receptacle. Do not use power plug adapters.

⚠ Always turn off and unplug the device before cleaning.

⚠ The patient should not come into contact with metal parts which are earthed or which have an appreciable capacitance to earth. The use of antistatic sheeting is recommended for this purpose. Treatment bed or chair should not be electric.

⚠ Use the lowest output setting necessary to achieve the desired treatment effect. The higher RF is applied, the greater the possibility of unintended thermal damage.

⚠ Failure of the equipment could result in an unintended increase of output power.

⚠ The cables of the Applicator should be positioned in such a way that contact with the PATIENT or other leads is avoided.

⚠ Fire / Explosion Hazard - The following substances will contribute to increased fire and explosion hazards in the operating room:

- Flammable substances (such as alcohol-based skin prepping agents and tinctures).
- Naturally occurring flammable gases which may accumulate in body cavities such as the bowel.
- Oxygen enriched atmospheres.
- Oxidizing agents (such as nitrous oxide [N2O] atmospheres).

– Endogenous gases.

⚠ The RF energy and heating associated with the System can provide an ignition source. Observe fire precautions at all times. When using InMode System with Morpheus8 Applicator in the same room with any of these substances or gases, prevent their accumulation or pooling within the area where Morpheus8 procedures are performed.

⚠ The operation of the InMode System with Morpheus8 Applicator may adversely influence the operation of other electronic EQUIPMENT.

⚠ To avoid the RISK of electric shock, this equipment must only be connected to a SUPPLY MAINS with protective earth.

⚠ Do not use Morpheus8 on patients with pacemakers or internal defibrillators.

2.9 Device Labels

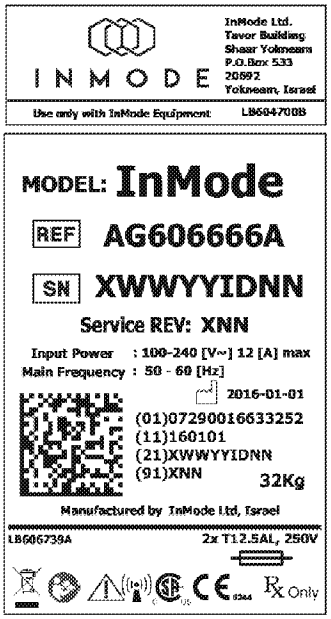


Figure 2-1: InMode Device label

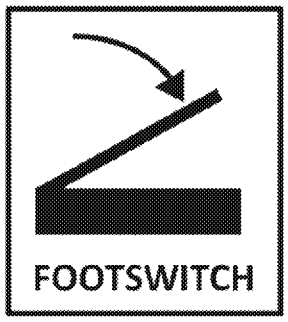


Figure 2-2: Footswitch Label

2.10 Applicator Labels

As required by national and international regulatory agencies, appropriate warning and information labels have been attached in specific locations on the instrument as identified below.

The following device labels are located on the InMode System with Morpheus8 Applicator device console and the Applicator:

The Applicator certifications and identification labels are attached to connectors on the Applicators. It states that the product conforms to the performance standards, and indicates the manufacturer's name, date of manufacturing, model and serial number of the Applicator. The following labels are located on the Applicator: Manufacturer identification labeling is placed on the Applicator:

Figure 2-3: Morpheus8 Applicator Identification Labels

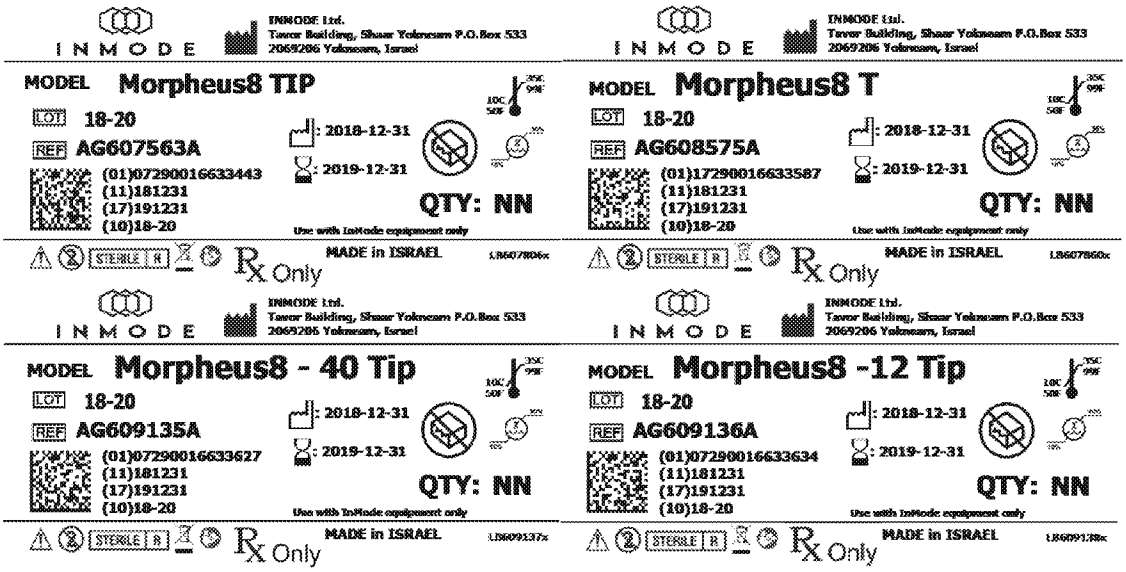


Figure 2-4: : Morpheus8 (24 Pin) Tip (Upper Left), Morpheus8 T Tip, Morpheus8 Body (40 Pin) Tip (Lower Left), Morpheus8 Prime (12 Pin) Tip (Lower Right)

2.11 Equipment Classification

The following is a list of the different equipment used and their classifications.

- Electric shock protection: Class I, Type BF for the RF Applicator.
- Protection against ingress of liquids: Ordinary equipment.
- Not suitable for use in presence of flammable substance.
- Power receptacle must include protective earth and must be checked before connecting the System.

The InMode Systems with the Morpheus8 Applicators is classified as Class II device defined by the FDA CDRH and complies with 21 CFR subparts E.

3 Section 3: System Installation

3.1 Electrical Requirements

- The System will require a separate line supply of single phase (100Vac; 15A) or (115Vac; 15A) or (230Vac; 15A) or (240Vac; 15A) 50-60Hz. Zmax = 0.03Ω.
- Power receptacles must be within 15 feet of the System site.
- The System should not share a power line with other equipment.
- Power receptacle must include protective earth and must be checked before connecting the System.

⚠ For continued protection against fire, replace the fuse only with one of the same types and rating.

⚠ Proper grounding is essential for safe operation.

3.2 Environmental Requirements

- Corrosive materials can damage electronic parts; therefore, the System should operate in a non-corrosive atmosphere.
- For optimal operation of the System, maintain room temperature between 20º-27ºC (68º-79ºF) and relative humidity of less than 80%.

3.3 Equipment List

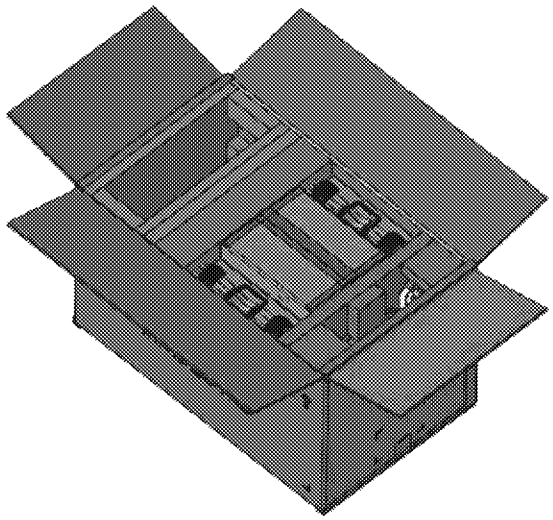
The System includes the following:

- System platform
- Applicator Handle & Detachable Tips
- Applicators cradles
- Footswitch
- Operator manual
- Power cord

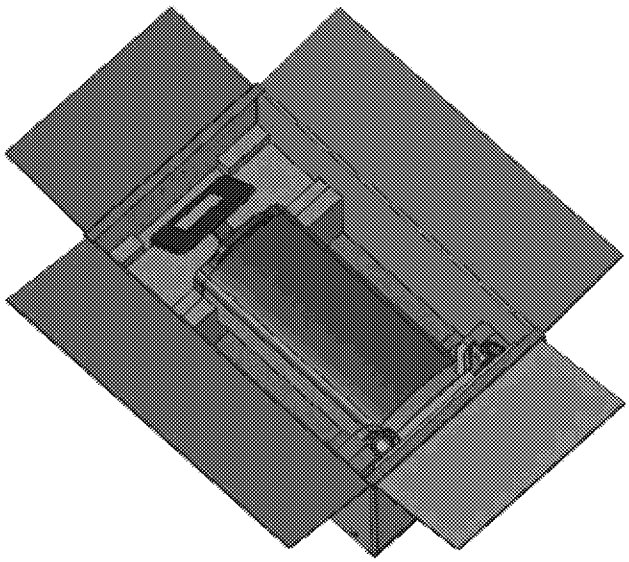
3.4 Unpacking

In order to unpack the device:

1. Remove the paper strip and open the box



2. Remove accessories and foams around the device.



3. Take device out of the box using top and bottom handles.

3.5 Installation

The System is designed for installation in a clinic environment. To install the System, perform the following tasks:

- Check the System and all its components for damage.
- Connect cradle to the device.
- Connect Applicator to the connector and place into the cradle.
- Connect the Footswitch.
- Connect the power cord to the System inlet.
- Plug the System Power Cord into an appropriate electrical outlet.

3.6 Moving the System

- Turn the System off.
- Disconnect the Power Cord.
- Disconnect the Applicator.
- Disconnect the Footswitch.
- Release the Wheel Brakes.
- Slowly push or pull the System using the handle.
- When moving the System to another facility, lift the System to the vehicle and lay it carefully on its side.

Never lift, pull or push the System using the operating panel.

Always use the handles when moving the System.

Upon unpacking, check the System for mechanical damage (e.g., cracks in the cable insulation).

3.7 System Disposal

To comply with European Commission Directive 2002/96/EC on Waste Electrical and Electronic Equipment (WEEE) and other country and state regulations, please DO NOT dispose of this equipment in any location other than designated locations.

4 Section 4: Device Description

4.1 Rear Panel

	**Power Cord Inlet** 100-240V~, 15A, 50-60Hz.
	**Fuse Holder** Rating is T 12.5A, 250V. Replace fuses if needed, only with fuses having exactly the same rating.
	**Software Flash Memory Plug** The software plug is a flash memory with the machine software. The software plug should be screwed to the connectors. To tighten and/or loosen the screws use fingertips only. Do not use screwdriver as it can damage the connectors.
	**Footswitch Connector** Footswitch is connected to the inlet. Footswitch activates RF energy if the System is in Ready mode. Place the Footswitch on the floor near the treatment area.

4.2 Operator Control Panel

The Operator Control Panel is located on the upper side of the System. The Operator Control Panel consists of On-Off switch, four function keys, an information screen and hand piece connectors (Figure 4.1).

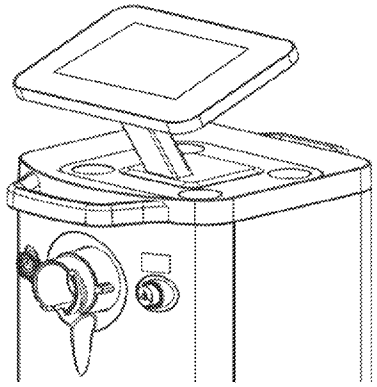


Figure 4-1: Operator Control Panel

Power On-Off Switch	Power switch turns System On and Off.
Hand piece connector	RF power cannot be activated if Applicator is not connected to the connector.
LCD Screen	LCD screen shows information about machine status, treatment parameter. Touch screen allows to user change treatment parameters and device mode

4.3 Software Screens

The Progress screen appears after the On-Off switch is turned on.

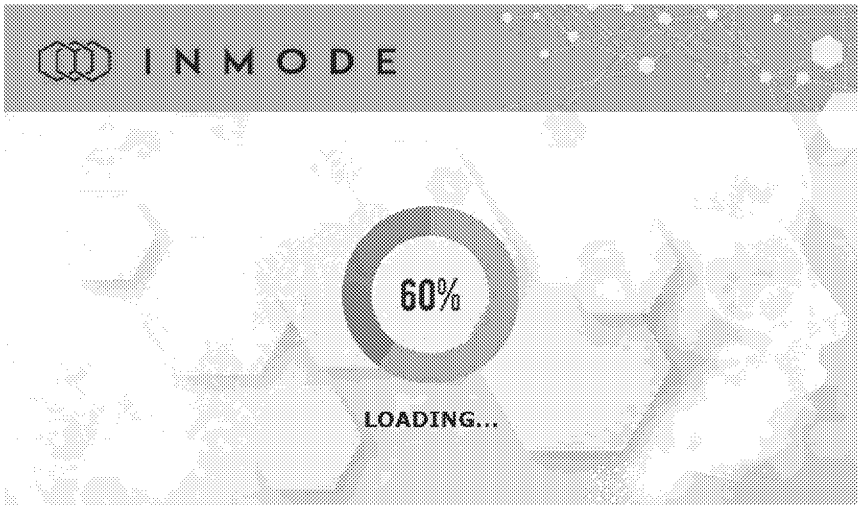


Figure 4-2: Progress Screen

*The SW version number will be displayed according to the software version.

After entering the individual code on the Login Screen, non-authorized use of the device is prevented.

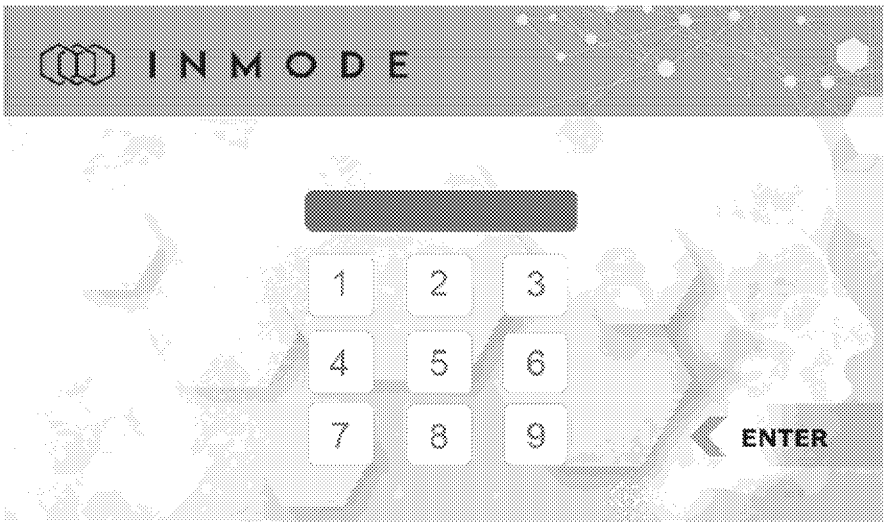


Figure 4-3: Login Screen

Software is loaded from the plug and self-test of the System modules is performed. After the end of the self-test the Menu Screen appears.

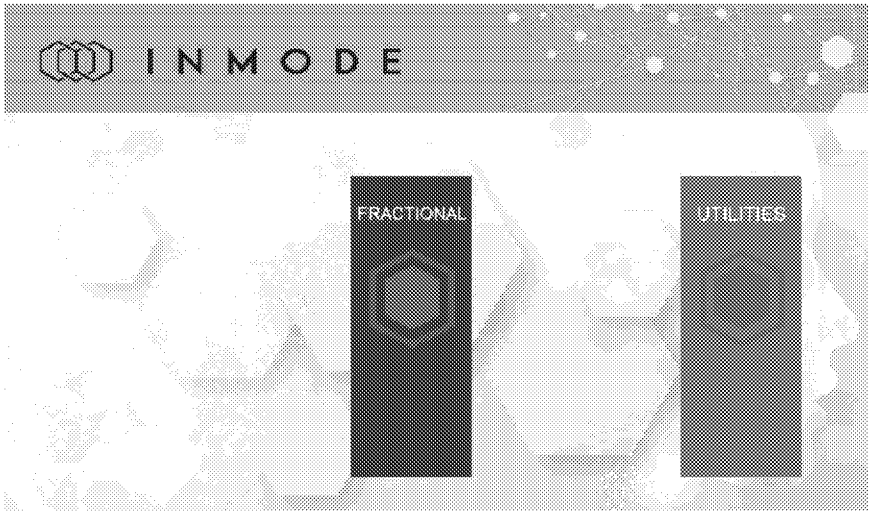


Figure 4-4: Menu Screen

The Menu Screen allows the selection of the connected Applicator, or entry to the Utilities Screen.

Figure 4-5: Utilities Screen

The Utility Screen contains:

Volume	This function allows the user to adjust the System volume.
Change Password	Change the password by entering the old password and then entering another 4-digit password.
Calibration	N/A
Main Menu	Return to the Main Menu to select an applicator.

After returning to the Menu Screen and choosing the application on the Menu Screen, the corresponding Treatment Screen appears.

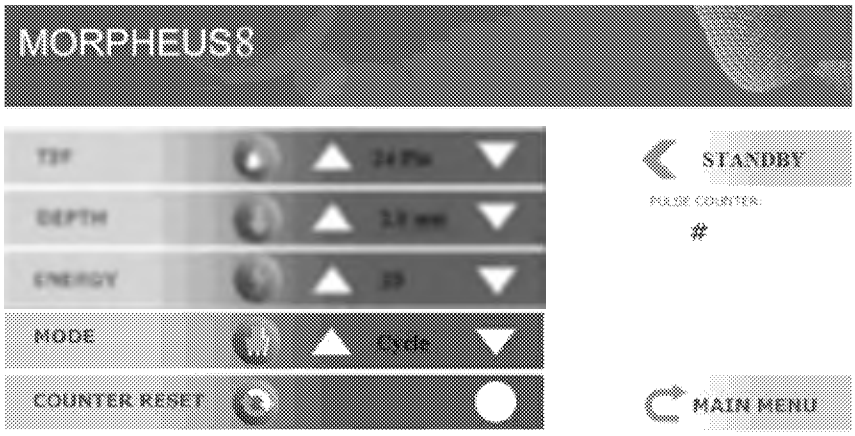


Figure 4-6: Morpheus8 Treatment Screen

Tip	Allows selecting the Tip. Available Tips are: T, 12 Pin, 24 Pin tip and 40 Pin.
Depth	Allows selecting the pins length and penetration depth according to dermis thickness in treated area to provide effective sub-dermal treatment. Available depths for Morpheus 8 are: For the Morpheus8 Prime (12 pins) Tip: 1 to 4mm (In increments of 1mm) For the Morpheus8 (24 pin) Tip 1 to 7mm (In increments of 1mm) For the Morpheus8 Body (40 pins) Tip 2 to 7mm (In increments of 1mm) When connecting the Morpheus8 T Tip, depth control is disabled and the pin length is fixed (0.5mm).
Energy	Delivered energy is changed from level 5 to 60 energy levels and the System starts up at the minimal energy setting.
Mode	Selects between Cycle mode when needle goes out and in at each pulse and Fixed mode which is solely used for T tip.
Counter Reset	Counter can be reset.
Pulse Counter	Shows number of pulses delivered on one zone and total number of pulses from the beginning of the treatment.
System Mode	The System has three treatment modes: Standby, Ready, and Active. Standby mode allows the user to set treatment parameters. Activation of energy is not allowed in Standby mode. In Ready mode, the system is waiting for a signal from the foot switch to activate the energy. Any attempt to change the treatment settings switches the system to Standby mode. When the signal from the footswitch is indicated, the system switches to Active mode. Any attempt to change the treatment settings switches the system to Standby mode.
Main Menu	Return to the Main Menu to select another applicator and change the applicator if needed.

4.4 Sound Indicator

Periodic beeping signal is emitted when RF energy is delivered.

4.5 Applicator

Morpheus8 Applicator (Figure 4.7) comprise motor with actuator pushing needle electrodes out to pre-determined depth of up to 7mm. The tip (Figure 4.8) is connected or disconnected with the Applicator.

Figure 4-7: Morpheus8 Applicator

Tip	See below table for Tip specifications.
Handle	The Applicator handle is made of plastic and has an ergonomic design for easy treatment, with high visibility of the treated area.
Cable	The Cable has a length of 270cm.
Connector	The Connector is connected to the front panel of the System.

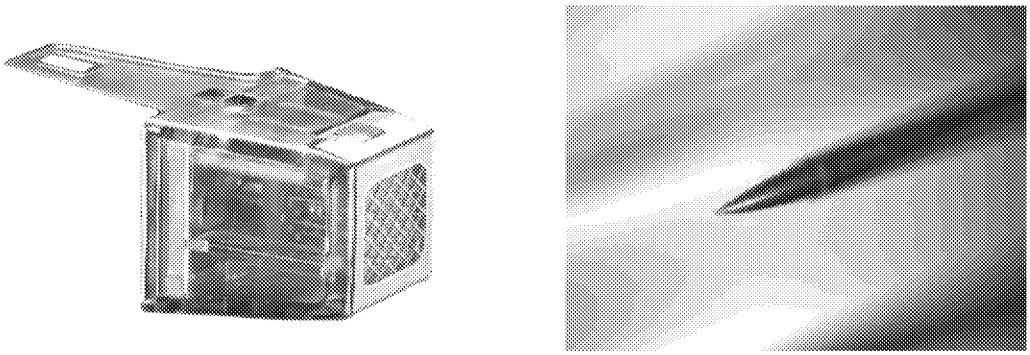


Figure 4-8: Morpheus8 Tip (Left) and Coated Needle (Right)

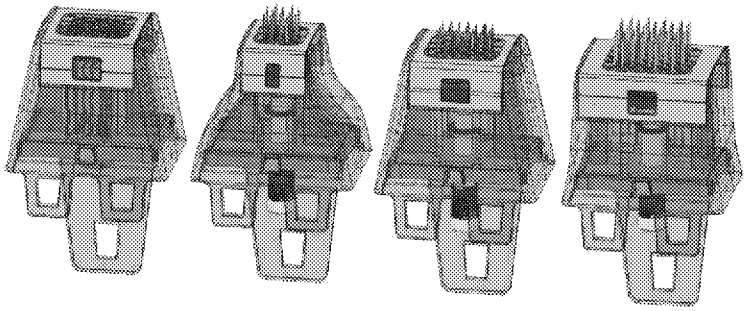


Figure 4-9: Morpheus8 T Tip (Left), Morpheus8 Prime (12 Pins) Tip (Center-Left), Morpheus8 (24 Pins) Tip (Center-Right), Morpheus8 Body (40 Pins) Tip (Right)

⚠ Morpheus8 Tips are for single-use only!

The table below summarizes the specifications of the various Morpheus8 tips:

Tip Name	Pins number	Depth mm	Energy Levels	Cycle Mode	Fixed Mode
Morpheus8 – Body	40	2, 3, 4, 5, 6, 7	5-60	Yes	NA
Morpheus8 -	24	1, 2, 3, 4, 5, 6, 7	5-60 (1mm-5-30)	Yes	NA
Morpheus8 – Prime	12	1, 2, 3, 4	5-30	Yes	NA
Morpheus8 T	24	0.5 Fixed	5-30	NA	Yes

5 Section 5: System Operation

This section of the manual explains how to start the device, operate it, and turn it off.

Prior to using or connecting the Applicator, inspect the System and Applicator for possible mechanical damage.

5.1 Device Start-Up

1. Connect the Applicator to the Applicator connector socket on the System.
2. Press the On-Off button on the control panel to turn the device on. The System loads the software and enters the Login Screen.
3. Enter password to get access to the device. If password is correct the System enters Menu Screen.
4. The System loads the software and enters a self-test mode. If any problem is detected during the test the error message will appear (See Troubleshooting Section in this manual). If the test is passed correctly then the System automatically enters the Menu Screen.
5. Select the application from the Menu Screen and System will enter the Treatment Screen.
6. Verify on the screen that the Software version is properly displayed and the connected Applicator type is recognized correctly.
7. Select the treatment parameters using Up and Down keys.
8. Press the Standby icon that will change to Ready.
9. To start treatment, press the Footswitch for RF applicators.
10. Apply Applicator to the treated area, ensuring a full contact with pressure.

5.2 System Shutdown

- To shut down the System turn the On-Off switch off.
- Turn the Main Power switch off at the end of the day.

6 Section 6: Morpheus8 Treatment Information

6.1 Sub-dermal Fractional Treatment

The Morpheus8 Applicators are designed for delivering RF energy to the dermal and sub-subdermal tissue in a fractional manner with the energy applied to <5% of the total coverage area. The energy is delivered to the skin through bipolar arrays of coated needles and results in localized heating and coagulation of the tissue that is in direct contact with the needle tip. The Morpheus8 Applicator is a versatile fractional technology to treat different body areas.

6.2 Indications for Use

The Morpheus8 Applicators are intended for use in dermatological procedures for electrocoagulation and hemostasis.

At higher energy levels greater than 62 mJ/pin, use of the Morrpheus8 (Fractora) Applicator is limited to Skin Types I-IV.

6.3 Contraindications

- Pacemaker or internal defibrillator, or other metallic or electronic implant anywhere in the body. The Hand piece should be used at least 1cm away from cochlear implants in the ear.
- Permanent implant in the treated area such as metal plates, screws and metal piercing or silicon, unless deep enough in the periosteal plane.
- Intra-dermal or superficial sub-dermal areas injected with Botox®/HA/collagen/fat injections or other augmentation methods with bio-material, before the product has been dissipated (up to 6 months), except Botox after binding to the facial muscles (3-7 days). It is possible to treat sooner over injectable products placed in the deep, periosteal plane, as soon as the area has healed (1-3 weeks).
- Current or history of skin cancer, or any other type of cancer, or pre-malignant moles.
- Pregnancy and nursing.
- Severe concurrent conditions, such as cardiac disorders or sensory disturbances.
- Impaired immune system due to immunosuppressive diseases such as AIDS and HIV, or use of immunosuppressive medications.

- Patients with history of diseases stimulated by heat, such as recurrent Herpes Simplex in the treatment area, may be treated only following a prophylactic regime.
- Poorly controlled endocrine disorders, such as diabetes or thyroid dysfunction and hormonal virilization.
- Any active skin condition in the treatment area, such as sores, psoriasis, eczema, and rash.
- History of skin disorders, keloids, abnormal wound healing, as well as very dry and fragile skin.
- History of bleeding coagulopathies or use of anticoagulants in the last 10 days
- Any facial surgery performed within a year prior to treatment.
- Facial dermabrasion, facial resurfacing, or deep chemical peeling within the last three months, if face is treated.
- Having received treatment with light, laser, RF, or other devices in the treated area within 2-3 weeks for non-ablative procedures, and 6-12 weeks for ablative fractional laser resurfacing (according to treatment severity) prior to treatment, except special recommendations.
- Use of Isotretinoin (Accutane®) within 6 months prior to treatment.
- Use of non-steroidal anti-inflammatory drugs (NSAIDS, e.g., ibuprofen-containing agents) one week before and after each treatment session, as per the practitioner's discretion.
- Treating over tattoo or permanent makeup to be kept.
- Treating over the lips.
- Skin type VI and dark VI patients treat with caution.
- Treating over hair bearing surfaces.
- Irritable skin like excessively tanned skin from sun, tanning beds or tanning creams and sprays within the last two weeks.
- As per the practitioner's discretion, refrain from treating any condition that might make it unsafe for the patient.

6.4 Possible Adverse Side Effects

- Possible adverse effects include but are not limited by: discomfort or pain, excessive skin redness (erythema) and/or swelling (edema), damage to natural skin texture (crust, blister, and burn), change of pigmentation (hyper- and hypo-pigmentation), and scarring.
- Erythema lasting not longer than 24h and edema for 1-3 weeks is a typical skin reaction to the treatment.
- Crusting from the ablated dots will exfoliate naturally after 1-3 weeks.
- The patient must understand the importance of pre-treatment and post-treatment instructions and that failure to comply with these instructions may increase the probability of complications.

6.5 Pre-treatment Recommendations

During the patient's first visit the treating attendant should:

- Complete or update the patient's medical and physical history.
- Exclude from treatment anyone with the listed contraindications.
- Determine why the patient is seeking treatment and what his/her expectations are.
- Determine accurately the patients Fitzpatrick skin type.
- Inform the patient about treatment arrangement, typical treatment results and possible side effects and discomfort.
- Instruct the patient about the safety warnings.
- Advise the patient to avoid skin irritation or intentional skin tanning. Sunscreen is advisable when outdoors during daylight hours
- Asian patients and those with skin types IV-VI should be treated gradually by bleaching products 6 weeks prior treatment and stop at least 48 hours prior Morpheus8 treatment to minimize risk of post inflammatory hyper-pigmentation.
- Prophylactic antiviral therapy should be prescribed for patients with history of cold sores (Herpes Simplex) when treating around the mouth.
- Stop anticoagulants 7-10 days prior to treatment, if medically permitted.
- Clean the treatment area.

- Apply anesthesia:
  - Topical anesthetic can be applied as needed prior to treatment.
- Cooling methods, such as air cooling, sterile ice-packs, or sterile latex gloves filled with ice, help patient comfort during and after treatment.

The patient should shave the area to be treated. Long and dense hairs prevent electrode contact with the skin's surface.

The operator shall inspect the hand pieces functionality prior to use, by attaching the disposable tip, pressing the footswitch and observing the pins to come out and returning back.

In case of engine failure when the pins of the hand pieces do not retract out of the skin, detach the disposable tip from the hand piece and release the spring mechanism manually.

6.6 Handling Instructions Prior to Use

The Applicator should be thoroughly cleaned before and after use by applying 70% alcohol-absorbed pad for at least 30 sec.

Before each use thoroughly inspect the Applicator for visible damage and cleanliness.

Inspect all components of the Hand piece for visible damage.

The Morpheus8 tips arrive sterile and are for single use only!

6.7 Test Spots

A small test spot should be performed in a non-conspicuous area of the treatment site, prior to the first complete session. Test spot is performed to establish the following requirements:

- Confirm the patient's suitability for treatment:
  - For skin types I – III wait 10-15 minutes before assessing the skin response.
  - For skin types V-VI wait 2-3 days if energy level <30 is used and 7-10 days if energy level >30 is used.
- Establish and confirm treatment parameters: if the desired end-point of erythema and edema – in a tip-shaped pattern – has not been achieved within 10-15 minutes, increase the RF energy. If the response is excessive, decrease the parameters.

6.8 Treatment Recommendations

1. Apply the necessary means of anesthesia. If topical, make sure that it is cleaned off the face before treatment and the skin is dried with alcohol 70%.
2. Ensure that skin is clean and dried with alcohol 70%.
3. Take an alcohol cleaned and dry tip and connect it to the Applicator in the groove.
4. Connect Applicator to the System.
5. Follow Device Start-Up Procedure from System Operation section.
6. Select tip and set treatment parameters.
7. Make sure that the treatment settings correlate to the treated tissue depth.
8. Always start with a low energy level, test patient comfort and observe the skin's response before increasing the energy. Tips, depth and energy levels may vary according to physician discretion, based on patient response.
9. On sensitive thin skin area apply lower parameters.
10. Dark skin (V-VI) treat with restricted energy, starting at the minimal suggested energy level or lower, adding 5 levels each visit (every 3-4 weeks).
11. Apply the Applicator to the treated area ensuring a contact with pressure to minimize discomfort, and press footswitch to deliver RF energy.
12. Move Applicator to the adjacent area and activate RF again.

13. Move to adjacent areas with no overlapping of side-electrodes (30-50% overlap).

14. The endpoint is substantial erythema and edema, visible ablative craters, and burnt tissue smell often accompanied by tingling heat sensation.

The below list summarizes the Treatment recommendations per each tip type:

Tip name	Treatment areas
Morpheus8 Prime (12 pin) Tip	Dermal and subdermal treatment of small areas difficult to maneuver
Morpheus8 T Tip	Superficial (epidermal) treatment
Morpheus8 (24 pin) Tip	Dermal and subdermal treatment
Morpheus8 Body (40 pin) Tip	Dermal and sub-dermal treatment of large body areas
Typical number of treatments is 1 to 6 and depends on used energy and treatment goal	
Typical down time is 1 to 6 days and depends on used energy and number of passes	

6.9 Treatment Schedule

The number of treatment sessions depends on the individual patient and treatment aggressiveness and may vary from 1-6 sessions, depending on used energy and treatment goal, as well as patient tolerance and skin response. Treatments are typically repeated every 3-6 weeks.

It is recommended to schedule a follow-up session 2-3 days after the treatment to ensure safe healing process.

Typical down time is 1 to 6 days and depends on used energy.

Treatment should be concluded when the results are satisfactory to the patient or according to the physician's discretion. Generally, 3-6 sessions are needed for mild to moderate depth settings. It is not typical to perform more than five consecutive sessions; however, more sessions can be performed as per physician discretion. In some instances, 1-2 sessions may be sufficient.

6.10 Post-treatment Recommendations

After each treatment session, the physician should advise the patient on proper care.

- Cool the skin for 10-20 min.
- Emollient cream or occlusive dressing could be applied to the treatment area.
- Alternatively, prophylactic antibiotic treatment may be prescribed for 1-3 days post treatment. Patient is to contact the physician if there is any indication of infection, excessive swelling, redness, undue pain, or any other unusual or untoward symptom.
- Tiny scabs may appear after 1-3 days and stay for several days following the treatment. The scabs should not be touched or scratched even if they itch and should be allowed to flake off naturally.
- Blisters may be treated with a prescribed antibiotic ointment or burn treatment cream as per physician's discretion.
- During the first two days following treatment the skin should be kept clean to avoid contamination or infection; any mechanical or thermal damage to the area must be avoided.
- Prophylactic antiviral therapy should be continued for patients with history of cold sores (Herpes Simplex) when treating around the mouth.
- Moisturizer may be applied 24-72 hours after each treatment and then should be applied regularly throughout the course of the treatment. Make-up may be applied only 24-72 hours after each treatment session. Generally, 24 hours after treatment, patients may use regular soaps, but not scrub soaps or exfoliates.
- The patient should use a high-factor sunscreen (at least 30 SPF) and protect the treated area from over-exposure to sunlight for at least one month after the treatment, starting 24-72 hours post treatment. Excessive tanning of any sort (sun exposure, tanning beds, and artificial tanning lotions) is not allowed in the treated areas during the entire course of the treatment.
- For Asian patients and skin types IV and V, a prescription or compounded bleaching regimen may be prescribed by the physician for 6-12 weeks, 2-3 times a week following the healing of treatment area (typically 7 days) to minimize risk of post inflammatory hyper-pigmentation. It should be stopped 48-72 hours before another Morpheus8 session.

7 Section 7: Troubleshooting

The InMode System with Morpheus8 Applicator provides monitoring of all critical parameters to ensure safety of patient and user. If any of the following faults are detected system automatically goes to STAND BY mode.

7.1 Description of Faults with All Applicator

Problem	Description and Checks
System does not turn on	▪ Check power cord connection. ▪ Check that On/Off switch on front panel is on. ▪ Check fuses on back panel of the System. ▪ Call Technical Service if problem persists.
System shuts down by itself	▪ Check power cord connection. ▪ Check fuses on back panel of the System. ▪ Call Technical Service if problem persists.
Checksum	▪ The software was not loaded properly from software plug. ▪ Check the plug connection and reboot the System. ▪ Call Technical Service if the problem persists.
Fault H8002 - Applicator is not connected	▪ Check the connection of the Applicator. ▪ Replace the Applicator. ▪ Call Technical Service if the problem persists.
Fault H8005, H800F, H8010 – System Memory Fault	Call Technical Service if the problem persists.
Fault H800E- System Incompatible Software Version	Call Technical Service if the problem persists.
Fault H800F- System Memory Fault	Call Technical Service if the problem persists.
Faults H8003, H8006, H8007 - RF Related Faults	Call Technical Service if the problem persists.

8 Section 8: System Specifications

Input Power		
Main Line Frequency (nominal)	50-60Hz	
Input Voltage (nominal)	100-240VAC	
Input Current (rms)	12A	
Operating Parameters		
Ambient Temperature Range	15 – 30°C [59 – 86°F]	
Relative Humidity	30% to 80%, non-condensing	
Atmospheric Pressure	90 - 110kPa	
Warm-up Time	If transported or stored at temperatures outside the operating temperature range, allow one hour for the device to reach room temperature before use.	
Transport and Storage		
Ambient Temperature Range	-20– 65°C [-4 – 149°F]	
Relative Humidity	0% to 80%, non-condensing	
Atmospheric Pressure	50 to 110kPa	
Dimensions		
System	46cm W x 46cm D x 100cm H	[18.2'' W x 18.2'' D x 40'' H]
Applicator Cable	270cm L	[100`` L]
Weight		
System	32.000kg	[70.548lb]
Morpheus8 Applicator	0.400kg	[1.268lb]
Morpheus8 Output Parameters		
Maximum Output Power	65[W]	
Frequency	1MHz	
Crest Factor (Rated Load)	1.4± 2%	

8.1 Output Power Curves

The curves that follow depict the changes for each RF mode at specific power settings.

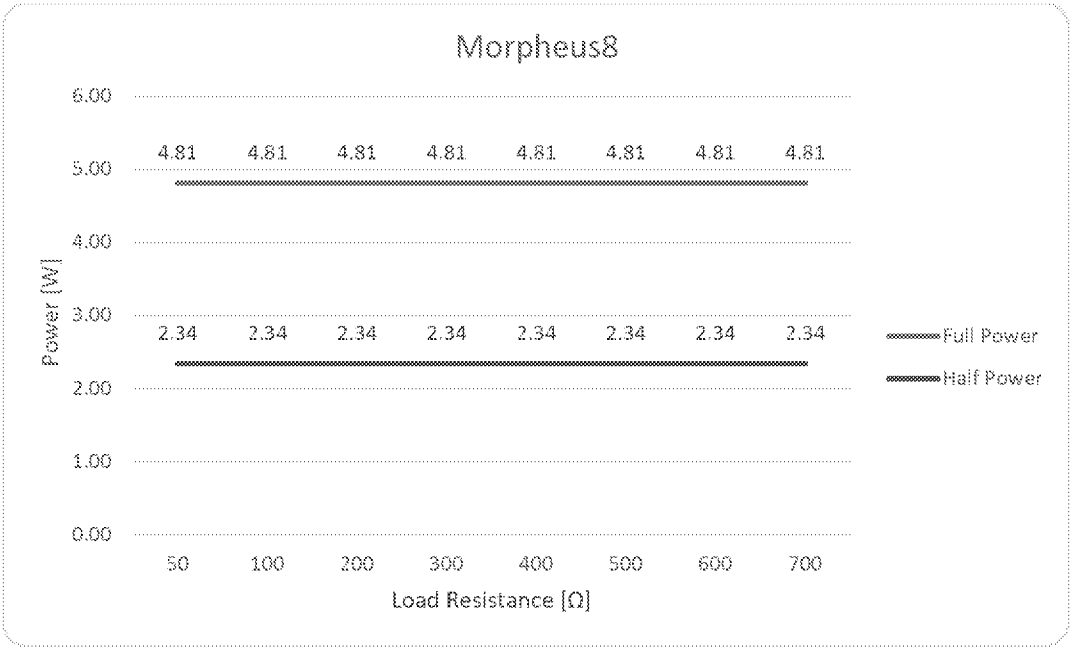


Figure 8-1: Morpheus Output Power versus Impedance

8.2 EMC Safety

The device has been tested and found to comply with the limits for the medical devices to the IEC 60601-1-2. These limits are designed to provide reasonable protection against harmful interference in a typical clinical installation. This device generates uses and can radiate radio frequency energy. If not installed and used in accordance with the instructions, may cause harmful interference to other devices in the vicinity. However, there is no guarantee that the interference to other devices, which can be determined by turning the device off and on, is caused by this instrument.

The user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving device.
- Increase the separation between the devices.
- Connect the device into an outlet on a circuit different from that which was previously used.

- Consult InMode service personnel for help.

Interference to the device may be caused by portable and mobile RF communication equipment. In case of an interruption, beware of such a device in the vicinity.

- Use of the System with any accessory, transducer or cable other than those specified may result in increased EMISSIONS or decreased IMMUNITY than those specified.

- The System should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the System should be observed to verify normal operation in the configuration in which it will be used.

Guidance and manufacturer's declaration – electromagnetic emissions		
The InMode System with Morpheus8Hand pieces is intended for use in the electromagnetic environment specified below. The customer or the user of the InMode System with Morpheus8Hand pieces should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment – guidance**
RF emissions CISPR 11	Group 1	The InMode System with Morpheus8 Hand pieces uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class A	The InMode System with Morpheus8 Hand pieces is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Complies	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

Guidance and manufacturer's declaration – electromagnetic immunity

The InMode System with Morpheus8Hand pieces is intended for use in the electromagnetic environment specified below. The customer or the user of the InMode System with Morpheus8Hand pieces should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Electrostatic discharge (ESD) IEC 61000-4-2	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	± 2 kV for power supply lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV differential mode ± 2 kV common mode	± 1 kV differential mode ± 2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5 % U_T (>95 % dip in U_T) for 0,5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles <5 % U_T (>95 % dip in U_T) for 5sec	>95 % dip for 10 ms 60 % dip for 100 ms 30 % dip for 500 ms 95 % dip for 5000 ms	Mains power quality should be that of a typical commercial or hospital environment. If the user of the InMode System with Morpheus8 Hand pieces requires continued operation during power mains interruptions, it is recommended that the InMode System with Morpheus8Hand pieces be powered from an uninterruptible power supply.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

NOTE - U_T is the AC mains voltage prior to application of the test level.

Guidance and manufacturer's declaration – electromagnetic immunity

The InMode System with Morpheus8Hand pieces is intended for use in the electromagnetic environment specified below. The customer or the user of the InMode System with Morpheus8Hand pieces should assure that it is used in such an environment.

IMMUNITY Test	IEC 60601 Test Level	Compliance Level	Electromagnetic environment – guidance
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3 Vrms 150 kHz to 80 MHz 3 V/m 80 MHz to 2,5 GHz	[3] V [3] V/m	Portable and mobile RF communications equipment should be used no closer to any part of the device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = \left[\frac{3,5}{V_1}\right]\sqrt{P} = \left[\frac{3,5}{3}\right]\sqrt{65} = \mathbf{9.4}\ [m]$ $80\ MHz\ to\ 800\ MHz$ $d = \left[\frac{7}{E_1}\right]\sqrt{P} = \left[\frac{7}{3}\right]\sqrt{65} = \mathbf{18.81}\ [m]$ $80\ MHz\ to\ 2{,}5\ GHz$ Where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and *d* is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol: 

NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the InMode System with Morpheus8Hand pieces is used exceeds the applicable RF compliance level above, the InMode System with Morpheus8Hand pieces should be observed to verify normal operation. If abnormal performance is observed, additional

measures may be necessary, such as re-orienting or relocating the InMode System with Morpheus8Hand pieces.

b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Recommended separation distances between portable and mobile RF communications equipment and the InMode System with Morpheus8Hand pieces System

The InMode System with Morpheus8Hand pieces System is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the InMode System with Morpheus8Hand pieces can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the InMode System with Morpheus8Hand pieces as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter [W]	Separation distance according to frequency of transmitter [m]		
	150 kHz to 80 MHz $d = \left[\frac{3,5}{V_1}\right]\sqrt{P}$	80 MHz to 800 MHz $d = \left[\frac{3,5}{E_1}\right]\sqrt{P}$	800 MHz to 2,5 GHz $d = \left[\frac{7}{E_1}\right]\sqrt{P}$
0,01	0.117	0.117	0.233
0,1	0.369	0.369	0.738
1	1.167	1.167	2.333
10	3.689	3.689	7.379
100	11.667	11.667	23.333

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

IEC 60601-1-2 Edition 4.0 (2014)

Environment of intended uses:

Professional Healthcare Facility Environment

Summary of Test Results

Test	Standard	Class/ Severity level	Test result
Documentation (IEC 60601-1-2 sections 4 and 5)			
General requirements for EMC	section 4.1.1.	---	Complies
External labels	section 5.1	---	Complies
Conformity of Users' Manual	section 5.2.1	---	Complies
Accuracy of Technical Descri.	section 5.2.2	---	Complies
Emission (IEC 60601-1-2 section 7 and IEC 60601-2-2 section 202.6.1)			
Conducted emission Freq. range:150 kHz - 30 MHz	sec. 7.1 & CISPR 11	Group 1 Class A on 230, 120 & 100 VAC mains	Complies
Radiated emission Freq. range: 30 - 1000 MHz	sec. 7.1 & CISPR 11	Group 1 Class A	Complies
Harmonic current emission test	sec. 7.2.1 & IEC 61000-3-2	AC mains (EUT with HP BodyTite, PLUS90, PLUSPLUS and BodyFX)	Complies
		AC mains (EUT with HP FaceTite and Fractora)	N/A
Voltage changes, Voltage fluctuations and Flicker test	sec. 7.2.2 & IEC 61000-3-3	AC mains	Complies
Immunity (IEC 60601-1-2 section 8 and IEC 60601-2-2 section 202.6.2)			
Immunity from Electrostatic discharge (ESD)	IEC 61000-4-2	8 kV contact discharges & 15 kV air discharges	Complies
Immunity from radiated electromagnetic fields	IEC 61000-4-3	3.0 V/m; 80 MHz ÷ 2.7 GHz, 80% AM, 1 kHz	Complies
Immunity from Proximity field from wireless communications equipment	IEC 61000-4-3	List of frequencies, from 9 V/m up to 28 V/m, PM (18 Hz or 217 Hz), FM 1 kHz	Complies
Immunity from Electrical Fast transient (EFT)	IEC 61000-4-4	± 2.0 kV on AC mains, Tr/Th – 5/50 ns, 100 kHz	Complies
Immunity from Surge	IEC 61000-4-5	±1.0 kV DM / ±2.0 kV CM on AC mains; Tr/Th – 1.2/50 (8/20) µs	Complies
Immunity from conducted disturbances induced by radio-frequency fields	IEC 61000-4-6	3.0; 6.0 V_{RMS} on AC mains & HP cables; 0.15÷ 80 MHz, 80% AM, 1 kHz	Complies
Immunity from Voltage dips, short interruptions and voltage variations	IEC 61000-4-11	On 230 & 100 VAC mains: 0 % - 0.5 cycle & 1 cycle; 70% - 25 cycles; 0% - 250 cycles	Complies

Appendix 4.0: Revised Brochure

INMODE

MORPHEUS8

The Deepest Subdermal Fractional Technology

WWW.INMODEMD.COM

MORPHEUS8

MORPHEUS8

The InMode System with the Morpheus8 Applicators employs fractional RF multi-electrode technology for dermatological procedure requiring electrocoagulation and hemostasis.

It is designed to deliver RF energy to the target tissue in a fractional manner, via an array of 12, 24 or 40 pin electrodes arranged on a detachable sterilized disposable tip.

The pin array delivers RF energy to the tissue, resulting in heating of surrounding tissue around the electrodes contact, to temperatures leading to electrocoagulation and hemostasis of micro tissue zones.

BENEFITS

- Advanced design creates extremely uniform effect.
- Little to no thermal damage to dermis.

- Morpheus8 Prime (12 pin) Tip : Dermal and subdermal treatment of small areas difficult to maneuver.
- Morpheus8 T Tip: Superficial (epidermal) treatment.
- Morpheus8 (24 pin) Tip : Dermal and subdermal treatment.
- Morpheus8 Body (40 pin) Tip : Dermal and sub-dermal treatment of large body areas.

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April 02, 2020

510(k) Document Mail Center (WO66-0609)
Office of Device Evaluation
Center for Devices and Radiological Health
Food and Drug Administration
10903 New Hampshire Avenue, Silver Spring, MD 20993-0002
U.S.A.

Re: Premarket Notification (510(k)) for the InMode System with the Morhpeus8 Applicators

Attention: Document Mail Clerk

InMode Ltd. has requested that I represent them in the capacity of authorized regulatory agent for the purpose of obtaining FDA marketing clearance for the InMode System with the Morhpeus8 Applicators. It is in that capacity that I am communicating with you.

Attached please find the premarket notification submission for the InMode System with the Morhpeus8 Applicators. A table of contents for this 510(k) is presented following the cover letter.

The eCopy is an exact duplicate of the paper copy.

Following is information required under 21 CFR 807.87 and suggested by FDA Guidance Document; "*Refuse to Accept Policy for 510(k)s" issued Jan 30, 2018.*

Type of 510(k) submission: Traditional

510(k) Submitter: InMode Ltd.
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E-mail: amit@asteinrac.com

This is to notify you of the intention of InMode Ltd., to manufacture and market the following device:

Device trade or proprietary name: InMode System with the Morhpeus8 Applicators

Common Name: Fractional RF skin treatment system

Classification and Product Code: The subject of this 510(k) is the InMode System with the Morhpeus8 Applicators, with the CFR classification section 878.4400; Electrosurgical cutting and coagulation device and accessories, and product code GEI.

Device Class and Panel: An RF Skin Treatment device for use in dermatological procedures is a Class II device. The classification panel is the General & Plastic Surgery Devices Panel.

(b)(4)

Establishment Registration Number: InMode Ltd. has been assigned an establishment registration number 3010511300.

514 Performance Standards: There are no performance standards or special controls under the Federal Food, Drug and Cosmetic Act. However, InMode Ltd. has chosen to comply with the recognized consensus standards stated in Section 9 of this 510(k). Furthermore, this submission is based on the FDA Guidance Document: *"Premarket notification 510(k) submissions for electrosurgical devices for general surgery" issued March 09, 2020.*

Manufacturing Location:

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Israel
Tel: +972-4-9097470
Fax: +972-4-9097471

Reason for Submission:

The subject device of this 510(k) file application; the InMode System with the Morpheus8 Applicators is the exact device as was FDA cleared in K192695 .

The reason for this submission is in the ability of the subject device to reach for deeper penetration tissue depths of up to 7 mm as appose to the predicate device where the maximal penetration depth was 4 mm .

The main change is in device SW to support this design modification .

SW V&V, Safety, EMC and ex-vivo tissue test reports are enclosed to this submission to justify device safety and effectiveness as well as substantial equivalence to predicate.

Substantial Equivalence:

InMode System with the Morhpeus8 Applicators is substantially equivalent to the following predicate device;

Manufacturer	Device	510(k) No.
InMode Ltd.	InMode System with the Morpheus8 Applicators	K192695

A comparison table and detailed discussion are presented in Section 12 – Substantial Equivalence Discussion of this application.

Proposed Labeling: The user's manual for the InMode System with the InMode System with the Morhpeus8 Applicators is attached in Section 13 (Proposed Labeling Section). These instructions describe the InMode System with the Morhpeus8 Applicators, its intended use and the directions for its use. Device labels and product brochure are also included in the Product Labeling Section.

Confidentiality: InMode Ltd. considers its intent to market the InMode System with the Morhpeus8 Applicators in the USA as confidential commercial information. The Company has not disclosed its intent to market this device to anyone except its employees, others with a financial interest in the Company, its advertising or law firms, and its consultants. The Company, therefore, requests FDA not to disclose the existence of this application until such time as final action on the submission is taken. In addition, some of the material in this application may be trade secret or confidential commercial or financial information within the meaning of 21 CFR § 20.61 and therefore not disclosable under the Freedom of Information Act, even after the existence of the application becomes public. We ask that FDA consult with the Company as provided in 21 CFR § 20.45 before making any part of this submission publicly available.

This document presents additional information and data that are intended to establish substantial equivalence and meet the requirements of a 510(k). This supportive information is divided into the following sections, according to the FDA Guidance Document on "*Format for Traditional and Abbreviated 510(k)s*" *issued Sep 13, 2019*;

1. Medical Device User Fee Cover Sheet
2. CDRH Premarket Review Submission Cover Sheet
3. 510(k) Cover Letter
4. Indications for use Statement
5. 510(k) Summary
6. Truthful and Accuracy Statement
7. Class III Summary and Certifications – Not Applicable
8. Financial Certifications or Disclosure Statements – Not Applicable
9. Declaration of Conformity
10. Executive Summary
11. Device Description
12. Substantial Equivalence Discussion, including comparison table of predicate devices and discussion.
13. Proposed Labeling
14. Sterilization Information
15. Biocompatibility Information
16. Software
17. Electromagnetic Compatibility and Electrical Safety
18. Performance Testing – Bench
19. Performance Testing – Pre-Clinical – Not Applicable
20. Performance Testing – Clinical – Not Applicable
21. Other – Not Applicable

I trust that the information included in this application will be adequate to allow for its prompt review. If you have any questions or comments, please don't hesitate to contact me at the following telephone number: +972-9-767-0002, fax number: +972-9-7668534 or e-mail address: amit@asteinrac.com.

Sincerely yours,

(b)(6)

Amit Goren, PhD,
Senior Regulatory Affairs Consultant,
A. Stein – Regulatory Affairs Consulting Ltd.,
for InMode Ltd.

July 2, 2020</br></br> We have completed our review. Please refer to the attached letter for details.

If you have any questions, please contact the lead reviewer assigned to your submission, Mykhaylo Nosovskyy.

 *** This is a system-generated email notification ***

U.S. FOOD & DRUG ADMINISTRATION

Food and Drug Administration
CDRH/OPEQ/OHTIV/DHTIVA
WO66 RM4676
10903 New Hampshire Ave
Silver Spring, MD 20993-0002
301-796-3745

Premarket Notification 510(k) Review

Date: July 1, 2020

Reviewer: Mykhaylo Nosovskyy

Subject: Traditional 510(k)# K200947/S001

Applicant: InMode Ltd.	**Device Trade Name:** InMode System with the Morhpeus8 Applicators
Contact Name: Amit Goren	**Contact Title:** Regulatory Manager
Correspondent Firm: A. Stein - Regulatory Affairs Consulting Ltd.	**Phone:** 972 (9) 767-0002 **Email:** amit@asteinrac.com
Received Date: June 12, 2020	**Due Date:** July 12, 2020
Pro Code(s): GEI **Class:** II **Reg #:** 878.4400	**Reg Name:** Electrosurgical Cutting And Coagulation Device And Accessories

Predicate Devices:

Submission #	Pro Code	Device Trade Name	Applicant
K192695	GEI	InMode System with the Morpheus8 (Fractora) Applicators	Inmode MD Ltd.

Recommendation

I recommend that the InMode System with the Morhpeus8 Applicators is/are Substantially Equivalent (SESE)

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Digital Signature Concurrence Table (Doc ID: 04500.14.01)

This document represents a high-level summary of the Agency's determination on whether the applicant's device is substantially equivalent to a legally marketed predicate device. In determining whether the subject device is substantially equivalent to a predicate device, we carefully considered the relevant regulatory and statutory criteria for Agency decision-making under 21 CFR part 807 and section 513(i) of the Federal Food, Drug and Cosmetic Act (FD&C Act). We considered the burden that may be incurred by the applicant's attempt to follow the premarket notification process. The deficiencies provided in this review, if any, represent the required minimum information necessary to support a substantial equivalence determination. Therefore, we believe that we have considered the least burdensome requirements, under section 513(i)(1)(D) of the FD&C Act, for a 510(k) determination of substantial equivalence.

Reviewer Sign-Off	Mykhaylo B. Nosovskyy -S 2020.07.01 01:58:34 -04'00'

Long H. Chen -S Digitally signed by Long H. Chen -S Date: 2020.07.01 08:05:59 -04'00'

510(K) SUMMARY

INMODE SYSTEM WITH THE MORPHEUS8 APPLICATORS

510(k) Number K200947

Applicant Name:

Company Name: InMode MD Ltd.
Address: Tabor Building, Shaar Yokneam
Yokneam 20692
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.
Address: 20 Hata'as Str., Suite 102
Kfar Saba 44425
Israel
Tel: +972-9-7670002
Fax: +972-9-7668534
E-mail: amit@asteinrac.com

Date Prepared: July 02, 2020

Trade Name: InMode System with the Morpheus8 Applicators

Classification Name: CFR Classification section 878.4400; (Product code GEI)

Classification: Class II Medical Device

Predicate Device:

The InMode System with the Morpheus8 Applicators is substantially equivalent to the following predicate device;

Manufacturer	Device	510(k) No.
InMode Ltd.	InMode System with the Morpheus8 Applicators	K192695

Device Description:

The InMode System with the Morpheus8 Applicators is a computerized, programmed, RF technology based device intended for dermatological applications which requires skin electrocoagulation and hemostasis.

The device platform is basically constituted on the same system platform as FDA-Cleared InMode System with the Morpheus8 Applicators (K192695). The InMode System with the Morpheus8 Applicators employs fractional RF multi-electrode technology for procedures requiring electrocoagulation and hemostasis. The Morpheus8 Applicators are designed to deliver radiofrequency energy to the skin in a fractional manner, via an array of multi-electrode pins. The Device provides enhanced safety while minimizing possible side effects by monitoring RF parameters.

The InMode System with the Morpheus8 Applicators consists of an AC/DC power supply unit, RF generator, controller and user interface including LCD touch screen. The Morpheus8 Applicators are connected to the console via a cable and a foot switch activates the energy delivery to the applicator. The Morpheus8 Applicator comprises handle and detachable, sterilized, disposable, single use 12, 24, 40 pin and T tip head accessory.

Following are the InMode System with the Morpheus8 Applicators specifications:

RF Max Output Power:	65 Watt
RF Output Frequency:	1[MHz]
Dimension:	46cm W x 46cm D x 100cm H (18.2'' W x 18.2'' D x 40'' H)
Weight:	30 Kg (70.4 lbs.)
Main Line Frequency (nominal):	50-60 Hz
Input Voltage (nominal):	100-240 VAC

Intended Use/Indication for Use:

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.

Performance Standards:

The InMode System with the Morpheus8 Applicators has been tested and complies with the following voluntary recognized standards:

- 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.

- 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.

- 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.

Non-Clinical (Bench) Performance Data:

The performance and safety of the InMode System with the Morpheus8 Applicators treatment in dermatological procedures requiring electrocoagulation and hemostasis in deeper tissues of up to 5, 6 and 7 mm was evaluated in an *ex-vivo* tissue study. The study was conducted on a porcine animal model and included a single treatment of two different harvested porcine tissues: muscle and fat utilizing the InMode System with the Morpheus8 applicator 40 pin tip head. Treatment was followed by biopsy sampling of slices trimmed along the pin's penetration path and collection immediately stained by TTC staining to visualize the tissue coagulation necrosis pattern. The *ex-vivo* study results show that the Morpheus8 Applicators is safe for use and effective in achieving the specified indications of dermatological and general electrocoagulation and hemostasis.

Animal Performance Data / Histology Data:

Not Applicable

Clinical Performance Data:

Not Applicable

Substantial Equivalence:

A comparison table is provided below comparing the intended use and basic technological characteristics of the subject device to the intended use and basic technological characteristics of the predicate device.

Technological Characteristic	InMode System with the Morpheus8 Applicators InMode Ltd. K200947 (Subject Device)	InMode System with the Morpheus8 Applicators InMode Ltd. K192695 (Predicate Device)
Product Code, Class	GEI Class II	GEI Class II
Indications for Use	The InMode System with the Morpheus8 Applicators is intended for use in dermatological and general surgical procedures for electrocoagulation and hemostasis. At higher energy levels greater than 62 mJ/pin, use of these Applicators is limited to Skin Types I-IV.	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 these Applicators is limited to Skin Types I-IV.
Anatomical Sites	Body parts requiring treatment as specified in the indication for use	idem
Target Population	Adults requiring treatment as specified in the indication for use	idem
Environment Used	Hospital or Clinic setting	idem
Energy Used / Delivered	RF energy	idem
Design:	Fractional RF: Use of RF energy delivered through a matrix of multiple pin electrodes allocated on the applicator tip	idem
- Mechanism of Action	Treatment is based on fractional RF technology for localized dermis and	idem

Technological Characteristic	InMode System with the Morpheus8 Applicators InMode Ltd. K200947 (Subject Device)	InMode System with the Morpheus8 Applicators InMode Ltd. K192695 (Predicate Device)
	sub dermis coagulation triggering slow collagen regeneration and fibroblast cells' proliferation.	
- Components	The InMode Morpheus8 Applicators are add-on applicators to the FDA cleared InMode System (K192695). The system consists of the following components: - Console, including a power supply, RF generator, controller, and touch screen control and display panel. - Applicator connected to the console via a cable, with tip including 12, 24, 40 & T tip heads. - Footswitch	idem
- System Dimensions	46cm W x 46cm D x 100cm H [18.2'' W x 18.2'' D x 40'' H]	idem
- Weight Platform weight Applicator weight	30 Kg (70.4 lbs.) Applicator – 0.4 Kg (0.88 lbs.) Tip – 0.02 Kg	idem
Number of pins	12, 24 and 40 pins	idem
Maximal Treatment depth	0.5mm (for T tip head) 4.0mm (for 12 pin tip head) 7.0mm (for 24 and 40 pin tip heads)	0.5mm (for T tip head) 4.0mm (for 12 pin tip head) 4.0mm (for 24 and 40 pin tip heads)

Technological Characteristic	**InMode System with the Morpheus8 Applicators InMode Ltd. K200947 (Subject Device)**	**InMode System with the Morpheus8 Applicators InMode Ltd. K192695 (Predicate Device)**
RF energy level	5-30 (for 24 tip head up to 1 mm) 5-30 (for T tip head and for 12 tip head) 5-60 (for 24 and 40 in the range of 2-7mm)	5-30 (for 24 tip head up to 1 mm) 5-30 (for T tip head and for 12 tip head up to 1 mm) 5-60 (for 12 tip head in the range of 2-4mm) 5-60 (for 24 and 40 in the range of 2-4mm)
Cable Dimensions:	270 cm	idem
Performance	Frequency: 1 MHz Maximal RF output power: 65W Maximal pulse duration: up to 74msec	idem
Standards Met	AAMI/ANSI ES 60601-1 IEC 60601-1-2 IEC 60601-2-2	idem
Biocompatibility	All materials are biocompatible	idem
Compatibility with Environment and Other Devices	InMode System with the Morpheus8 Applicators is compliant with the IEC 60601-1-2 (EMC Safety) standard	idem
Sterility	The 12, 24, 40 and T tip head are Gamma sterilized and for single use. The Morpheus8 Applicator handle is for multiple use	idem
Electrical Safety	Power Requirements:	idem

Technological Characteristic	InMode System with the Morpheus8 Applicators InMode Ltd. K200947 (Subject Device)	InMode System with the Morpheus8 Applicators InMode Ltd. K192695 (Predicate Device)
	100-240 VAC 50-60 Hz The InMode System with the Morpheus8 Applicators is compliant with the IEC 60601-1 standard.	
Mechanical Safety	The InMode System with the Morpheus8 Applicator is compliant with the IEC 60601-1 standard.	idem
Chemical Safety	Not Applicable	Not Applicable
Thermal Safety	The InMode System with the Morpheus8 Applicators is compliant with the IEC 60601-1 standard.	idem
Radiation Safety	The InMode System with the Morpheus8 Applicators is compliant with the IEC 60601-1-2 (EMC Safety) standard.	idem

The indications for use and technological characteristics of the InMode System with the Morpheus8 Applicators are substantially equivalent to the indications for use and technological characteristics of the FDA-Cleared InMode System with the Morpheus8 Applicators (K192695).

The design and components in the InMode System, including the console (with power supply, RF generator, controller and display panel) and the Applicator (with cable, connector to console, handle and tip) are similar to the design and components found in the predicate. The performance specifications (including RF frequency, pulse duration and RF energy per pin) of the subject device were shown to be identical and yielded the same RF energy per pin values to those of the predicate device. The safety features and compliance with safety standards in the InMode System with the Morpheus8 Applicators are identical to the safety features and compliance with safety standards found in the predicate device. Patient contact materials are also identical. Any minor differences in the technological characteristics do not raise new safety or effectiveness

concerns. Furthermore, the new InMode System with the Morpheus8 Applicators 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, comparative bench testing and *ex-vivo* tissue testing to evaluate and compare the fractional coagulation necrosis pattern of target tissues, formed by thermal effect of the InMode System with the Morpheus8 Applicators 24 and 40 pin tip heads in different tissue depths. These performance tests demonstrated that the minor differences in the device design and specifications meet the system requirements and do not raise new safety or effectiveness concerns.

Consequently, it can be concluded that the InMode System with the Morpheus8 Applicators are substantially equivalent to the predicate InMode System with the Morpheus8 Applicators, FDA-Cleared in 510(k) K192695, and therefore, may be legally marketed in the USA.

U.S. FOOD & DRUG ADMINISTRATION

Food and Drug Administration
CDRH/OPEQ/OHTIV/DHTIVA
WO66 RM4676
10903 New Hampshire Ave
Silver Spring, MD 20993-0002
301-796-3745

Premarket Notification 510(k) Review

Date: June 7, 2020

Reviewer: Mykhaylo Nosovskyy

Subject: Traditional 510(k)# K200947

Applicant: InMode Ltd.	**Device Trade Name:** InMode System with the Morhpeus8 Applicators
Contact Name: Amit Goren	**Contact Title:** Regulatory Manager
Correspondent Firm: A. Stein - Regulatory Affairs Consulting Ltd.	**Phone:** 972 (9) 767-0002 **Email:** amit@asteinrac.com
Received Date: April 8, 2020	**Due Date:** July 7, 2020
Pro Code(s): GEI **Class:** II **Reg #:** 878.4400	**Reg Name:** Electrosurgical Cutting And Coagulation Device And Accessories

Predicate Devices:

Submission #	Pro Code	Device Trade Name	Applicant
K192695	GEI	InMode System with the Morpheus8 (Fractora) Applicators	Inmode MD Ltd.

Recommendation

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Digital Signature Concurrence Table (Doc ID: 04500.14.01)

This document represents a high-level summary of the Agency's determination on whether the applicant's device is substantially equivalent to a legally marketed predicate device. In determining whether the subject device is substantially equivalent to a predicate device, we carefully considered the relevant regulatory and statutory criteria for Agency decision-making under 21 CFR part 807 and section 513(i) of the Federal Food, Drug and Cosmetic Act (FD&C Act). We considered the burden that may be incurred by the applicant's attempt to follow the premarket notification process. The deficiencies provided in this review, if any, represent the required minimum information necessary to support a substantial equivalence determination. Therefore, we believe that we have considered the least burdensome requirements, under section 513(i)(1)(D) of the FD&C Act, for a 510(k) determination of substantial equivalence.

Reviewer Sign-Off	Mykhaylo B. Nosovskyy -S 2020.06.07 06:43:20 -04'00'

Long H. Chen -S Digitally signed by Long H. Chen -S Date: 2020.06.07 07:16:33 -04'00'

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K200947

Device Name
InMode System with the Morpheus8 Applicators

Indications for Use *(Describe)*
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.

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.

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Department of Health and Human Services
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PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(K) SUMMARY

INMODE SYSTEM WITH THE MORPHEUS8 APPLICATORS

510(k) Number K200947

Applicant Name:

Company Name: InMode MD Ltd.
Address: Tabor Building, Shaar Yokneam
Yokneam 20692
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.
Address: 20 Hata'as Str., Suite 102
Kfar Saba 44425
Israel
Tel: +972-9-7670002
Fax: +972-9-7668534
E-mail: amit@asteinrac.com

Date Prepared: July 02, 2020

Trade Name: InMode System with the Morpheus8 Applicators

Classification Name: CFR Classification section 878.4400; (Product code GEI)

Classification: Class II Medical Device

Predicate Device:

The InMode System with the Morpheus8 Applicators is substantially equivalent to the following predicate device;

Manufacturer	Device	510(k) No.
InMode Ltd.	InMode System with the Morpheus8 Applicators	K192695

Device Description:

The InMode System with the Morpheus8 Applicators is a computerized, programmed, RF technology based device intended for dermatological applications which requires skin electrocoagulation and hemostasis.

The device platform is basically constituted on the same system platform as FDA-Cleared InMode System with the Morpheus8 Applicators (K192695). The InMode System with the Morpheus8 Applicators employs fractional RF multi-electrode technology for procedures requiring electrocoagulation and hemostasis. The Morpheus8 Applicators are designed to deliver radiofrequency energy to the skin in a fractional manner, via an array of multi-electrode pins. The Device provides enhanced safety while minimizing possible side effects by monitoring RF parameters.

The InMode System with the Morpheus8 Applicators consists of an AC/DC power supply unit, RF generator, controller and user interface including LCD touch screen. The Morpheus8 Applicators are connected to the console via a cable and a foot switch activates the energy delivery to the applicator. The Morpheus8 Applicator comprises handle and detachable, sterilized, disposable, single use 12, 24, 40 pin and T tip head accessory.

Following are the InMode System with the Morpheus8 Applicators specifications:

RF Max Output Power:	65 Watt
RF Output Frequency:	1[MHz]
Dimension:	46cm W x 46cm D x 100cm H (18.2'' W x 18.2'' D x 40'' H)
Weight:	30 Kg (70.4 lbs.)
Main Line Frequency (nominal):	50-60 Hz
Input Voltage (nominal):	100-240 VAC

Intended Use/Indication for Use:

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.

Performance Standards:

The InMode System with the Morpheus8 Applicators has been tested and complies with the following voluntary recognized standards:

- 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.

- 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.

- 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.

Non-Clinical (Bench) Performance Data:

The performance and safety of the InMode System with the Morpheus8 Applicators treatment in dermatological procedures requiring electrocoagulation and hemostasis in deeper tissues of up to 5, 6 and 7 mm was evaluated in an *ex-vivo* tissue study. The study was conducted on a porcine animal model and included a single treatment of two different harvested porcine tissues: muscle and fat utilizing the InMode System with the Morpheus8 applicator 40 pin tip head. Treatment was followed by biopsy sampling of slices trimmed along the pin's penetration path and collection immediately stained by TTC staining to visualize the tissue coagulation necrosis pattern. The *ex-vivo* study results show that the Morpheus8 Applicators is safe for use and effective in achieving the specified indications of dermatological and general electrocoagulation and hemostasis.

Animal Performance Data / Histology Data:

Not Applicable

Clinical Performance Data:

Not Applicable

Substantial Equivalence:

A comparison table is provided below comparing the intended use and basic technological characteristics of the subject device to the intended use and basic technological characteristics of the predicate device.

Technological Characteristic	InMode System with the Morpheus8 Applicators InMode Ltd. K200947 (Subject Device)	InMode System with the Morpheus8 Applicators InMode Ltd. K192695 (Predicate Device)
Product Code, Class	GEI Class II	GEI Class II
Indications for Use	The InMode System with the Morpheus8 Applicators is intended for use in dermatological and general surgical procedures for electrocoagulation and hemostasis. At higher energy levels greater than 62 mJ/pin, use of these Applicators is limited to Skin Types I-IV.	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 these Applicators is limited to Skin Types I-IV.
Anatomical Sites	Body parts requiring treatment as specified in the indication for use	idem
Target Population	Adults requiring treatment as specified in the indication for use	idem
Environment Used	Hospital or Clinic setting	idem
Energy Used / Delivered	RF energy	idem
Design:	Fractional RF: Use of RF energy delivered through a matrix of multiple pin electrodes allocated on the applicator tip	idem
- Mechanism of Action	Treatment is based on fractional RF technology for localized dermis and	idem

Technological Characteristic	InMode System with the Morpheus8 Applicators InMode Ltd. K200947 (Subject Device)	InMode System with the Morpheus8 Applicators InMode Ltd. K192695 (Predicate Device)
	sub dermis coagulation triggering slow collagen regeneration and fibroblast cells' proliferation.	
- Components	The InMode Morpheus8 Applicators are add-on applicators to the FDA cleared InMode System (K192695). The system consists of the following components: - Console, including a power supply, RF generator, controller, and touch screen control and display panel. - Applicator connected to the console via a cable, with tip including 12, 24, 40 & T tip heads. - Footswitch	idem
- System Dimensions	46cm W x 46cm D x 100cm H [18.2'' W x 18.2'' D x 40'' H]	idem
- Weight Platform weight Applicator weight	30 Kg (70.4 lbs.) Applicator – 0.4 Kg (0.88 lbs.) Tip – 0.02 Kg	idem
Number of pins	12, 24 and 40 pins	idem
Maximal Treatment depth	0.5mm (for T tip head) 4.0mm (for 12 pin tip head) 7.0mm (for 24 and 40 pin tip heads)	0.5mm (for T tip head) 4.0mm (for 12 pin tip head) 4.0mm (for 24 and 40 pin tip heads)

Technological Characteristic	**InMode System with the Morpheus8 Applicators InMode Ltd. K200947 (Subject Device)**	**InMode System with the Morpheus8 Applicators InMode Ltd. K192695 (Predicate Device)**
RF energy level	5-30 (for 24 tip head up to 1 mm) 5-30 (for T tip head and for 12 tip head) 5-60 (for 24 and 40 in the range of 2-7mm)	5-30 (for 24 tip head up to 1 mm) 5-30 (for T tip head and for 12 tip head up to 1 mm) 5-60 (for 12 tip head in the range of 2-4mm) 5-60 (for 24 and 40 in the range of 2-4mm)
Cable Dimensions:	270 cm	idem
Performance	Frequency: 1 MHz Maximal RF output power: 65W Maximal pulse duration: up to 74msec	idem
Standards Met	AAMI/ANSI ES 60601-1 IEC 60601-1-2 IEC 60601-2-2	idem
Biocompatibility	All materials are biocompatible	idem
Compatibility with Environment and Other Devices	InMode System with the Morpheus8 Applicators is compliant with the IEC 60601-1-2 (EMC Safety) standard	idem
Sterility	The 12, 24, 40 and T tip head are Gamma sterilized and for single use. The Morpheus8 Applicator handle is for multiple use	idem
Electrical Safety	Power Requirements:	idem

Technological Characteristic	InMode System with the Morpheus8 Applicators InMode Ltd. K200947 (Subject Device)	InMode System with the Morpheus8 Applicators InMode Ltd. K192695 (Predicate Device)
	100-240 VAC 50-60 Hz The InMode System with the Morpheus8 Applicators is compliant with the IEC 60601-1 standard.	
Mechanical Safety	The InMode System with the Morpheus8 Applicator is compliant with the IEC 60601-1 standard.	idem
Chemical Safety	Not Applicable	Not Applicable
Thermal Safety	The InMode System with the Morpheus8 Applicators is compliant with the IEC 60601-1 standard.	idem
Radiation Safety	The InMode System with the Morpheus8 Applicators is compliant with the IEC 60601-1-2 (EMC Safety) standard.	idem

The indications for use and technological characteristics of the InMode System with the Morpheus8 Applicators are substantially equivalent to the indications for use and technological characteristics of the FDA-Cleared InMode System with the Morpheus8 Applicators (K192695).

The design and components in the InMode System, including the console (with power supply, RF generator, controller and display panel) and the Applicator (with cable, connector to console, handle and tip) are similar to the design and components found in the predicate. The performance specifications (including RF frequency, pulse duration and RF energy per pin) of the subject device were shown to be identical and yielded the same RF energy per pin values to those of the predicate device. The safety features and compliance with safety standards in the InMode System with the Morpheus8 Applicators are identical to the safety features and compliance with safety standards found in the predicate device. Patient contact materials are also identical. Any minor differences in the technological characteristics do not raise new safety or effectiveness

concerns. Furthermore, the new InMode System with the Morpheus8 Applicators 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, comparative bench testing and *ex-vivo* tissue testing to evaluate and compare the fractional coagulation necrosis pattern of target tissues, formed by thermal effect of the InMode System with the Morpheus8 Applicators 24 and 40 pin tip heads in different tissue depths. These performance tests demonstrated that the minor differences in the device design and specifications meet the system requirements and do not raise new safety or effectiveness concerns.

Consequently, it can be concluded that the InMode System with the Morpheus8 Applicators are substantially equivalent to the predicate InMode System with the Morpheus8 Applicators, FDA-Cleared in 510(k) K192695, and therefore, may be legally marketed in the USA.

Section 1:

Medical Device User Fee Cover Sheet
(Form FDA 3601)

Form Approved: OMB No. 0910-0511 Expiration Date: August 31, 2022. See Instructions for OMB Statement.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION
MEDICAL DEVICE USER FEE COVER SHEET

PAYMENT IDENTIFICATION NUMBER: (b)(4)
Write the Payment Identification number on your check.

A completed cover sheet must accompany each original application or supplement subject to fees. If payment is sent by U.S. mail or courier, please include a copy of this completed form with payment. Payment and mailing instructions can be found at: https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/ucm370879.htm

1. COMPANY NAME AND ADDRESS (include name, street address, city state, country, and post office code)

INMODE MD LTD
Tabor House (POB 44)
Industrial Park South
Yokneam
20692
IL

1.1 EMPLOYER IDENTIFICATION NUMBER (EIN)

2. CONTACT NAME
Ahava Stein
2.1 E-MAIL ADDRESS
ahava@asteinrac.com
2.2 TELEPHONE NUMBER (include Area code)
972-97670002
2.3 FACSIMILE (FAX) NUMBER (Include Area code)
97297668534

3. TYPE OF PREMARKET APPLICATION (Select one of the following in each column; if you are unsure, please refer to the application descriptions at the following web site: http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm345263.htm

Select an application type:
[X] Premarket notification(510(k)); except for third party
[ ] 513(g) Request for Information
[ ] Biologics License Application (BLA)
[ ] Premarket Approval Application (PMA)
[ ] Modular PMA
[ ] Product Development Protocol (PDP)
[ ] Premarket Report (PMR)
[ ] 30-Day Notice
[ ] De Novo Request

3.1 Select a center
[X] CDRH
[ ] CBER

3.2 Select one of the types below
[X] Original Application

Supplement Types:
[ ] Efficacy (BLA)
[ ] Panel Track (PMA, PMR, PDP)
[ ] Real-Time (PMA, PMR, PDP)
[ ] 180-day (PMA, PMR, PDP)

4. ARE YOU A SMALL BUSINESS? (See the instructions for more information on determining this status)
[ ] YES, I meet the small business criteria and have submitted the required qualifying documents to FDA
[X] NO, I am not a small business
4.1 If Yes, please enter your Small Business Decision Number:

5. FDA WILL NOT ACCEPT YOUR SUBMISSION IF YOUR COMPANY HAS NOT PAID AN ESTABLISHMENT REGISTRATION FEE THAT IS DUE TO FDA. HAS YOUR COMPANY PAID ALL ESTABLISHMENT REGISTRATION FEES THAT ARE DUE TO FDA?
[X] YES (All of your establishments have registered and paid the fee, or this is your first device and you will register and pay the fee within 30 days after entering into an operation that requires you to register and submit device listing information.)
[ ] NO (If you currently market a medical device and your establishment is required to register and submit device listing information, FDA will not accept your submission until you have paid all fees due to FDA. See http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/RegistrationandListing/ucm053165.htm for additional information)

6. IS THIS PREMARKET APPLICATION COVERED BY ANY OF THE FOLLOWING USER FEE EXCEPTIONS? IF SO, CHECK THE APPLICABLE EXCEPTION.
[ ] This application is the first PMA submitted by a qualified small business, including any affiliates
[ ] This biologics application is submitted under section 351 of the Public Health Service Act for a product licensed for further manufacturing use only
[ ] The sole purpose of the application is to support conditions of use for a pediatric population
[ ] The application is submitted by a state or federal government entity for a device that is not to be distributed commercially

7. IS THIS A SUPPLEMENT TO A PREMARKET APPLICATION FOR WHICH FEES WERE WAIVED DUE TO SOLE USE IN A PEDIATRIC POPULATION THAT NOW PROPOSES CONDITION OF USE FOR ANY ADULT POPULATION? (If so, the application is subject to the fee that applies for an original premarket approval application (PMA).
[ ] YES [X] NO

PAPERWORK REDUCTION ACT STATEMENT
Public reporting burden for this collection of information is estimated to average 18 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to the address below.

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paper Reduction Act (PRA) Staff

PRAStaff@fda.hhs.gov

[Please do NOT return this form to the above address, except as it pertains to comments on the burden estimate.]

8. USER FEE PAYMENT AMOUNT SUBMITTED FOR THIS PREMARKET APPLICATION

$ (b)(4) 01-Apr-2020

Form FDA 3601 (08/19)

"Close Window" Print Cover sheet

(b)(4)

Section 2:

CDRH Premarket Review Submission Cover Sheet (Form FDA 3514)

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

CDRH PREMARKET REVIEW SUBMISSION COVER SHEET

Form Approval
OMB No. 0910-0120
Expiration Date: June 30, 2020
See PRA Statement on page 5.

Date of Submission	User Fee Payment ID Number	FDA Submission Document Number *(if known)*
02/04/2020	(b)(4)	

SECTION A TYPE OF SUBMISSION

PMA	PMA & HDE Supplement	PDP	510(k)	Request for Feedback
☐ Original Submission	☐ Regular (180 day)	☐ Original PDP	☒ Original Submission:	☐ Pre-Submission
☐ Premarket Report	☐ Special	☐ Notice of Completion	☒ Traditional	☐ Informational Meeting
☐ Modular Submission	☐ Panel Track (PMA Only)	☐ Amendment to PDP	☐ Special	☐ Submision Issue Meeting
☐ Amendment	☐ 30-day Supplement		☐ Abbreviated (Complete section I, Page 5)	☐ Day 100 Meeting
☐ Report	☐ 30-day Notice		☐ Additional Information	☐ Agreement Meeting
☐ Report Amendment	☐ 135-day Supplement		☐ Third Party	☐ Determination Meeting
☐ Licensing Agreement	☐ Real-time Review			☐ Study Risk Determination
	☐ Amendment to PMA & HDE Supplement			☐ Other *(specify):*
	☐ Other			

IDE	Humanitarian Device Exemption (HDE)	Class II Exemption Petition	Evaluation of Automatic Class III Designation (De Novo)	Other Submission
☐ Original Submission	☐ Original Submission	☐ Original Submission	☐ Original Submission	☐ 513(g)
☐ Amendment	☐ Amendment	☐ Additional Information	☐ Additional Information	☐ Other *(describe submission):*
☐ Supplement	☐ Supplement			
	☐ Report			
	☐ Report Amendment			

Have you used or cited Standards in your submission? ☒ Yes ☐ No *(If Yes, please complete Section I, Page 5)*

SECTION B SUBMITTER, APPLICANT OR SPONSOR

Company / Institution Name	Establishment Registration Number *(if known)*		
InMode Ltd.	3010511300		
Division Name *(if applicable)*	**Phone Number *(including area code)***		
	(972) 4-9097470		
Street Address	**FAX Number *(including area code)***		
Tabor Building, Shaar Yokneam	(972) 4-9097471		
City	**State / Province**	**ZIP/Postal Code**	**Country**
Yoqneam Illit		2069200	Israel
Contact Name			
Amit Goren			
Contact Title	**Contact E-mail Address**		
Regulatory Manager	amit@asteinrac.com		

SECTION C APPLICATION CORRESPONDENT (e.g., consultant, if different from above)

Company / Institution Name			
A. Stein – Regulatory Affairs Consulting Ltd.			
Division Name *(if applicable)*	**Phone Number *(including area code)***		
	(+ 972) 9-7670002		
Street Address	**FAX Number *(including area code)***		
20 Hata'as Str., Suite 102	(+972) 9-7668534		
City	**State / Province**	**ZIP Code**	**Country**
Kfar Saba		4442520	Israel
Contact Name			
Amit Goren			
Contact Title	**Contact E-mail Address**		
Regulatory Manager	amit@asteinrac.com		

PSC Publishing Services (301) 443-6740 EF

SECTION D1 REASON FOR APPLICATION - PMA, PDP, OR HDE

- ☐ New Device
- ☐ Withdrawal
- ☐ Additional or Expanded Indications
- ☐ Request for Extension
- ☐ Post-approval Study Protocol
- ☐ Request for Applicant Hold
- ☐ Request for Removal of Applicant Hold
- ☐ Request to Remove or Add Manufacturing Site
- ☐ Process change:
  - ☐ Manufacturing ☐ Packaging
  - ☐ Sterilization
  - ☐ Other *(specify below)*
- ☐ Response to FDA correspondence:
- ☐ Change in design, component, or specification:
  - ☐ Software / Hardware
  - ☐ Color Additive
  - ☐ Material
  - ☐ Specifications
  - ☐ Other *(specify below)*
- ☐ Labeling change:
  - ☐ Indications
  - ☐ Instructions
  - ☐ Performance Characteristics
  - ☐ Shelf Life
  - ☐ Trade Name
  - ☐ Other *(specify below)*
- ☐ Location change:
  - ☐ Manufacturer
  - ☐ Sterilizer
  - ☐ Packager
- ☐ Report Submission:
  - ☐ Annual or Periodic
  - ☐ Post-approval Study
  - ☐ Adverse Reaction
  - ☐ Device Defect
  - ☐ Amendment
- ☐ Change in Ownership
- ☐ Change in Correspondent
- ☐ Change of Applicant Address
- ☐ Other Reason *(specify):*

SECTION D2 REASON FOR APPLICATION - IDE

- ☐ New Device
- ☐ New Indication
- ☐ Addition of Institution
- ☐ Expansion / Extension of Study
- ☐ IRB Certification
- ☐ Termination of Study
- ☐ Withdrawal of Application
- ☐ Unanticipated Adverse Effect
- ☐ Notification of Emergency Use
- ☐ Compassionate Use Request
- ☐ Treatment IDE
- ☐ Continued Access
- ☐ Change in:
  - ☐ Correspondent / Applicant
  - ☐ Design / Device
  - ☐ Informed Consent
  - ☐ Manufacturer
  - ☐ Manufacturing Process
  - ☐ Protocol - Feasibility
  - ☐ Protocol - Other
  - ☐ Sponsor
- ☐ Report submission:
  - ☐ Current Investigator
  - ☐ Annual Progress Report
  - ☐ Site Waiver Report
  - ☐ Final
- ☐ Response to FDA Letter Concerning:
  - ☐ Conditional Approval
  - ☐ Deemed Approved
  - ☐ Deficient Final Report
  - ☐ Deficient Progress Report
  - ☐ Deficient Investigator Report
  - ☐ Disapproval
  - ☐ Request Extension of Time to Respond to FDA
  - ☐ Request Meeting
  - ☐ Request Hearing
- ☐ Other Reason *(specify):*

SECTION D3 REASON FOR SUBMISSION - 510(k)

- ☐ New Device
- ☐ Additional or Expanded Indications
- ☐ Change in Technology
- ☒ Other Reason *(specify):*

The subject device of this 510(k) file application; the InMode System with the Morpheus8 Applicators is the exact device as was FDA cleared in K192695.
The reason for this submission is in the ability of the subject device to reach for deeper penetration tissue depths of up to 7 mm as appose to the predicate device where the maximal penetration depth was 4 mm.
The main change is in device SW to support this design modification.
SW V&V, Safety, EMC and ex-vivo tissue test reports are enclosed to this submission to justify device safety and effectiveness and the equivalency to predicate.

SECTION E ADDITIONAL INFORMATION ON 510(K) SUBMISSIONS

Product codes of devices to which substantial equivalence is claimed

1	GEI	2		3		4	
5		6		7		8	

Summary of, or statement concerning, safety and effectiveness information

- [x] 510 (k) summary attached
- [ ] 510 (k) statement

Information on devices to which substantial equivalence is claimed *(if known)*

	510(k) Number		*Trade or Proprietary or Model Name*		*Manufacturer*
1	K192695	1	The InMode System with the Morpheus8 (Fractora) Applicators	1	InMode Ltd.
2		2		2	
3		3		3	
4		4		4	
5		5		5	
6		6		6	

SECTION F PRODUCT INFORMATION - APPLICATION TO ALL APPLICATIONS

Common or usual name or classification name

Electrosurgical, cutting and coagulation device & accessories

	Trade or Proprietary or Model Name for This Device		Model Number
1	InMode System with the Morhpeus8 Applicators	1	
2		2	
3		3	
4		4	
5		5	

FDA document numbers of all prior related submissions *(regardless of outcome)*

1	2	3	4	5	6
7	8	9	10	11	12

Data included in Submission

- [x] Laboratory Testing
- [ ] Animal Trials
- [ ] Human Trials

SECTION G PRODUCT CLASSIFICATION - APPLICATION TO ALL APPLICATIONS

Product Code	C.F.R. Section *(if applicable)*	Device Class
GEI	§ 878.4400	[ ] Class I [x] Class II
Classification Panel		[ ] Class III [ ] Unclassified
General & Plastic Surgery		

Indications *(from labeling)*

(b)(4)

Note: Submission of the information entered in Section H does not affect the need to submit device establishment registration.	FDA Document Number *(if known)*

SECTION H — MANUFACTURING / PACKAGING / STERILIZATION SITES RELATING TO A SUBMISSION

☒ Original ☐ Add ☐ Delete	Facility Establishment Identifier (FEI) Number	☒ Manufacturer ☐ Contract Sterilizer ☐ Contract Manufacturer ☐ Repackager / Relabeler	
Company / Institution Name InMode Ltd.		Establishment Registration Number 3010511300	
Division Name *(if applicable)*		Phone Number *(including area code)* (972) 4-9097470	
Street Address Tabor Building, Shaar Yokneam		FAX Number *(including area code)* (972) 4-9097471	
City Yoqneam Illit	State / Province	ZIP Code 2069200	Country Israel
Contact Name Amit Goren	Contact Title Regulatory Manager	Contact E-mail Address amit@asteinrac.com	

☐ Original ☐ Add ☐ Delete	Facility Establishment Identifier (FEI) Number	☐ Manufacturer ☐ Contract Sterilizer ☐ Contract Manufacturer ☐ Repackager / Relabeler	
Company / Institution Name		Establishment Registration Number	
Division Name *(if applicable)*		Phone Number *(including area code)*	
Street Address		FAX Number *(including area code)*	
City	State / Province	ZIP Code	Country
Contact Name	Contact Title	Contact E-mail Address	

☐ Original ☐ Add ☐ Delete	Facility Establishment Identifier (FEI) Number	☐ Manufacturer ☐ Contract Sterilizer ☐ Contract Manufacturer ☐ Repackager / Relabeler	
Company / Institution Name		Establishment Registration Number	
Division Name *(if applicable)*		Phone Number *(including area code)*	
Street Address		FAX Number *(including area code)*	
City	State / Province	ZIP Code	Country
Contact Name	Contact Title	Contact E-mail Address	

SECTION I	UTILIZATION OF STANDARDS				
Note: Complete this section if your application or submission cites standards or includes a *"Declaration of Conformity to a Recognized Standard"* statement.					
	Standards No.	Standards Organization	Standards Title	Version	Date
1	60601-1	AAMI / ANSI	Medical Electrical Equipment - Part 1: General Requirements For Basic Safety And Essential Performance (IEC 60601-1:2005, MOD) (General II (ES/EMC))		01/01/2012
	Standards No.	Standards Organization	Standards Title	Version	Date
2	60601-1-2	IEC	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests. (General II (ES/EMC))	Edition 4.0	01/02/2014
	Standards No.	Standards Organization	Standards Title	Version	Date
3	60601-2-2	IEC	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.	Edition 6.0	01/03/2017
	Standards No.	Standards Organization	Standards Title	Version	Date
4					
	Standards No.	Standards Organization	Standards Title	Version	Date
5					
	Standards No.	Standards Organization	Standards Title	Version	Date
6					
	Standards No.	Standards Organization	Standards Title	Version	Date
7					
Please include any additional standards to be cited on a separate page.					

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

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF ADDRESS BELOW.

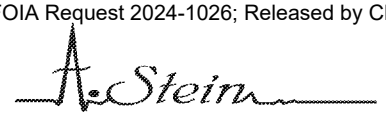
The burden time for this collection of information is estimated to average 0.5 hour per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
1350 Piccard Drive, Room 400
Rockville, MD 20850

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

Section 3:

510(k) Cover Letter



REGULATORY AFFAIRS CONSULTING
Beit Hapa'amon (Box 124)
20 Hata'as St., 44425 Kfar Saba ISRAEL
Tel: +972-9-767-0002 Fax: +972-9-766-8534
E-mail: ahava@asteinrac.com

April 02, 2020

510(k) Document Mail Center (WO66-0609)
Office of Device Evaluation
Center for Devices and Radiological Health
Food and Drug Administration
10903 New Hampshire Avenue, Silver Spring, MD 20993-0002
U.S.A.

Re: Premarket Notification (510(k)) for the InMode System with the Morhpeus8 Applicators

Attention: Document Mail Clerk

InMode Ltd. has requested that I represent them in the capacity of authorized regulatory agent for the purpose of obtaining FDA marketing clearance for the InMode System with the Morhpeus8 Applicators. It is in that capacity that I am communicating with you.

Attached please find the premarket notification submission for the InMode System with the Morhpeus8 Applicators. A table of contents for this 510(k) is presented following the cover letter.

The eCopy is an exact duplicate of the paper copy.

Following is information required under 21 CFR 807.87 and suggested by FDA Guidance Document; "*Refuse to Accept Policy for 510(k)s" issued Jan 30, 2018.*

Type of 510(k) submission: Traditional

510(k) Submitter: InMode Ltd.
Tabor Building, Shaar Yokneam
POB 44, Yokneam 20692
Israel
Tel: +972-4-9097470

Fax: +972-4-9097471
E-mail: amit@asteinrac.com

Contact Person: Amit Goren, PhD
A. Stein – Regulatory Affairs Consulting Ltd.
20 Hata'as Str., Suite 102
Kfar Saba 44425 Israel
Tel: + 972-9-7670002
Fax: +972-9-7668534
E-mail: amit@asteinrac.com

This is to notify you of the intention of InMode Ltd., to manufacture and market the following device:

Device trade or proprietary name: InMode System with the Morhpeus8 Applicators

Common Name: Fractional RF skin treatment system

Classification and Product Code: The subject of this 510(k) is the InMode System with the Morhpeus8 Applicators, with the CFR classification section 878.4400; Electrosurgical cutting and coagulation device and accessories, and product code GEI.

Device Class and Panel: An RF Skin Treatment device for use in dermatological procedures is a Class II device. The classification panel is the General & Plastic Surgery Devices Panel.

(b)(4)

Establishment Registration Number: InMode Ltd. has been assigned an establishment registration number 3010511300.

514 Performance Standards: There are no performance standards or special controls under the Federal Food, Drug and Cosmetic Act. However, InMode Ltd. has chosen to comply with the recognized consensus standards stated in Section 9 of this 510(k). Furthermore, this submission is based on the FDA Guidance Document: *"Premarket notification 510(k) submissions for electrosurgical devices for general surgery" issued March 09, 2020.*

Manufacturing Location:

InMode Ltd.
Tabor Building, Shaar Yokneam
Yokneam 20692
Israel
Tel: +972-4-9097470
Fax: +972-4-9097471

Reason for Submission:

The subject device of this 510(k) file application; the InMode System with the Morpheus8 Applicators is the exact device as was FDA cleared in K192695 .

The reason for this submission is in the ability of the subject device to reach for deeper penetration tissue depths of up to 7 mm as appose to the predicate device where the maximal penetration depth was 4 mm .

The main change is in device SW to support this design modification .

SW V&V, Safety, EMC and ex-vivo tissue test reports are enclosed to this submission to justify device safety and effectiveness as well as substantial equivalence to predicate.

Substantial Equivalence:

InMode System with the Morhpeus8 Applicators is substantially equivalent to the following predicate device;

Manufacturer	Device	510(k) No.
InMode Ltd.	InMode System with the Morpheus8 Applicators	K192695

A comparison table and detailed discussion are presented in Section 12 – Substantial Equivalence Discussion of this application.

Proposed Labeling: The user's manual for the InMode System with the InMode System with the Morhpeus8 Applicators is attached in Section 13 (Proposed Labeling Section). These instructions describe the InMode System with the Morhpeus8 Applicators, its intended use and the directions for its use. Device labels and product brochure are also included in the Product Labeling Section.

Confidentiality: InMode Ltd. considers its intent to market the InMode System with the Morhpeus8 Applicators in the USA as confidential commercial information. The Company has not disclosed its intent to market this device to anyone except its employees, others with a financial interest in the Company, its advertising or law firms, and its consultants. The Company, therefore, requests FDA not to disclose the existence of this application until such time as final action on the submission is taken. In addition, some of the material in this application may be trade secret or confidential commercial or financial information within the meaning of 21 CFR § 20.61 and therefore not disclosable under the Freedom of Information Act, even after the existence of the application becomes public. We ask that FDA consult with the Company as provided in 21 CFR § 20.45 before making any part of this submission publicly available.

This document presents additional information and data that are intended to establish substantial equivalence and meet the requirements of a 510(k). This supportive information is divided into the following sections, according to the FDA Guidance Document on "*Format for Traditional and Abbreviated 510(k)s*" *issued Sep 13, 2019*;

1. Medical Device User Fee Cover Sheet
2. CDRH Premarket Review Submission Cover Sheet
3. 510(k) Cover Letter
4. Indications for use Statement
5. 510(k) Summary
6. Truthful and Accuracy Statement
7. Class III Summary and Certifications – Not Applicable
8. Financial Certifications or Disclosure Statements – Not Applicable
9. Declaration of Conformity
10. Executive Summary
11. Device Description
12. Substantial Equivalence Discussion, including comparison table of predicate devices and discussion.
13. Proposed Labeling
14. Sterilization Information
15. Biocompatibility Information
16. Software
17. Electromagnetic Compatibility and Electrical Safety
18. Performance Testing – Bench
19. Performance Testing – Pre-Clinical – Not Applicable
20. Performance Testing – Clinical – Not Applicable
21. Other – Not Applicable

I trust that the information included in this application will be adequate to allow for its prompt review. If you have any questions or comments, please don't hesitate to contact me at the following telephone number: +972-9-767-0002, fax number: +972-9-7668534 or e-mail address: amit@asteinrac.com.

Sincerely yours,

(b)(6)

Amit Goren, PhD,
Senior Regulatory Affairs Consultant,
A. Stein – Regulatory Affairs Consulting Ltd.,
for InMode Ltd.

Table of Contents

Acceptance Checklist for Traditional 510(k)s

(Should be completed within 15 days of DCC receipt)

The following information is not intended to serve as a comprehensive review.
FDA recommends that the submitter include this completed checklist as part of the submission.

510(k)#: K **Date Received by DCC:** **Lead Reviewer:**
Branch: **Division:** **Center/Office:**

Note: If an element is left blank on the checklist, it does not mean the checklist is incomplete; it means the reviewer did not assess the element during the RTA review and that the element will be assessed during substantive review.

Preliminary Questions **Answers in the shaded blocks indicate consultation with a Center advisor is needed. (Boxes checked in this section represent FDAs preliminary assessment of these questions at the time of administrative review.)**			
	Yes	**No**	**N/A**
1. Is the product a device (per section 201(h) of the FD&C Act) or a combination product (per 21 CFR 3.2(e)) with a device constituent part subject to review in a 510(k)? If it appears not to be a device (per section 201(h) of the FD&C Act) or such a combination product, or you are unsure, consult with the CDRH Jurisdictional Officer or the CBER Product Jurisdiction Liaison to determine the appropriate action, and inform division management. *Provide a summary of the Jurisdictional Officer's/Liaison's determination.* If the product does not appear to be a device or such a combination product, mark "No."	✓		
Comments:			
2. Is the submission with the appropriate Center? If the product is a device or a combination product with a device constituent part, is it subject to review by the Center in which the submission was received? If you believe the submission is not with the appropriate Center or you are unsure, consult with the CDRH Jurisdictional Officer or the CBER Product Jurisdiction Liaison to determine the appropriate action and inform your division management. *Provide a summary of the Jurisdictional Officer's/Liaison's determination.* If submission should not be reviewed by your Center mark "No."	✓		
Comments:			

3. If a Request for Designation (RFD) was submitted for the device or combination product with a device constituent part and assigned to your center, identify the RFD # and confirm the following: **a) Is the device or combination product the same (e.g., design, formulation) as that presented in the RFD submission?** **b) Are the indications for use for the device or combination product identified in the 510(k) the same as those identified in the RFD submission?** If you believe the product or the indications presented in the 510(k) have changed from the RFD, or you are unsure, consult with the CDRH Jurisdictional Officer or the CBER Product Jurisdiction Liaison to determine the appropriate action and inform your division management. *Provide summary of Jurisdictional Officer's/Liaison's determination.* If the answer to either question above is no, mark "No." If there was no RFD, mark "N/A."			✓
Comments:			
4. Is this device type eligible for a 510(k) submission? If a 510(k) does not appear to be appropriate (e.g., Class III type and PMA required, or Class I or II type and 510(k)-exempt), you should consult with the CDRH 510(k) Program Director or appropriate CBER staff during the acceptance review. If 510(k) is not the appropriate regulatory submission, mark "No."	✓		
Comments:			
5. Is there a pending PMA for the same device with the same indications for use? If yes, consult division management and the CDRH 510(k) Program Director or appropriate CBER staff to determine the appropriate action.		✓	
Comments:			
6. If clinical studies have been submitted, is the submitter the subject of an Application Integrity Policy (AIP)? If yes, consult with the CDRH Office of Compliance/Division of Bioresearch Monitoring (OC/DBM) or CBER Office of Compliance and Biologics Quality/Division of Inspections and Surveillance/Bioresearch Monitoring Branch (OCBQ/DIS/BMB) to determine the appropriate action. Check on web at http://www.fda.gov/ICECI/EnforcementActions/ApplicationIntegrityPolicy/ucm134453.htm. If no clinical studies have been submitted, mark "N/A."			✓
Comments:			

- If the answer to 1 or 2 appears to be "No," then stop review of the 510(k) and issue the "Original Jurisdictional Product" letter.
- If the answer to 3a or 3b appears to be "No," then stop the review and contact the CDRH Jurisdictional Officer or CBER Office of Jurisdiction Liaison.

- If the answer to 4 is "No", the lead reviewer should consult division management and other Center resources to determine the appropriate action.
- If the answer to 5 is "Yes," then stop review of the 510(k), contact the CDRH 510(k) Staff and PMA Staff, or appropriate CBER staff.
- If the answer to 6 is "Yes," then contact CDRH/OC/DBM or CBER/OCBQ/DIS/BMB, providea summary of the discussion with DBM or BMB Staff, and indicate their recommendation/action.

Organizational Elements Failure to include these items should not result in an RTA designation.				
***Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.**		**Yes**	**No**	***Page #**
1.	Submission contains a Table of Contents.	✓		17-19
2.	Each section is labeled (e.g., headings or tabs designating Device Description section, Labeling section, etc.).	✓		*
3.	All pages of the submission are numbered. *All pages should be numbered in such a manner that information can be referenced by page number. This may be done either by consecutively numbering the entire submission, or numbering the pages within a section (e.g., 12-1, 12-2…).*	✓		*
4.	Type of 510(k) is identified (i.e., Traditional, Abbreviated, or Special) *If type of 510(k) is not designated, review as a Traditional 510(k).*	✓		*
Comments: *see top header of each page				

- Any "No" answer will result in a "Refuse to Accept" decision; however, FDA staff has discretion to determine whether missing items are needed to ensure that the submission is administratively complete to allow the submission to be accepted or to request missing checklist items interactively from submitters during the RTA review.
- Each element on the checklist should be addressed within the submission. The submitter may provide a rationale for omission for any criteria that are deemed not applicable. If a rationale is provided, the criterion is considered present (Yes). An assessment of the rationale will be considered during the review of the submission.

Elements of a Complete Submission (RTA Items)
(21 CFR 807.87 unless otherwise indicated)
Submission should be designated RTA if not addressed

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. *Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.				Yes	No	N/A	*Page #
A.	**Administrative**						
	1.	All content used to support the submission is written in English (including translations of test reports, literature articles, etc.).		✓			
		Comments:					
	2.	Submission identifies the following (FDA recommends use of the CDRH Premarket Review Submission Cover Sheet form [Form 3514]):		✓			6-10
		a.	Device trade/proprietary name	✓			
		b.	Device class and panel or Classificati on regulation or Statement that device has not been classified with rationale for that conclusion	✓			
		Comments:					
	3.	Submission contains an Indication for Use Statement with Rx and/or OTC designated (see also 21 CFR 801.109, and FDA's guidance "Alternative to Certain Prescription Devices Labeling Requirements.") *See recommended format (http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM360431.pdf).*		✓			58

		Comments:				
	4.	Submission contains a 510(k) Summary or 510(k) Statement. *Refer to 21 CFR 807.92 and 21 CFR 807.93 for contents of 510(k) Summary and Statement, respectively. Adequacy of the content will be assessed during substantive review.*	✓			60-63
		Comments:				
	5.	Submission contains a Truthful and Accuracy Statement per 21 CFR 807.87(k). *See recommended format (http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm142707.htm).*	✓			64
		Comments:				

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. ***Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.**				**Yes**	**No**	**N/A**	***Page #**
	6.	Submission is a Class III 510(k) Device. *Select "N/A" only if submission is not a Class III 510(k).*				✓	
		a.	Contains Class III Summary and Certification *See recommended content (http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/PremarketNotification510k/ucm142662.htm). Select "N/A" only if submission is not a Class III 510(k).*				
		Comments:	The submission is not a class III 510(k)				
	7.	Submission contains clinical data. *Select "N/A" if the submission does not contain clinical data. If "N/A"is selected, parts a and b below are omitted from the checklist.*				✓	
		a.	Submission includes completed Financial Certification (FDA Form 3454) or Disclosure (FDA Form 3455) information for each covered clinical study included in the submission. *Select "N/A" if the submitted clinical data is not a "covered clinical study" as defined in the Guidance for Industry- Financial Disclosures by Clinical Investigators.*		✓		

		b.	Submission includes completed Certification of Compliance with requirements of ClinicalTrials.gov Data Bank (FDA Form 3674) (42 U.S.C. 282(j)(5)(B)) for each applicable device clinical trial included in the submission. *Select "N/A" if the submitted clinical data is not an "applicable device clinical trial" as defined in Title VIII of FDAAA, Sec. 801(j)*		✓		
		Comments:					
	8.	The submission identifies prior submissions for the same device included in the current submission (e.g., submission numbers for a prior not substantially equivalent [NSE] determination, prior deleted or withdrawn 510(k), Pre-Submission, IDE, PMA, etc.). **OR** States that there were no prior submissions for the subject device. *Prior submissions (or no prior submissions) for this device should be included in Section F (prior related submissions) of the CDRH Premarket Review Submission Cover Sheet form (Form 3514).*	✓			8

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. ***Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.**				**Yes**	**No**	**N/A**	***Page #**
		This information may also be included in the Cover Letter (i.e., as a statement that there were no prior submissions for the device or a listing of the number(s) of the prior submissions).					
		a.	If there were prior submissions, the submitter has identified where in the current submission any issues related to a determination of substantial equivalence from prior submissions for this device are addressed. *To address this criterion, it is recommended that the submission include a separate section with the prior submission number(s), a copy of the FDA feedback (e.g., letter, meeting minutes), and a statement of how or where in the submission this prior feedback was addressed. Note that adequacy of how the feedback was addressed will be assessed during the substantive review.* *Select "N/A" if the submitter states there were no prior submissions.*			✓	
		Comments:					
B.	**Device Description**						87-114
	9.	The device has a device-specific guidance document, special controls document, and/or requirements in a device-specific regulation regarding device description that is applicable to the subject device. *If "N/A"is selected, parts a and b below are omitted from the checklist.*		✓			87-114

		a.	The submission addresses device description recommendations outlined in the device-specific guidance. **OR** The submission provides an alternative approach intended to address the applicable statutory and/or regulatory criteria. *Select "N/A" if there is no applicable device-specific guidance. Select "No" if the submission does not include a rationale for any omitted information or any alternative approach as outlined above. Note that the adequacy of how recommendations in a device-specific guidance, etc., have been addressed should be assessed during the substantive review.*	✓			102-105

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. *Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.				Yes	No	N/A	*Page #
		b.	The submission includes device description information that addresses relevant mitigation measures set forth in a special controls document or device-specific regulation applicable to the device. **OR** The submission uses alternative mitigation measures and provides rationale why the alternative measures provide an equivalent assurance of safety and effectiveness. *Select "N/A" if there is no applicable special controls document or device-specific regulation. Select "No" if the submission does not include a rationale for any omitted information or any alternative approach as outlined above. Note that the adequacy of how such mitigation measures have been addressed should be assessed during the substantive review.*			✓	
		Comments:					
	10.	Descriptive information is present and consistent within the submission (e.g., the device description section is consistent with the device description in the labeling).		✓			87-114 157-202
		Comments:					
	11.	The submission includes descriptive information for the device, including the following:		✓			
		a.	A description of the principle of operation or mechanism of action for achieving the intended effect.	✓			97-105 175-180

		b.	A description of proposed conditions of use, such as surgical technique for implants; anatomical location of use; user interface; how the device interacts with other devices; and/or how the device interacts with the patient.	✓			175-180
		c.	A list and description of each device for which clearance is requested. *Select "N/A" if there is only one device or model. "Device" may refer to models, part numbers, various sizes, etc.*			✓	
		d.	Submission contains representative engineering drawing(s), schematics, illustrations, photos and/or figures of the device. **OR**	✓			112-114
			Submission includes a statement that engineering drawings, schematics, etc. are not applicable to the device (e.g., device is a reagent and figures are not pertinent to describe the device). *In lieu of engineering drawings, schematics, etc. of each device to be marketed, "representative" drawings, etc. may be provided, where "representative" is intended to mean that the drawings, etc. provided capture the differences in design, size, and other important characteristics of the various models, sizes, or versions of the device(s) to be marketed.*			✓	
		Comments:					
	12.	Device is intended to be marketed with multiple components, accessories, and/or as part of a system. *Select "N/A" if the device is not intended to be marketed with multiple components, accessories, and/or as part of a system. If "N/A" is selected, parts a-c below are omitted from the checklist.*				✓	

		a.	Submission includes a list of all components and accessories to be marketed with the subject device.			✓	
		b.	Submission includes a description (as detailed in item 11a., 11b., and 11d. above) of each component or accessory. *Select "N/A" if the component(s)/accessory(ies) has been previously cleared, or is exempt, and the proposed indications for use are consistent with the cleared indications.*			✓	
		c.	A 510(k) number is provided for each component or accessory that received a prior 510(k) clearance **AND** A statement is provided that identifies components or accessories that have not received prior 510(k) clearance.			✓	
		Comments:					
C.	**Substantial Equivalence Discussion**						116-153
	13.	Submitter has identified a predicate device(s), including the following information:		✓			116-153
		a.	Predicate device identifier provided (e.g., 510(k) number, de	✓			145-153

			novo number, reclassified PMA number, regulation number if exempt or statement that the predicate is a preamendment device). For predicates that are preamendments devices, information is provided to document preamendments status. *Information regarding documenting preamendment status is available online (http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/MedicalDeviceQualityandCompliance/ucm379552.ht m).*				

		b.	The identified predicate(s) is consistent throughout the submission (e.g., the predicate(s) identified in the Substantial Equivalence section is the same as that listed in the 510(k) Summary (if applicable) and that used in comparative performance testing.	✓			116-153 62-63 882-954
		Comments:					
	14.	Submission includes a comparison of the following for the predicate(s) and subject device and a discussion why any differences between the subject and predicate(s) do not impact safety and effectiveness [see section 513(i)(1)(A) of the FD&C Act and 21 CFR 807.87(f)] *See "The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)]" guidance document for more information on comparing intended use and technological characteristics.*		✓			116-153
		a.	Indications for use *If there are no differences between the subject device and the predicate(s) with respect to indications and intended use, this should be explicitly stated.*	✓			123
		b.	Technology, including features, materials, and principles of operation *Examples of technological characteristics include, but are not limited to design, features, materials, energy source, and principle of operation.* *FDA recommends a tabular format for comparing technological characteristics. Any characteristic that is the*	✓			123-129

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. ***Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.**				**Yes**	**No**	**N/A**	***Page #**
			same as the predicate(s) should be explicitly stated. Differences in technological characteristics should be identified and a rationale provided why they do not raise different questions of safety and effectiveness.				
		Comments:					
D.	**Proposed Labeling (see also 21 CFR parts 801 and 809 as applicable)**						155-202
	15.	Submission includes proposed package labels and labeling (e.g., instructions for use, package insert, operator's manual).		✓			155-196
		a.	Indications for use are stated in labeling and are identical to Indications for Use form and 510(k) Summary (if 510(k) Summary provided)	✓			182
		b.	Labeling includes: - Statements of conditions, purposes or uses for which the device is intended (e.g., hazards, warnings, precautions, contraindications) (21 CFR 801.5) **AND** - Includes adequate directions for use (see 21 CFR 801.5) **OR** - Submission states that	✓			182-188

			device qualifies for exemption per 21 CFR 801 Subpart D				
		Comments:					
	16.	Labeling includes name and place of business of the manufacturer, packer, or distributor (21 CFR 801.1)		✓			158
		Comments:					
	17.	Labeling includes the prescription statement (see 21 CFR 801.109(b)(1)) or Rx Only symbol (see also Section 502(a) of the FD&C Act and FDA's guidance "Alternative to Certain Prescription Device Labeling Requirements"). *Select "N/A" if not indicated for prescription use.*		✓			58, 162, 168-170, 198-199
		Comments:					

	18.	The device has a device-specific guidance document, special controls document, and/or requirements in a device-specific regulation regarding labeling that is applicable to the subject device. *If "N/A"is selected, parts a and b below are omitted from the checklist.*			✓	

		a.	The submission addresses labeling recommendations outlined in the device-specific guidance. **OR** The submission provides an alternative approach intended to address the applicable statutory and/or regulatory criteria. *Select "N/A" if there is no applicable device-specific guidance. Select "No" if the submission does not include a rationale for any omitted information or any alternative approach as outlined above. Note that the adequacy of how recommendations in a device-specific guidance, etc., have been addressed should be assessed during the substantive review.*			✓	
		b.	The submission includes labeling information that addresses relevant mitigation measures set forth in a special controls document or device-specific regulation applicable to the device. **OR** The submission uses alternative mitigation measures and provides rationale why the alternative measures provide an equivalent assurance of safety and effectiveness. *Select "N/A" if there is no applicable special controls document or device-specific regulation. Select "No" if the submission does not include a rationale for any omitted information or any alternative approach as outlined above. Note that the adequacy of how such mitigation measures have been addressed should be assessed during the substantive review.*			✓	

		Comments:				
	19.	If the device is an in vitro diagnostic device, provided labeling includes all applicable information required per 21 CFR 809.10. Select "N/A" if not an in vitro diagnostic device.			✓	

		Comment:				
E.	**Sterilization** *If an in vitro diagnostic (IVD) device and sterilization is not applicable, select "N/A." The criteria in this section will be omitted from the checklist if "N/A" is selected.*				✓	
	Submission states that the device, and/or accessories, and/or components are: (*one of the below must be checked*) ☐ Provided sterile, intended to be single-use ☐ Requires processing during its use-life ☒ Non-sterile when used (and no processing required) Information regarding the sterility status of the device is not provided (if this box is checked, please also check one of the two boxes below) ☐ Sterility status not needed for this device (e.g., software-only device) ☐ Sterility status needed or need unclear This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination. *If "non-sterile when used" or "not provided and not needed" is selected, the sterility-related criteria below are omitted from the checklist. If information on sterility status is not provided, and it is needed or the need for this information is unclear, select "No."* *The "Requires processing during its use-life" option refers to devices falling into one of the four categories below:* • *Supplied sterile and requires reprocessing prior to subsequent patient use* • *Supplied non-sterile and requires user to process the device for initial use, as well*		✓			

	as to reprocess the device after each use • *Reusable medical device (single-user) reprocessed between eachuse* • *Single-use medical devices initially supplied as non-sterile to the user, and requiring the user to process the device prior to its use* *Please refer to the guidance document titled "Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling" for additional information.*					
	Comments:					
	20.	Assessment of the need for cleaning and subsequent disinfection				

			or sterilization information.				✓	
			a.	Identification of device, and/or accessories, and/or components that are provided sterile. *Select "N/A" if no part of the device, accessories, or components is provided sterile.*			✓	

			b.	Identification of device, and/or accessories, and/or components that are end user sterilized or disinfected. *Select "N/A" if no part of the device, accessories, or components is end user sterilized or disinfected.*			✓	
			c.	Identification of device, and/or accessories, and/or components that are reusable. *Select "N/A" if no part of the device, accessories, or components is reusable.*			✓	
			Comments:					
		21.	If the device, and/or accessory, and/or a component is provided sterile: *Select "N/A" if no part of the device, accessories, or components is provided sterile, otherwise complete a-f below.*			✓		
			a.	Sterilization method is stated for each component (including dose for radiation sterilization)			✓	
			b.	A description of method to validate the sterilization parameters is provided for each proposed sterilization method (e.g., half-cycle method and full citation of FDA- recognized standard, including date). *Note: the sterilization validation report is not required.*			✓	

			c.	For devices sterilized using chemical sterilants such as ethylene oxide (EO) and hydrogen peroxide, submission states maximum levels of sterilant residuals remaining on the device and sterilant residual limits. *Select "N/A" if not sterilized using chemical sterilants.*			✓	
			d.	Sterility Assurance Level (SAL) stated			✓	
			e.	Submission includes description of packaging			✓	
			f.	For products labeled "non-pyrogenic," a description of the method used to make the determination stated (e.g., limulus amebocyte lysate [LAL]). *Select "N/A" if not labeled "non-pyrogenic."*			✓	
		Comments: Disinfection Process Validation Protocol and report						
	22.	If the device, and/or accessory, and/or a component is reusable or end user sterilized or disinfected: *Select "N/A" if no part of the device, accessories, or components are reusable or end user sterilized or disinfected, otherwise complete a-d below.*				✓		
		a.	Cleaning method is provided in labeling for each device, and/or accessory, and/or component. *Select "N/A" if not reusable and does not need cleaning prior to disinfection or sterilization*				✓	

		b.	Disinfection method is provided in labeling for each device, and/or accessory, and/or component. *Select "N/A" if not disinfected (i.e., undergoes terminal sterilization) prior to use*			✓	
		c.	Sterilization method is provided in labeling for each device and/or accessory, and/or component. *Select "N/A" if not sterilized (i.e., undergoes disinfection) prior to use*			✓	
		d.	Device types in this submission are listed in Appendix E of the FDA's guidance "Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling." *Device types identified in Appendix E of the reprocessing guidance represent devices posing a greater likelihood of microbial transmission and represent a high risk of infection. Select "N/A" if the device type in the submission is not included in Appendix E of the reprocessing guidance.*			✓	
			i. If device types in this submission are included in Appendix E of the reprocessing guidance, the submission includes protocols and test reports for validating the reprocessing instructions. *Select "N/A" if the device type in the submission is not included in Appendix E of the reprocessing guidance.*				
		Comments:					

	23.	The device has a device-specific guidance document, special controls document, and/or requirement in a device-specific regulation regarding sterility and/or reprocessing that is applicable to the subject device *If "N/A"is selected, parts a and b below are omitted from the checklist.*				✓	
		a.	The submission addresses sterility and/or reprocessing recommendations outlined in the device-specific guidance. **OR** The submission provides an alternative approach intended to address the applicable statutory and/or regulatory criteria. *Select "N/A" if there is no applicable device-specific guidance. Select "No" if the submission does not include a rationale for any omitted information or any alternative approach as outlined above. Note that the adequacy of how recommendations in a device-specific guidance, etc., have been addressed should be assessed during the substantive review.*			✓	
		b.	The submission includes sterility and/or reprocessing information that addresses relevant mitigation measures set forth in a special controls document or device-specific regulation applicable to the device. **OR** The submission uses alternative mitigation measures and provides rationale why the alternative measures provide an equivalent assurance of safety and effectiveness. *Select "N/A" if there is no applicable special controls document or device-specific regulation. Select "No" if the*			✓	

			submission does not include a rationale for any omitted information or any alternative approach as outlined above. Note that the adequacy of how such mitigation measures have been addressed should be assessed during the substantive review.				
		Comments:					
F.	**Shelf-Life**						204-205
	24.	Proposed shelf life/ expiration date stated		✓			204-205
		OR Statement that shelf-life is not applicable because of low likelihood of time-dependent product degradation					
		Comments: same as predicate					
	25.	For a sterile device, submission includes summary of methods used to establish that device packaging will maintain a sterile barrier for the entirety of the proposed shelf-life. *Select "N/A" if the device is not provided sterile.*		✓			204-205
		Comments:					
	26.	Submission includes summary of methods used to establish that device performance is maintained for the entirety of the proposed shelf-life (e.g., mechanical properties, coating integrity, pH, osmolality, etc.). **OR** Statement why performance data is not needed to establish maintenance of device performance characteristics over the shelf-life period.				✓	

	Comments:				
G.	**Biocompatibility** *If an in vitro diagnostic (IVD) device, select "N/A." The criteria in this section will be omitted from the checklist if "N/A" is selected.*	✓			207-208
	Submission states that there: (*one of the below must be checked*) x Are direct or indirect patient-contacting components Are no direct or indirect patient-contacting components Information regarding patient contact status of the device is not provided (if this box checked, please also check one of the two boxes below) ☐ Patient contact information not needed for this device (e.g., software- only device) ☐ Patient contact information is needed or need unclear This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination. *If "are no" or "not provided and not needed" is selected, the biocompatibility-*		✓		
	related criteria below are omitted from the checklist. If information on the patient-contact status is not provided, and contact information is needed or its contact status is unclear, select "No." *An example of a direct patient-contacting device would be an implant that has direct contact with patient tissues during use. An example of an indirect patient-contacting device would be fluid entering the patient's body following passing through device/device components not in direct contact with the patient.*				
	Comments:				

	27.	Submission includes a list identifying each patient-contacting device component (e.g., implant, delivery catheter) and associated materials of construction for each component, including identification of color additives, if present.	✓			207-208
		Comments:				
	28.	Submission identifies contact classification (e.g., surface-contacting, less than 24 hour duration) for each patient-contacting device component (e.g., implant, delivery catheter).	✓			207-208
		Comments:				
	29.	Biocompatibility assessment of patient-contacting components Submission includes: Test protocol (including identification and description of test article), methods, pass/fail criteria, and results provided for each completed test. **OR** A statement that biocompatibility testing is not needed with a rationale (e.g., materials and manufacturing/processing are identical to the predicate).	✓			207-208
		Comments:				
H.	**Software**					210-551
	Submission states that the device: (*one of the below must be checked*) x Does contain software/firmware			✓		

		Information on whether device contains software/firmware is not provided (if this box checked, please also check one of the two boxes below) ☐ Software/firmware information not needed for this device (e.g., surgical suture, condom) Software/firmware information is needed or need unclear This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination. *If "does not contain" or "not provided and not needed" is selected, the software-related criteria below are omitted from the checklist. If information on software is not provided, and this information is needed or the need is unclear, select "No."*				
	Comments:					
	30.	Submission includes a statement of software level of concern and rationale for the software level of concern	✓			245-246
		Comments:				
	31.	All applicable software documentation provided based on level of concern identified by the submitter, as described in Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices, or the submission includes information to establish that the submitter has otherwise met the applicable statutory or regulatory criteria through an alternative approach (i.e., the submitter has identified an alternate approach with a rationale). *Note: This element is also applicable to non-internally generated or off-the-shelf (OTS) software used in the device.*	✓			216-551
		Comments:				
I.	**Electrical Safety and EMC**					553-880

	Electrical Safety: Submission states that the device: (one of the below must be checked) xDoes require electrical safety evaluation Information on whether device requires electrical safety evaluation not	✓		553

	provided (if this box checked, please also check one of the two boxes below) ☐ Electrical safety information not needed for this device (e.g., surgical suture, condom) ☐ Electrical safety information needed or need unclear This information will determine whether and what type of additional information may be necessary for a substantial equivalence determination. *If "does not require" or "not provided and not needed" is selected, the electrical safety criteria below are omitted from the checklist. If information on electrical safety is not provided, and it is needed or the need for this information is unclear, select "No."*				
	Comments:				
	32. Submission includes evaluation of electrical safety (e.g., per IEC 60601-1, or equivalent FDA-recognized standard, and if applicable, a device-specific standard). **OR** Submission includes electrical safety evaluation using methods or standards that are not FDA-recognized and submission includes information to establish that the submitter has otherwise met the applicable statutory or regulatory criteria through this alternative approach (i.e., the submitter has identified alternate methods or standards with a rationale).	✓			555-706
	Comments:				

	EMC: Submission states that the device: (*one of the below must be checked*) x Does require EMC evaluation Information on whether device requires EMC evaluation not provided (if this box checked, please also check one of the two boxes below) ☐ EMC information not needed for this device (e.g., surgical suture, condom) ☐ EMC information needed or need unclear This information will determine whether and what type of additional	✓		553

	information may be necessary for a substantial equivalence determination. *If "does not require" or "not provided and not needed" is selected, the EMC criteria below are omitted from the checklist. If information on EMC is not provided, and it is needed or the need for this information is unclear, select "No."*				
	Comments:				
	33. Submission includes evaluation of electromagnetic compatibility (e.g., per IEC 60601-1-2 or equivalent FDA- recognized standard and if applicable, a device-specific standard). **OR** Submission includes electromagnetic compatibility evaluation using methods or standards that are not FDA-recognized and submission includes information to establish that the submitter has otherwise met the applicable statutory or regulatory criteria through this alternative approach (i.e., the submitter has identified alternate methods or standards with a rationale).	✓			708-831
	Comments:				
J.	**Performance Data General** *If an in vitro diagnostic (IVD) device, select "N/A." The criteria in this section will be omitted from the checklist if "N/A" is selected.* *Performance data criteria relating to IVD*	✓			882-954

	devices is addressed in Section K.						
	Comments:						
	34.	Full test report is provided for each completed test. A full test report includes: objective of the test, description of the test methods and procedures, study endpoint(s), pre-defined pass/fail criteria, results summary, conclusions. *Full test reports provided for all completed tests/evaluations (e.g., bench evaluations, comparative performance tests, etc.). Select "N/A" if the submission does not include performance data.*	✓			914-954
		a.	Submission includes an explanation of how the data generated from each test report supports a finding of substantial equivalence (e.g., comparison to predicate device testing, dimensional analysis, etc.). *Select "N/A" if the submission does not include performance*	✓			882-954

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. ***Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.**				**Yes**	**No**	**N/A**	***Page #**
			data.				
		Comments:					
	35.	The device has a device-specific guidance document, special controls document, and/or requirement in a device-specific regulation regarding performance data that is applicable to the subject device *If "N/A"is selected, parts a and b below are omitted from the checklist.*		✓			882-945
		a.	The submission addresses performance data recommendations outlined in the device-specific guidance. **OR** The submission provides an alternative approach intended to address the applicable statutory and/or regulatory criteria. *Select "N/A" if there is no applicable device-specific guidance. Select "No" if the submission does not include a rationale for any omitted information or any alternative approach as outlined above. Note that the adequacy of how recommendations in a device-specific guidance, etc., have been addressed should be assessed during the substantive review.*	✓			882-945

		b.	The submission includes performance data that addresses relevant mitigation measures set forth in a special controls document or device-specific regulation applicable to the device. **OR** The submission uses alternative mitigation measures and provides rationale why the alternative measures provide an equivalent assurance of safety and effectiveness. *Select "N/A" if there is no applicable special controls document or device-specific regulation. Select "No" if the submission does not include a rationale for any omitted information or any alternative approach as outlined above. Note that the adequacy of how such mitigation measures have been addressed should be assessed during the substantive review.*		✓		
		Comments:					

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. ***Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.**				**Yes**	**No**	**N/A**	***Page #**
	36.	If literature is referenced in the submission, submission includes: *Select "N/A" if the submission does not reference literature. If "N/A"is selected, parts a and b below are omitted from the checklist.* *Note that the applicability of the referenced article to support a substantial equivalence finding should be assessed during the substantive review; only the presence of a discussion is required to support acceptance.*				✓	
		a.	Legible reprints or a summary of each article.			✓	
		b.	Discussion of how each article is applicable to support the substantial equivalence of the subject device to the predicate.			✓	
		Comments:					
	37.	For each completed animal study, the submission provides the following: *Select "N/A" if no animal study was conducted. If "N/A"is selected, parts a-c below are omitted from the checklist. Note that this section does not address biocompatibility evaluations, which are assessed in Section G of the checklist.*				✓	
		a.	Submission includes a study protocol which includes all elements as outlined in 21 CFR 58.120			✓	
		b.	Submission includes final study report which includes all elements outlined in 21 CFR 58.185			✓	

		c.	Submission contains a statement that the study was conducted in compliance with applicable requirements in the GLP regulation (21 CFR Part 58), or, if the study was not conducted in compliance with the GLP regulation, the submission explains why the noncompliance would not impact the validity of the study data provided to support a substantial equivalence determination.			✓	
		Comments:					
K.	**Performance Characteristics – In Vitro Diagnostic Devices Only (see also 21 CFR 809.10(b)(12))**					✓	
	Submission indicates that device: (*one of the below must be checked*) ☐ Is an in vitro diagnostic device						

Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. ***Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.**				**Yes**	**No**	**N/A**	***Page #**
	Is not an in vitro diagnostic device *If "is not" is selected, the performance data-related criteria below are omitted from the checklist.*					✓	
	38.	Submission includes the following studies, as appropriate for the device type, including associated protocol descriptions, study results and line data:				✓	
		a.	Precision/reproducibility			✓	
		b.	Accuracy (includes as appropriate linearity; calibrator or assay traceability; calibrator and/or assay stability protocol and acceptance criteria; assay cut-off; method comparison or comparison to clinical outcome; matrix comparison; and clinical reference range or cutoff.			✓	
		c.	Sensitivity (detection limits, LoB, LoD, LoQ where relevant for the device type).			✓	
		d.	Analytical specificity			✓	
		Comments:					
	39.	The device has a device-specific guidance document, special controls document, and/or requirement in a device-specific regulations regarding performance data that is applicable to the subject device. *If "N/A"is selected, parts a and b below are omitted from the checklist.*				✓	

		a.	The submission addresses performance data recommendations outlined in the device-specific guidance. **OR** The submission provides an alternative approach intended to address the applicable statutory and/or regulatory criteria. *Select "N/A" if there is no applicable device-specific guidance. Select "No" if the submission does not include a rationale for any omitted information or any alternative approach as outlined above. Note that the adequacy of how recommendations in a device-specific guidance, etc., have been addressed should be assessed during the substantive review.*			✓	
		b.	The submission includes performance data that addresses				

			Check "Yes" if item is present, "N/A" if it is not needed and "No" if it is not included but needed. ***Submitters including the checklist with their submission should identify the page numbers where requested information is located. Use the comments section for an element if additional space is needed to identify the location of supporting information.**	**Yes**	**No**	**N/A**	***Page #**
			relevant mitigation measures set forth in a special controls document or device-specific regulation applicable to the device. **OR** The submission uses alternative mitigation measures and provides rationale why the alternative measures provide an equivalent assurance of safety and effectiveness. *Select "N/A" if there is no applicable special controls document or device-specific regulation. Select "No" if the submission does not include a rationale for any omitted information or any alternative approach as outlined above. Note that the adequacy of how such mitigation measures have been addressed should be assessed during the substantive review.*			✓	
		Comments					

Section 4:

Indications for Use Statement
(Form FDA 3881)

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

(b)(4)

Section 5:

510(k) Summary

510(K) SUMMARY

(b)(4)

(b)(4)

(b)(4)

(b)(4)

Section 6:

Truthful and Accuracy Statement

INMODE

Premarket Notification Truthful and Accuracy Statement

[As Required by 21 CFR 807.87(k)]

I certify that, in my capacity as CEO of InMode MD Ltd., I believe to the best of my knowledge, that all data and information submitted in the premarket notification are truthful and accurate and that no material fact has been omitted.

(b)(6)

(Signature)

Moshe Mizrahy, CEO

(Typed Name)

April 02, 2020

(Date)

Section 7:

Class III Summary and Certifications

Not Applicable

Section 8:

Financial Certifications or Disclosure Statements

Not Applicable

Section 9.0:

Declaration of Conformity with Standards

9.1 Declaration of Conformity to Recognized Standards

The InMode System with the Morpheus8 Applicators complies with the following FDA 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 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

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. Protocols and test reports for these tests are provided in section 17 of this 510(k) file submission.

A Declaration of Conformity (DOC) to FDA Recognized Consensus Standards is attached to this section in Appendix 9-1. The DOC is sponsor attestation that the subject device of this 510(k) file submission conforms to all of the requirements of the DOC specified FDA recognized consensus standard at the time of submission, in accordance to the FDA Guidance: "Appropriate Use of Voluntary Consensus Standards in Premarket Submissions for Medical Devices" issued on September 14, 2018 and section 514(c)(1)(B) of the FD&C Act.

APPENDIX 9-1

DECLARATION OF CONFORMITY TO FDA RECOGNIZED CONSENSUS STANDARDS

INMODE

Tavor building, POB 533
Yokneam 2069206, ISRAEL
Tel: +972(4)9097470
Fax: +972(4)9097471

Declaration of Conformity to Recognized Standards

I certify that, in my capacity as CEO of InMode Ltd., that the subject of this Traditional 510(k), the InMode RF Multi-System, conforms with the following FDA-recognized 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 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

All requirements were met, alternative series of tests were not performed, all requirements were applicable to the device, no deviations from each applicable standard were applied, and there were no differences between the tested device and the device to be marketed. All tests were performed by The Standards Institution of Israel, 42 Chaim Levanon St. Tel Aviv, Israel.

Signed: Mr. Moshe Mizrahy Date: March 31st, 2020

(b)(6)

Address:
Tavor Building, Shaar Yokneam
POB 533, Yokneam 2069206
Israel

Section 10:

Executive Summary

10.0 EXECUTIVE SUMMARY

10.1 Device Description

The InMode System with the Morpheus8 Applicators is based on FDA-Cleared Fractional RF system and the subject of K192695. It consists of the system platform, applicator handle, designated cable with connection ports to system platform and a single-use, sterile, 12, 24, 40 pin and T tip heads. The subject device and FDA-Cleared Morpheus8 Applicators (K192695) have identical indications for use but slightly different specifications. The change in specifications focuses on the maximal 24 and 40 pin tip microneedles penetration depth, which is controlled by the software. While the Morpheus8 Applicators (K192695) were previously limited to a penetration depth of 4mm, the current software update enables the Morpheus8 24 and 40 pin tips, which are basically the same tips, a penetration depth variety ranging between **(b)(4)** for the 24 tip head and **(b)(4)** for the 40 tip head. No mechanical or hardware modifications were performed on the device to support this change. The software and user interface were merely adjusted to fit this change.

The InMode System with the Morpheus8 Applicators employs fractional RF multi-electrode technology for dermatological and general surgical procedures requiring electrocoagulation and hemostasis. It is designed to deliver radiofrequency energy to the target tissue in a fractional manner, via an array of 12, 24 or 40 pin electrodes arranged on a detachable sterilized disposable tip. The pin array delivers RF energy to the tissue, resulting in heating of surrounding tissue around the electrodes contact, to temperatures leading to electrocoagulation and hemostasis of micro tissue zones.

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(b)(4)

The InMode System is depicted in *Figure 10.1* below.

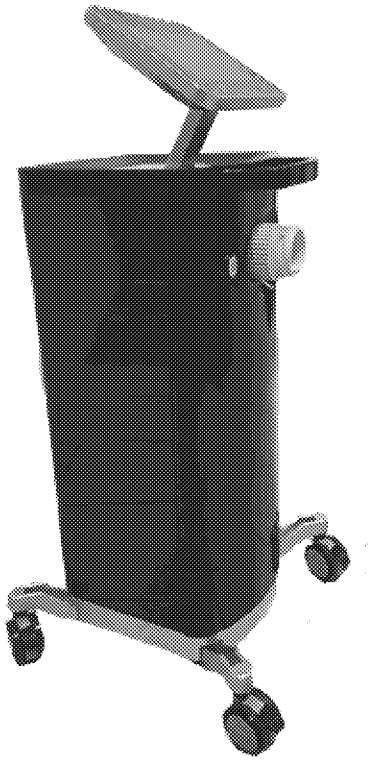

Figure 10.1: InMode System

The InMode System with the Morpheus8 Applicators (InMode Ltd.) is a computerized system generating RF energy, based on the underlying technology of Fractional RF. The system platform includes a power supply unit, an RF generator (RF output frequency; 1MHz, maximal power of 65W and energy controlled by RF pulse width), controller, footswitch pedal and LCD screen with touch panel. These modules are used for generating pulses of RF energy that heats the micro tissue zones to create fractional tissue coagulation.

The Morpheus8 Applicator comprises handle and detachable, sterilized, disposable, single use 12, 24, 40 pin and T tip head accessories. The applicator handle is made of plastic and has an ergonomic design for easy treatment with high visibility of the treated area. The applicator has a cable that is 270cm long and connects the applicator to the console via a connector. The applicator body design with adjustable tip head is shown in *Figure 10.2*.

Figure 10.2: Morpheus8 Applicator with tip

(b)(4)

10.2 Intended Use

(b)(4)

10.3 Comparison to Predicate Devices

The InMode System with the Morpheus8 Applicators is a fractional RF treatment modality based on the FDA-Cleared InMode System and Morpheus8 Applicators all FDA Cleared in 510(k) K192695 as a predicate device.

A comparison table is provided below comparing the intended use and basic technological characteristics of the InMode System with the subject device to the intended use and basic technological characteristics of the predicate device.

Comparison Table

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(b)(4)

The indications for use and technological characteristics of the InMode System with the Morpheus8 Applicators are substantially equivalent to the indications for use and technological characteristics of the InMode System with the Morpheus8 Applicators FDA-Cleared in K192695.

Both the subject and predicate devices utilize the InMode System platform for generating the Fractional RF energy and for general system control. Moreover, both systems utilize the same Morpheus8 set of Applicators (FDA Cleared in K192695) which supports the application and utilization of the 12, 24, 40 and T tip heads.

The only difference between the subject device and the predicate device is in the 24 and 40 tip head microneedles maximum penetration depth. While in the predicate device the maximal allowed penetration depth for the 24 and 40 tip heads was limited to 4mm, with the subject device this was extended for up to 7mm. The same mechanism of operation and the same mechanism of action is applied by both the subject and predicate device. The same performance specifications are used. The only change made was in the device software that controls the microneedles penetration depth.

The hardware components and underlying RF technology of the subject and predicate devices are identical.

In similar manner to the predicate device, the subject device system platform consists of RF generator, controller and user interface and perform identical functions of RF power delivery under similar performance specifications.

The safety features and compliance with safety standards in the InMode System with Morpheus8 Applicators are similar to the safety features and compliance with safety standards found in the predicate device.

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(b)(4)

Furthermore, the new InMode System with the Morpheus8 Applicators 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 comparative bench testing.

In order to ensure that the subject device performs safely and effectively on target tissues to achieve its intended use of electrocoagulation and hemostasis in deeper tissues of up to 5, 6 and 7 mm an *ex-vivo* tissue study was performed by the sponsor. The purpose of the *ex-vivo* test was to evaluate and compare the fractional coagulation necrosis pattern of target tissues, formed by thermal effect of the InMode System with the Morpheus8 Applicators 24 and 40 pin tip heads in different tissue depths. (b)(4)

(b)(4)

(b)(4) The results clearly proof that the device thermal effect on target tissue has the same effect regardless to the needles penetration depth and therefore the device can be safely and effectively used with the applied energy outputs and according to its intended use in a similar manner to its predicate device (K192695)

and in penetration depths of 5, 6, and 7 mm in addition to the already FDA cleared penetration depths (up to 4 mm).

Consequently, it can be concluded that the InMode System with the Morpheus8 Applicators is substantially equivalent to the predicate InMode System with the Morpheus8 Applicators, FDA-Cleared under 510(k) K192695, and therefore, may be legally marketed in the USA.

10.4 Description of performance and safety aspects

The InMode System with the Morpheus8 Applicators have been tested and complies with the following voluntary recognized 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 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

Performance bench tests were performed to measure the accuracy and consistency of the RF output parameters of the InMode System and compare them to the specific design requirements and to the RF output parameters of the predicate device. The results of the bench tests demonstrate that the InMode System complies with the design requirements and consists of similar RF output specifications as the predicate devices and therefore, is substantially equivalent to the predicate devices.

The performance and safety of the InMode System with the Morpheus8 Applicators treatment in dermatological procedures requiring electrocoagulation and hemostasis in deeper tissues of up to 5, 6 and 7 mm was evaluated in an *ex-vivo* tissue study. The study was conducted on a porcine animal model and included a single treatment of two different harvested porcine tissues: muscle and fat utilizing the InMode System

with the Morpheus8 applicator 40 pin tip head in its final, finished version. Treatment was followed by biopsy sampling of slices trimmed along the pin's penetration path and collection immediately stained by TTC staining to visualize the tissue coagulation necrosis pattern. The *ex-vivo* study results show that the InMode System with the Morpheus8 Applicators is safe for use and effective in achieving the specified indications of dermatological and general electrocoagulation and hemostasis, regardless to the needles penetration depth. Therefore, the device can be safely and effectively used with the applied energy outputs and according to its intended use in a similar manner to its predicate device (K192695) and in penetration depths of 5, 6, and 7 mm in addition to the already FDA cleared penetration depths (up to 4 mm).

Section 11:

Device Description

TABLE OF CONTENT

DEVICE INFORMATION

11.0 Introduction

The InMode System with the Morpheus8 Applicators is based on FDA-Cleared Fractional RF system and the subject of K192695. It consists of the system platform, applicator handle, designated cable with connection ports to system platform and a single-use, sterile, 12, 24, 40 pin and T tip heads. The subject device and FDA-Cleared Morpheus8 Applicators (K192695) have identical indications for use but slightly different specifications. The change in specifications focuses on the maximal 24 and 40 pin tip microneedles penetration depth, which is controlled by the software. While the Morpheus8 Applicators (K192695) were previously limited to a penetration depth of 4mm, the current software update enables the Morpheus8 24 and 40 pin tips, which are basically the same tips, a penetration depth variety ranging between 1-7 mm for the 24 tip head and 2-7 mm for the 40 tip head. No mechanical or hardware modifications were performed on the device to support this change. The software and user interface were merely adjusted to fit this change.

The InMode System with the Morpheus8 Applicators employs fractional RF multi-electrode technology for dermatological and general surgical procedures requiring electrocoagulation and hemostasis. It is designed to deliver radiofrequency energy to the target tissue in a fractional manner, via an array of 12, 24 or 40 pin electrodes arranged on a detachable sterilized disposable tip. The pin array delivers RF energy to the tissue, resulting in heating of surrounding tissue around the electrodes contact, to temperatures leading to electrocoagulation and hemostasis of micro tissue zones.

(b)(4)

(b)(4)

The following device description section will present in details the InMode platform system and the Morpheus8 Applicators.

11.1 Device Description

The InMode System with the Morpheus8 Applicators (InMode Ltd.) is a computerized system generating RF energy, based on the underlying technology of Fractional RF. The system platform includes a power supply unit, an RF generator (RF output frequency; 1MHz, maximal power of 65W and energy controlled by RF pulse width), controller, footswitch pedal and LCD screen with touch panel. These modules are used for generating pulses of RF energy that heats the micro tissue zones to create fractional tissue coagulation. The InMode System is depicted in *figure 11.1* below.

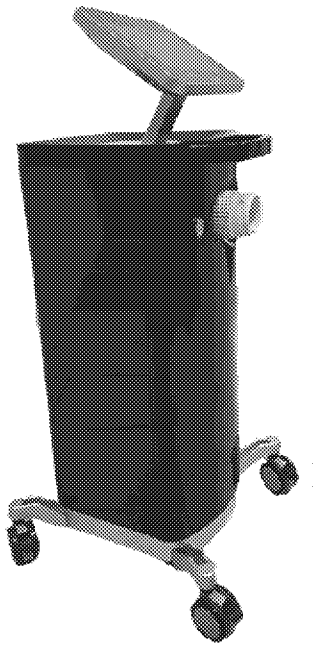


Figure 11.1: InMode System

(b)(4)

A detailed description on the device components is presented in the following sections.

11.2 Device Components

11.2.1 AC/DC power supply unit

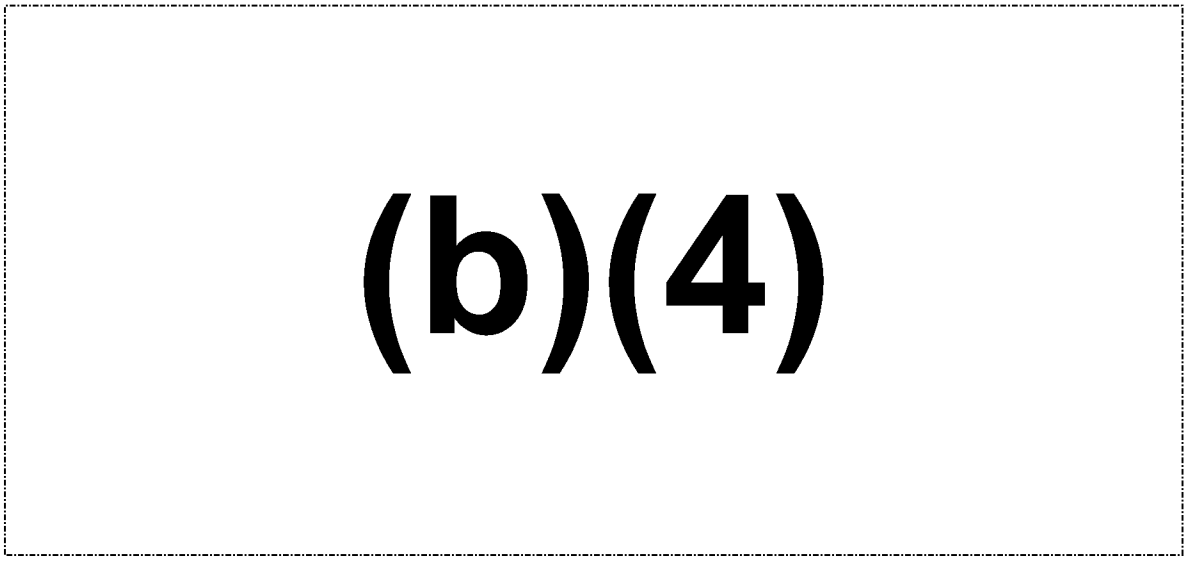
The medical grade AC/DC power supply unit converts AC input voltage (100-240 VAC) into stabilized DC voltage of 48 VDC.

11.2.2 RF Generator

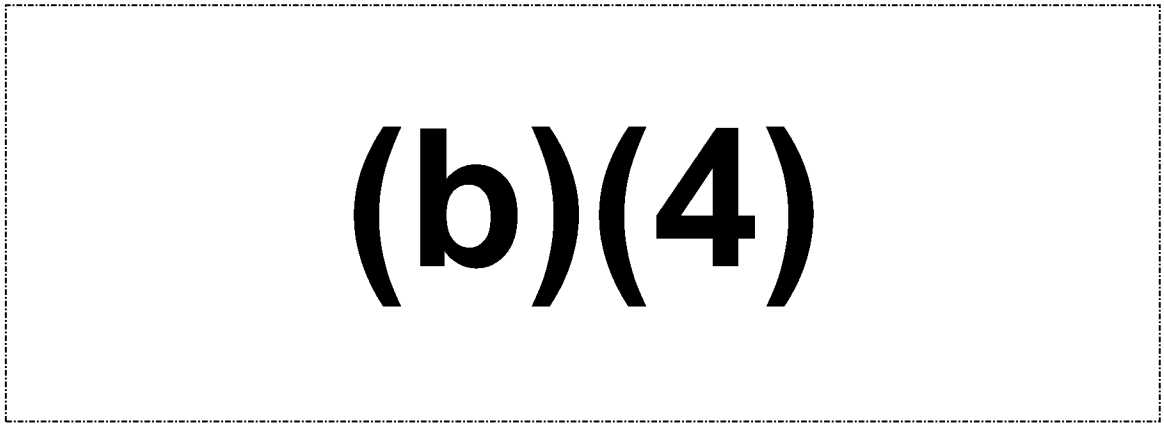
The RF generator generates RF power to the applicator according to user settings. The following are the specifications of the RF generator:

- Input Voltage <48VDC
- Maximal Output Power 65W
- RF frequency 1MHz

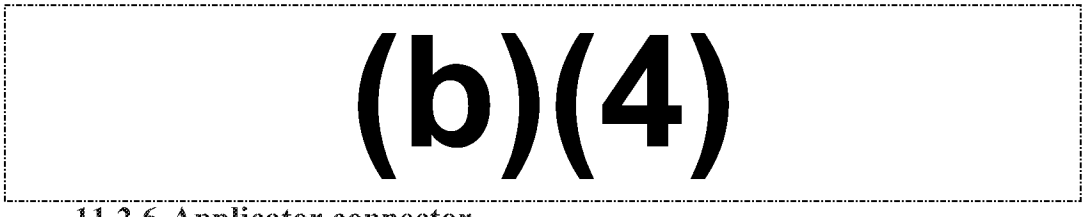
11.2.3 Controller/CPU Card



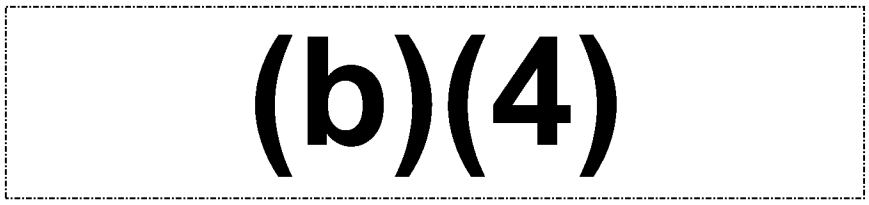
11.2.4 User Interface (Operator Control Panel)



11.2.5 RF measuring circuit



11.2.6 Applicator connector



(b)(4)

11.2.7 Footswitch

(b)(4)

11.2.8 Morpheus8 Applicator

The Morpheus8 Applicator comprises handle and detachable, sterilized, disposable, single use 12, 24, 40 pin and T tip head accessories. The applicator handle is made of plastic and has an ergonomic design for easy treatment with high visibility of the treated area. The applicator has a cable that is 270cm long and connects the applicator to the console via a connector. The applicator body design with adjustable tip head is shown in *Figure 11.3*.

Figure 11.3: Morpheus8 Applicator with tip

The Morpheus8 12, 24, 40 and T Applicators comprise motor with gear and actuator. The motor enables the insertion of the RF electrode pins based on a pre-determined

adjusted depth from 1 or 2mm up to 7mm in the 24 and 40 pin tip heads, respectively (in increments of 1 mm), 1mm-4.0mm for the 12 pin tip head and fixed depth of 0.5mm for the T tip head. (b)(4)

(b)(4)

The insertion motor mechanism is shown in *Figure 11.4*.

(b)(4)

Table 1 Summarizes the modified Morpheus8 Applicators specifications in comparison to the previously FDA-Cleared Morpheus8 Applicators.

Technological Characteristic	InMode System with the Morpheus8 Applicators InMode Ltd. (Subject Device)	InMode System with the Morpheus8 Applicators InMode Ltd. K192695 (Predicate Device)
(b)(4)		

(b)(4)

Tip geometry

The Morpheus8 Applicators possesses the same underlaying RF technology as the FDA-Cleared Morpheus8 Applicators (K192695). The RF power is transformed from the applicator handle to the tip head and emitted in a fractional manner by the tip's needle array to the treatment area. The Morpheus8 12, 24, 40 pin and T tip heads are disposable, gamma sterilized, and are intended for single use.

(b)(4)

(b)(4)

Engineering drawings of the Morpheus8 Applicator handle and tip head are provided in *Appendices 11-2 and 11-3* respectively.

11.3 Mechanism of Action

(b)(4)

11.4 Mode of Operation

The InMode System with the Morpheus8 Applicators can emit a maximal output power of 65W. The RF frequency is 1MHz (b)(4)

(b)(4)

(b)(4)

The device RF pulse duration is determined according to the preset RF energy level. The maximal pulse duration does not exceed 74 msec.

11.5 User Interface and Device Operation

The subject device user interface and software modules are merely the same user interface and software modules installed in the FDA-Cleared device (K192695). Slight adjustments were performed to enable the extended penetration depths of the 24 and 40 pin tips (5, 6 and 7mm). The Morpheus8 Applicators are operated using the same operation screen as in the FDA-Cleared device.

The InMode RF System with the Morpheus8 Applicators operate as follows:

- The device is turned on by pressing the ON/OFF button. The System loads the software via the splash screen.
- The login screen appears after the power switch is turned on. The user should provide his/her individual password in order to prevent non-authorized use of the device.
- Software is loaded from the plug and self-test of the device modules is performed. After the end of the self-test the menu screen appears.
- The Menu Screen allows the selection of the connected Applicator, or entry to the Utilities Screen (*Figure 11.6*).

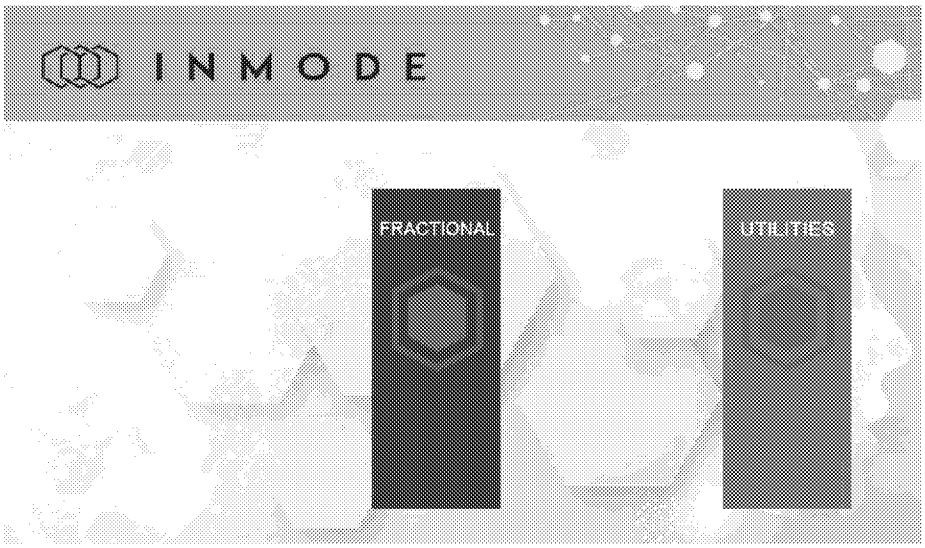


Figure 11.6: *Menu Screen*

Figure 11.7: *Utilities Screen*

The Utility Screen contains:

Volume	This function allows the user to adjust the System volume.
Change Password	Change the password by entering the old password and then entering another 4-digit password.
Calibration	N/A
Main Menu	Return to the Main Menu to select an applicator.

- After returning to the Menu Screen and choosing the application on the Menu Screen, the corresponding Treatment Screen appears. (Figure 11.8)

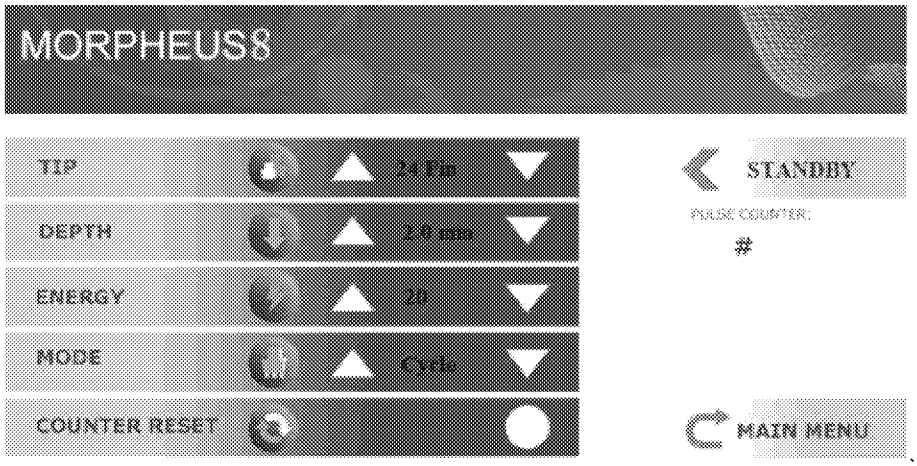


Figure 11.8: The Morpheus8 Applicator Treatment screen

Tip	Allows selecting the Tip. Available Tips are: T, 12 Pin, 24 Pin tip and 40 Pin.
Depth	Allows selecting the pins length and penetration depth according to dermis thickness in treated area to provide effective sub-dermal treatment. Available depths for Morpheus 8 are: For the 12 pins tip: 1, 2, 3 and 4mm For the 24 pin tip 1 to 7mm For the 40 pins tip 2 to 7mm When connecting the T tip, depth control is disabled and the pin length is constant (0.5mm).
Energy	Delivered energy is changed from level 5 to 60 energy levels and the System starts up at the minimal energy setting.
Mode	Selects between Cycle mode when needle goes out and in at each pulse and Fixed mode is used for T tip.
Counter Reset	Counter can be reset.
Pulse Counter	Shows number of pulses delivered on one zone and total number of pulses from the beginning of the treatment.
System Mode	The System has three treatment modes: Standby, Ready, and Active.

	Standby mode allows the user to set treatment parameters. Activation of energy is not allowed in Standby mode. In Ready mode, the system is waiting for a signal from the foot switch to activate the energy. Any attempt to change the treatment settings switches the system to Standby mode. When the signal from the footswitch is indicated, the system switches to Active mode. Any attempt to change the treatment settings switches the system to Standby mode.
Main Menu	Return to the Main Menu to select another applicator and change the applicator if needed.

11.6 Device additional features

11.6.1 Sound indicator

Periodic beeping signal is emitted when RF energy is delivered. (b)(4)

(b)(4)

11.7 Sterilization & Reprocessing

The Morpheus8 tip heads are provided sterile to the end-user. Additional information on sterilization validation is specified in Section 14 of this 510(k) application.

The Morphues8 tip heads are intended for single use and should be discarded upon usage.

The Morphues8 Applicator excluding the tip is intended for multiple use and should be thoroughly cleaned prior to reuse. Reprocessing information is provided in the device user manual (see Section 13 of this 510(k) application).

11.8 Treatment Information

General notes for treatment with the Morpheus8 Applicator:

- The tip head is intended for single use and should be discarded upon usage.
- Treatment parameters are set by the operator.
- Always start with a low energy level, test patient comfort and observe the skin's response before increasing the energy. Tips, depth and energy levels may vary according to physician discretion, based on patient response.
- On sensitive thin skin area lower parameters should be applied.
- Dark skin (V-VI) should be treated with restricted energy, starting at the minimal suggested energy level or lower, adding 5 levels each visit (every 3-4 weeks).

The table below summarizes the Treatment recommendations for each tip:

Tip name	Treatment Depth (mm)	Treatment Areas
(b)(4)		

11.8.1 Contraindications

- Pacemaker or internal defibrillator, or other metallic or electronic implant anywhere in the body. The Hand piece should be used at least 1cm away from cochlear implants in the ear.
- Permanent implant in the treated area such as metal plates, screws and metal piercing or silicon, unless deep enough in the periosteal plane.
- Intra-dermal or superficial sub-dermal areas injected with Botox®/HA/collagen/fat injections or other augmentation methods with bio-material, before the product has been dissipated (up to 6 months), except Botox after binding to the facial muscles (3-7 days). It is possible to treat sooner over injectable products placed in the deep, periosteal plane, as soon as the area has healed (1-3 weeks).
- Current or history of skin cancer, or any other type of cancer, or pre-malignant moles.
- Pregnancy and nursing.

- Severe concurrent conditions, such as cardiac disorders or sensory disturbances.
- Impaired immune system due to immunosuppressive diseases such as AIDS and HIV, or use of immunosuppressive medications.
- Patients with history of diseases stimulated by heat, such as recurrent Herpes Simplex in the treatment area, may be treated only following a prophylactic regime.
- Poorly controlled endocrine disorders, such as diabetes or thyroid dysfunction and hormonal virilization.
- Any active skin condition in the treatment area, such as sores, psoriasis, eczema, and rash.
- History of skin disorders, keloids, abnormal wound healing, as well as very dry and fragile skin.
- History of bleeding coagulopathies or use of anticoagulants in the last 10 days
- Any facial surgery performed within a year prior to treatment.
- Facial dermabrasion, facial resurfacing, or deep chemical peeling within the last three months, if face is treated.
- Having received treatment with light, laser, RF, or other devices in the treated area within 2-3 weeks for non-ablative procedures, and 6-12 weeks for ablative fractional laser resurfacing (according to treatment severity) prior to treatment, except special recommendations.
- Use of Isotretinoin (Accutane®) within 6 months prior to treatment.
- Use of non-steroidal anti-inflammatory drugs (NSAIDS, e.g., ibuprofen-containing agents) one week before and after each treatment session, as per the practitioner's discretion.

- Treating over tattoo or permanent makeup to be kept.
- Treating over the lips.
- Skin type VI and dark VI patients treat with caution.
- Treating over hair bearing surfaces.
- Irritable skin like excessively tanned skin from sun, tanning beds or tanning creams and sprays within the last two weeks.
- As per the practitioner's discretion, refrain from treating any condition that might make it unsafe for the patient.

11.9 Device Safety Features

The System incorporates the following safety features. All personnel operating the System should be familiar with these features.

- The System has unique password to avoid device operation by non-authorized personnel.
- The power electronics cannot be activated unless the applicator and Footswitch have been connected to the System. An audible tone indicates energy activation.
- An audible tone indicates energy activation.
- Tissue impedance monitoring prevents accidental energy emission to the patient.
- During activation, the System performs a self-test of the hardware.
- Hardware is tested every 10ms to ensure proper operation of electrical circuit.
- The System starts at a low setting.

11.10 Device Specifications

Input Power		
Main Line Frequency (nominal)	50-60Hz	
Input Voltage (nominal)	100-240VAC	
Input Current (rms)	12A	
Operating Parameters		
Ambient Temperature Range	15 – 30°C [59 – 86°F]	
Relative Humidity	30% to 80%, non-condensing	
Atmospheric Pressure	90 - 110kPa	
Warm-up Time	If transported or stored at temperatures outside the operating temperature range, allow one hour for the device to reach room temperature before use.	
Transport and Storage		
Ambient Temperature Range	-20– 65°C [-4 – 149°F]	
Relative Humidity	0% to 80%, non-condensing	
Atmospheric Pressure	50 to 110kPa	
Dimensions		
System	46cm W x 46cm D x 100cm H	[18.2'' W x 18.2'' D x 40'' H]
Applicator Cable	270cm L	[100`` L]
Weight		
System	32.000kg	[70.548lb]
Morpheus8 Applicator	0.400kg	[1.268lb]
Morpheus8 Output Parameters		
Maximum Output Power	65[W]	
Frequency	1MHz	
Crest Factor (Rated Load)	1.4± 2%	

11.11 Device Materials

The device components that come in direct contact with the user and patient's skin are the applicator handle and the tip heads. All device materials in contact with the patient are identical to the materials used in the FDA-Cleared device (K192695) and therefore are deemed biocompatible as well for the subject device of this 510(k) application.

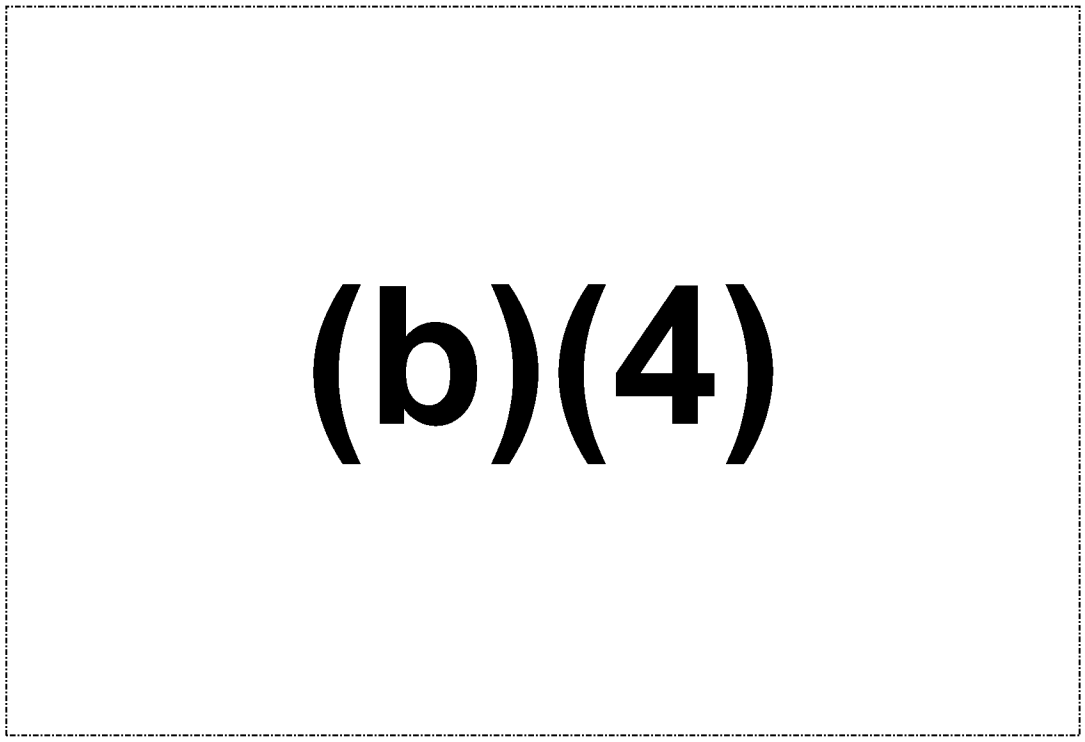
The following table lists the materials that come in direct contact with the human body:

(b)(4)

A detailed discussion on material biocompatibility is presented in Section 15 of this 510(k) file application.

11.12 RF Performance Specifications

The following curve depicts the device output Power vs. range of Load Impedance.



11.13 EMC Safety for the InMode System with Morpheus8 Applicators

The device has been tested and found to comply with the limits specified in IEC 60601-1-2 FDA recognized consensus standard. These limits are designed to provide reasonable protection against harmful interference in a typical clinical installation. This device generates RF energy and can radiate RF energy. If not installed and used in accordance with the instructions, may cause harmful interference to other devices in the vicinity. However, there is no guarantee that the interference to other devices, which can be determined by turning the device off and on, is caused by this instrument.

The user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving device.
- Increase the separation between the devices.
- Connect the device into an outlet on a circuit different from that which was previously used.
- Consult InMode service personnel for help.
- Interference to the device may be caused by portable and mobile RF communication equipment. In case of an interruption, beware of such a device in the vicinity.
- Use of the System with any accessory, transducer or cable other than those specified may result in increased EMISSIONS or decreased IMMUNITY than those specified.
- The System should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the System should be observed to verify normal operation in the configuration in which it will be used.

IEC 60601-1-2 Edition 4.0 (2014)

Environment of intended uses:

Professional Healthcare Facility Environment

Summary of Test Results

Test	Standard	Class/ Severity level	Test result
(b)(4)			

11.14 List of Appendices

The following engineering drawings of the InMode System with the Morpheus8 Applicator are attached to this section.

Figure 11.10 - Engineering drawing of InMode platform system

Figure 11.11 – Engineering drawing of Morpheus8 Applicator Handle

Figure 11.12 – Engineering drawing of Morpheus8 Applicator Tip Head

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(b)(4)

(b)(4)

Section 12:

Substantial Equivalence Discussion

12.0 SUBSTANTIAL EQUIVALENCE INFORMATION

12.1 Predicate Devices

The InMode System with the Morpheus8 Applicators is a fractional RF treatment modality based on the FDA-Cleared InMode System and Morpheus8 Applicators all FDA clarified in K192695. The subject device is an RF-based technology appliance, emitting RF energy by utilizing a scattered pattern of electrode pins for electrocoagulation and hemostasis procedures. As such, the subject device is substantially equivalent to the InMode System with the Morpheus8 Applicators (manufactured by InMode Ltd. and the subject of 510(k) document K192695). This predicate device utilizes the same platform system (InMode System) as does the subject device, hence, it's main functional units (Controller, RF Generator, Footswitch, User interface) are identical to those of the subject device. Both the subject device and the predicate device are constituted on the same mechanism of RF energy delivery.

The purpose of this 510(k) file submission is to report to the FDA on recent modifications performed on the predicate device. The only change performed is a minor change in the devise software that controls the penetration depth and the ability of the 24 and 40 pin microneedles to reach a deeper penetration depth of up to 7 mm.

No other modifications were performed in device system and applicators.

The 510(k) Summary of Safety and Effectiveness for the FDA cleared InMode System with the Morpheus8 Applicator (Predicate device) is provided in Appendix 12-2.
A comparison table is provided in Section 12.2 comparing the intended use and basic technological characteristics of the InMode System with the Morpheus8 Applicators to the intended use and basic technological characteristics of the predicate device.
A discussion of the similarities and differences between the subject device and the predicate device can be found following the comparison table in Section 12.3.

12.2 Comparison Table[1]

(b)(4)

[1] The differences between modified and FDA-Cleared predicate devices are underlined in the table and discussed in details in Paragraph 12.3.

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(b)(4)

(b)(4)

(b)(4)

12.3 Comparison Discussion

INTRODUCTION

The InMode System with the Morpheus8 Applicators, in a similar manner to its predicate device, delivers RF energy in a fractional manner to create electrocoagulation micro zones in target tissues. The InMode System with the Morpheus8 Applicators is intended for use in dermatological and general surgical procedures for electrocoagulation and hemostasis.

The subject device, similarly to the predicate device, comprises the InMode System (FDA-cleared in K180189) and with the Morpheus8 Applicators in K192695.

Both the predicate device and subject device are manufactured by InMode Ltd.

Both the subject and predicate devices utilize the InMode System platform for generating the Fractional RF energy and for general system control. Moreover, both systems utilize the same Morpheus8 set of Applicators (FDA Cleared in K192695) which supports the application and utilization of the 12, 24, 40 and T tip heads.

The only difference between the subject device and the predicate device is in the 24 and 40 tip head microneedles maximum penetration depth. While in the predicate device the maximal allowed penetration depth for the 24 and 40 tip heads was limited to 4mm, with the subject device this was extended for up to 7mm. The same mechanism of operation and the same mechanism of action is applied by both the subject and predicate device. The same performance specifications are used. The only change made was in the device software that controls the microneedles penetration depth.

The hardware components and underlying RF technology of the subject and predicate devices are identical.

In similar manner to the predicate device, the subject device system platform consists of RF generator, controller and user interface and perform identical functions of RF power delivery under similar performance specifications.

In both the subject device and predicate device, a footswitch paddle is included, facilitating device operation & control by user.

The following paragraphs will discuss the indication for use and the technological similarities of the new device and its proposed predicate device.

INDICATIONS FOR USE

The indications for use of the InMode System with the Morpheus8 Applicators is identical to the indication for use of the predicate device. Both applicators are intended for use in dermatologic and general surgical procedures for electrocoagulation and hemostasis.

The target population (subjects requiring the above treatments), anatomical sites (body parts requiring treatment) and environment of use (hospital or clinic) are the same for the subject device and the predicate device.

Thus, the indications for use and use related issues for the new device are substantially equivalent to the predicate devices.

TECHNOLOGICAL CHARACTERISTICS

(b)(4)

(b)(4) The differences between the subject device and predicate device are merely in the 24 and 40 tip head microneedles maximal penetration depth. While the predicate device presents a

maximal penetration depth ability of 4mm, the subject device 24 and 40 pin tip heads has an increased penetration scale for up to7mm of depth.

The abovementioned changes were done in the device software that controls the microneedles penetration depth. Apart from that, no modifications were performed in system platform and applicator hardware. The same RF performance specifications are applied by both the subject device and predicate device to apply for the same indication for use of dermatological and general surgical procedures for electrocoagulation and hemostasis.

Performance Specifications & Mechanism of Operation:

The mechanism of operation of the InMode System with the Morpheus8 Applicators is identical to the mechanism of operation of the predicate device and is based on the delivery of RF energy in a fractional way through an array of micro pin electrodes. (b)(4)

(b)(4)

The Morpheus8 set of applicators is compatible with the InMode System platform. The InMode System platform is used in both subject device and predicate device comprising identical RF performance specifications; it generates an RF frequency of 1MHz with a maximal RF output power of 65W and a maximal pulse duration of 74msec to deliver a maximal RF energy per pin of (b)(4)

In an identical manner to the predicate device, the Morpheus8 set of applicators comprise a handle and adjustable tip heads. These applicator components are identical to the predicate device applicator components and no change was performed in their hardware or materials. This 510(k)-file submission is solely focused on the modifications performed on the Morpheus8 24 and 40 pin tip heads.

The Morpheus8 set of applicators comprise different adjustable tip heads; 12, 24, 40 and T tip heads, all to be adjusted on the Morpheus8 Applicator Handle. (b)(4)

(b)(4)

(b)(4)

(b)(4) The 12 tip head microneedles can reach a maximal depth of 4mm while the 24 and 40 tip head microneedles can reach a maximal depth of 7mm. The T tip head possess a fixed, non-insulated, 0.5mm length microneedles.

(b)(4)

The InMode System with the Morpheus8 Applicators delivers a maximal power of 65W. The user can control the RF output energy by the adjustment of the energy level, ranged between 5 to 60 energy units. The same RF operating specifications are applied by the predicate device.

The subject and predicate device systems control the RF performance parameters (Output power, pulse width) in the same manner, providing the user with the desired energy per pin for an efficient and safe treatment.

Power requirements of the InMode System with the Morpheus8 Applicators and the predicate device are identical (100-240 VAC, 50-60 Hz).

The subject device and predicate device equally perform utilizing the same RF performance specifications with the same tip head pin arrangement and structure. Therefore, the subject device presents the same mechanism of action and treatment outcomes as the predicate device.

The subject device and predicate device microneedles are structured and operate in the same manner. The microneedles body is insulated except for a narrow tip head of 0.5mm were the RF energy is exerted. By this unique microneedle structure, the RF energy is focused to the target area without any thermal damage caused to the surrounding tissues.

(b)(4)

In order to address the thermal effect in deeper tissues, hence; tissues that are in range of 4-7mm, the sponsor (InMode Ltd.) had performed ex-vivo tissue testing.

A detailed description of the testing layout, methodology and results including the complete study protocol & study report are presented in Section 18 of this 510(k) file application.

The purpose of the *ex-vivo* test was to evaluate and compare the fractional coagulation necrosis pattern of target tissues, formed by thermal effect of the InMode System with the Morpheus8 Applicators 24 and 40 pin tip heads in different tissue depths.

The study design included a single treatment session performed on two different harvested porcine tissues: muscle and fat, utilizing the InMode System with the Morpheus8 applicator 40 pin tip head in its final, finished version. (b)(4)

(b)(4)

(b)(4)

(b)(4)

The testing results, demonstrating a similar pattern of the pin-points coagulation necrosis, clearly show that efficacy and safety issues that have been FDA-cleared Cleared in K192695 for the 4mm pin length (predicate device), may be applied to the 5-7mm pin length (subject device).

Device components & design:

The InMode System comprise the main console which possesses the RF generator, controller, user interface with touch panel and a designated footswitch. The subject device platform system is established on identical RF technology, identical device

components and identical operation procedures as with the predicate device platform system.

The design and components comprising the subject device and the predicate device are similar in terms of functionality and user operation.

The subject device applicator; the Morpheus8 Applicator comprises a connector cable, handle and detachable set of treatment tip heads. The handle is made from plastic and has an ergonomic design for easy treatment with high visibility of the treated area. The cable is 270cm long and connects the applicator to the console via a connector. The set of treatment tip heads includes a variety of tip heads which mainly differs in the footprint dimensions and in the number of microneedles. It includes 12, 24, 40 and T tip head microneedles (b)(4) (b)(4) The 12, 24 and 40 tip head microneedles (b)(4), leaving the pin's tip area (distal edge of 0.5 mm) (b)(4) where RF energy is exerted. The return electrodes are scattered throughout the treatment area, surrounding each pin for a better RF conductivity and heat transfer. (b)(4)

(b)(4)

In a similar manner to the predicate device, the subject device is equipped with a software-controlled movement mechanism which enables the user to set the desired pins' penetration depth. In the predicate device the user is able to select the desired penetration depth from a programmed depth range of 1.0 to 4.0 mm with the 12 and 24 tip heads and 2.0 to 4.0 mm with the 40-tip head, all with increments of 1.0mm. In the subject device 24 and 40 pin tip head operation, the user can select the desired penetration depth from a programmed depth range of 1.0 to 7.0mm with the 24 tip head and 2.0 to 7.0mm with the 40 pin tip head, same increments of 1.0mm are applied for both the subject and predicate device. No changes are in the operation of the 12 and T tip heads.

(b)(4)

Device operation:

Both the subject device and the predicate device operate in the same manner. The InMode System is turned ON/OFF through a single switch and the user can navigate and preset the RF treatment parameters using the user interface touch screen.

The applicators are held and positioned by the practitioner in a similar manner and the treatment methodology is similar with both types of Applicators.

Safety & compliance with standards:

(b)(4)

The InMode System with the Morpheus8 Applicators was tested and complies with the Electrical and Mechanical safety standard (IEC 60601-1) and the Electromagnetic Compatibility standard (IEC 60601-1-2). The test reports along with the test certificates are provided in Section 17. The predicate device was also tested and complies as well with these FDA recognized standards.

Sterilization and Biocompatibility:

The InMode System with the Morpheus8 Applicators is comprised of a cable and connector, handle and detachable set of tip heads. All of the tip heads are gamma sterilized and intended for single use. All tip heads to be discarded following the treatment. Further details on the sterilization procedures are described in Section 14 to this application. Similarly, the predicate device applicator tip heads are comprised of the same components, the tip heads are for single use and are provided gamma-sterilized to the user.

The only patient contacting components in the InMode System with the Morpheus8 Applicators are the materials found at the applicators handle and tip heads. (b)(4)

(b)(4)

The materials which are used for the InMode Morpheus8 Applicator design have been extensively used in the design of medical devices with similar intended use and technology as the InMode Morpheus8 Applicator. Please refer to Section 15 for further information on the device biocompatibility.

SUMMARY

The indications for use and technological characteristics of the InMode System with the Morpheus8 Applicators are substantially equivalent to the indications for use and technological characteristics of the predicate, the InMode System with the Morpheus8 Applicators (and the subject of K192695).

The design of and the components in the InMode System with the Morpheus8 Applicators, including the console (with power supply, RF generator, controller and display screen) and the applicator (with cable, connector to console, handle and tip

head) are identical to the design and components found in the predicate InMode System with the Morpheus8 Applicators, with the same dimensions and weight.

The performance specifications (including RF frequency and maximal pulse duration) of the InMode System with the Morpheus8 Applicators were shown to be identical to those of the predicate.

The thermal effect observed in the deeper tissues utilizing the Morpheus8 Applicator with the 24 and 40 tip heads with different RF energy settings for a penetration depth range of 4-7mm demonstrated of a similar thermal effect as shown for the predicate device in penetration depths of up to 4mm.

Therefore, it can be deduced that the InMode System with the Morpheus8 Applicators is as safe and effective as the predicate device, and that no new safety or effectiveness issues are raised regarding the subject device.

The safety features and compliance with safety standards in the subject device are similar to the safety features and compliance with safety standards found in the predicate device.

Patient contact materials are the same between the subject device and its predicate device. Any minor differences in the technological characteristics do not raise new safety or effectiveness concerns.

Furthermore, the new InMode System with the Morpheus8 Applicators underwent performance testing, including software validation testing (provided in Section 16), Electrical and Mechanical Safety testing according to IEC 60601-1 and Electromagnetic Compatibility testing according to IEC 60601-1-2 (provided in Section 17) and *ex-vivo* testing to evaluate the thermal effect of the device on target tissues (provided in Section 18). These performance tests demonstrated that the minor differences in the device design and specifications meet the system requirements and do not raise new safety or effectiveness concerns.

Consequently, it can be concluded that the InMode System with the Morpheus8 Applicators is substantially equivalent to the predicate device, the InMode System with

the Morpheus8 Applicators, FDA cleared under 510(k) K192695, and therefore, may be legally marketed in the USA.

APPENDIX 12-1

InMode System with the Morpheus8 Applicator

Risk – Benefit Analysis Report

InMode Morpheus8 Applicators

Benefit-Risk Analysis

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(b)(4)

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(b)(4)

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(b)(4)

(b)(4)

APPENDIX 12-2

510(k) Premarket Notification, SSE Summary for the InMode System with the Morpheus8 Applicators (Manufactured by InMode Ltd.)

510(k) K192695

December 27, 2019

Inmode MD Ltd.
% Amit Goren
Regulatory Manager
A. Stein- Regulatory Affairs Consulting Ltd.
20 Hata'as Str., Suite 102
Kfar Saba, 4442520 Il

Re: K192695
Trade/Device Name: InMode System with the Morpheus8 (Fractora) Applicators
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting And Coagulation Device And Accessories
Regulatory Class: Class II
Product Code: GEI
Dated: November 25, 2019
Received: November 27, 2019

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); 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,

Jitendra V. Virani -S

For Long Chen, 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

Device Name
InMode System with the Morpheus8 (Fractora) Applicators

Indications for Use *(Describe)*
The InMode System with the Morpheus8 (Fractora) Applicators is intended for use in Dermatological and General Surgical procedures for Electrocoagulation and Homeostasis.
At higher energy levels greater than 62 mJ/pin, use of the Morpheus8 (Fractora) Applicators 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.

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510(K) SUMMARY

INMODE RF SYSTEM

510(k) Number K192695

Applicant Name:

Company Name: InMode Ltd
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Israel
Tel: +972-4-9097470
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Date Prepared: November 25, 2019

Trade Name: InMode System with the Morpheus8 (Fractora) Applicators

Classification Name: CFR Classification section 878.4400; (Product code GEI)

Classification: Class II Medical Device

Predicate Device:

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

Device	Manufacturer	510(k) No.
InMode System with the Fractora3D/3D-90 Applicators	InMode MD Ltd.	K180189

Device Description:

The InMode System with the Morpheus8 (Fractora) Applicators is a computerized, programmed, RF technology-based device intended for dermatological applications which requires skin electrocoagulation and hemostasis.

The device platform is basically constituted on the same system platform as FDA cleared for the proposed predicate device; The InMode System with the Fractora3D/3D-90 Applicators (K180189). The device applicators employ fractional RF multi-electrode technology for procedures requiring electrocoagulation and hemostasis. The Morphues8 (Fractora) Applicators are designed to deliver radiofrequency energy to the skin in a fractional manner, via an array of multielectrode pins.

The Device provides enhanced safety while minimizing possible side effects by monitoring RF parameters. The InMode System with the Morpheus8 (Fractora) Applicators consists of an AC/DC power supply unit, RF generator, controller and user interface including LCD touch screen. The Morpheus8 (Fractora) Applicators are connected to the console via a cable and a foot switch activates the energy delivery to the applicator. The subject device applicator comprises a disposable, single use, fractional RF electrode pins tip head.

The InMode System with the Morpheus8 (Fractora) Applicators comprises the following applicator tip heads:

- Morpheus8 24 Pin Applicator (Fractora3D) tip (FDA Cleared in K180189)
- Morpheus8 40 Pin treatment tip (New tip)
- Morpheus8 12 Pin treatment tip (New tip)
- Morpheus8 T Pin treatment tip (New tip)

Device Specifications:

Main Line Frequency (nominal)	50 - 60 Hz
Input Voltage (nominal)	100 - 240 VAC
Electrosurgical Unit dimensions (inch)	18.2''W x18.2''D x40''H
Platform weight (lb.)	70.5
Applicator weight (lb.)	1.26
RF Max Output Power (Watt)	65
RF Output Frequency (MHz)	1± 2%

Intended Use/Indication for Use:

The InMode System with the Morpheus8 (Fractora) 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 Morrpheus8 (Fractora) Applicator is limited to Skin Types I-IV.

Performance Standards:

The InMode System with the Morpheus8 (Fractora) Applicators complies with the following FDA recognized consensus standards:

- AAMI/ANSI 60601-1 (2012), Medical Electrical Equipment - Part 1: General Requirements For Basic Safety And Essential Performance (IEC 60601-1:2005, Mod).
- IEC 60601-1-2 (Edition 3.0, 2007), Medical Electrical Equipment - Part 1-2: General Requirements For Basic Safety And Essential Performance - Collateral Standard: Electromagnetic Compatibility - Requirements And Tests.
- IEC 60601-2-2 Edition 5.0 2009-02, 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.

Non-Clinical (Bench) Performance Data:

The InMode System with the Morpheus8 (Fractora) Applicators was tested for its applicator tip RF output performance specifications. The device utilizing the Morphues8 12, 24, 40 pin and T tip heads preset to different RF energy levels, was tested under different resistance loads with the following parameters measured and compared to the results obtained in similar testing conducted on the predicate device: pulse duration, energy per pin, total energy, and pick to pick voltage. The results demonstrate equivalent measurements obtained for the subject and predicate devices.

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 predicate device manufacturing.

Substantial Equivalence:

A comparison table is provided below comparing the intended use and basic technological characteristics of the InMode System with the Morpheus8 (Fractora) Applicators to the intended use and basic technological characteristics of the predicate device.

Technological Characteristic	**InMode System with the Morpheus8 (Fractora) Applicators InMode Ltd. (K192695)**	**InMode System with the Fractora3D/3D-90 Applicators InMode MD Ltd. (K180189)**
Dimensions	46cm W x 46cm D x 100cm H [18.2'' W x 18.2'' D x 40'' H]	46cm W x 46cm D x 100cm H [18.2'' W x 18.2'' D x 40'' H]
Weight Platform weight Applicator weight	 32 Kg (70.5 lbs.) 0.4 Kg (1.26 lbs.) Tip weight - 0.02 Kg	 32 Kg (70.5 lbs.) 0.4 Kg (1.26 lbs.) Tip weight - 0.02 Kg
Applicator Tip Heads:	• Morpheus8 (Fractora) 12 tip head • Morpheus8 (Fractora) 24 tip head • Morpheus8 (Fractora) 40 tip head • Morpheus8 (Fractora) T tip head	Morpheus8 (Fractora3D) 24 tip head
Number of pins	12-40 pins	24 pins
Maximal Treatment depth	4.0mm T tip head – 0.5mm (Fixed)	4.0mm
Cable Dimensions:	250 cm	250 cm
Performance	Frequency: 1 MHz	Frequency: 1 MHz

Technological Characteristic	InMode System with the Morpheus8 (Fractora) Applicators InMode Ltd. (K192695)	InMode System with the Fractora3D/3D-90 Applicators InMode MD Ltd. (K180189)
	Maximal RF output power: 65W	Maximal RF output power: 65W
Standards Met	IEC 60601-1 IEC 60601-1-2 ANSI AAMI 60601-2-2 for safety of high frequency surgical equipment	IEC 60601-1 IEC 60601-1-2 ANSI AAMI 60601-2-2 for safety of high frequency surgical equipment
Reprocessing & Sterilization	For single use. All applicator tip heads are gamma sterilized.	For single use. Non-sterilized. To be sterilized prior to use.

Comparison Discussion:

The indications for use and technological characteristics of the modified device are substantially equivalent to the indications for use and technological characteristics of the predicate device.

The design and components of the modified device, including the console (with power supply, RF generator, controller and display panel) and the Applicator handle (with cable and connector to console) are identical to the design and components found in the predicate device. The modified device comprises the predicate device Morpheus8 (Fractora) 24 pin tip head and additional three compatible tip heads; the Morpheus8 (Fractora) 12, 40 pin and T tip heads. The performance specifications (including RF frequency, pulse duration, RF current distribution and RF energy per pin) of the modified device are comparable to those of the predicate device. The safety features and compliance with safety standards in the modified device are identical to the safety features and compliance with safety standards found in the predicate device. Patient contact materials are also identical. Any minor differences in the technological characteristics do not raise new safety or effectiveness concerns. Furthermore, the modified device underwent bench 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. Sterilization methods applied on the device applicator tip heads were validated in accordance with ISO 11137-1.

The performance tests demonstrated that the minor differences in the device design and specifications meet the system requirements and do not raise new safety or effectiveness concerns.

Consequently, it can be concluded that the InMode System with the Morpheus8 (Fractora) Applicators is substantially equivalent to the predicate InMode System with the Fractora3D/3D-90 Applicators, FDA cleared in 510(k) K180189, and therefore, may be legally marketed in the USA.

Section 13:

Proposed Labeling

13.0 DEVICE LABELING

13.1 Instructions for Use

The Instructions Manual for the InMode System with the Morpheus8 Applicators is provided in Appendix 13-1.

13.2 Package Labels

The device labels for the InMode System with the Morpheus8 Applicators are provided in Appendix 13-2.

13.3 Device Brochure

The InMode System with the Morpheus8 Applicators draft brochure is provided in Appendix 13-3.

Appendix 13-1:

Instructions Manual for the InMode System with the Morpheus8 Applicators

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IEC 60601-1-2 Edition 4.0 (2014)

Environment of intended uses:

Professional Healthcare Facility Environment

Summary of Test Results

Test	Standard	Class/ Severity level	Test result
Documentation (IEC 60601-1-2 sections 4 and 5)			
(b)(4)			

Appendix 13-2:

Device Labels for the InMode System with the Morpheus8 Applicators

The following device labels are located on the back panel of the InMode System with the Morpheus8 Applicators:

Figure 13.1: InMode Device label.

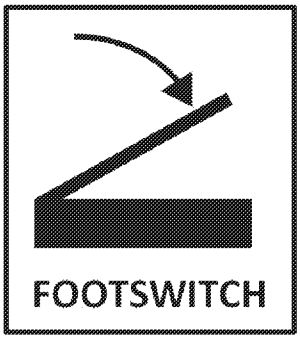

Figure 13.2: Footswitch Label.

The following device labels are affixed to the InMode Morpheus8 Applicators and tips:

Figure 13.3: InMode Morpheus8 Applicator Identification label.

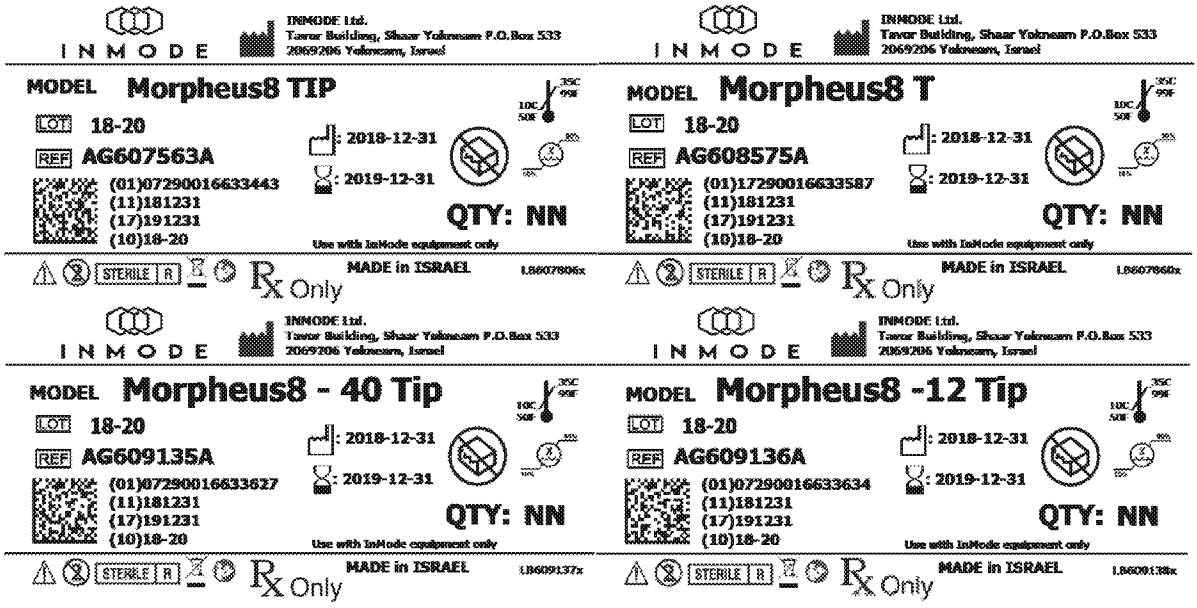

Figure 13.4: Morpheus8 (24 Pin) Tip (Upper Left), Morpheus8 T Tip (Upper Right), Morpheus8 Body (40 Pin) Tip (Lower Left), Morpheus8 Prime (12 Pin) Tip (Lower Right).

Appendix 13-3:

The InMode System with the Morpheus8 Applicators Draft Brochure

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Section 14:

Sterilization, Reprocessing, Shelf Life and Use Life information

14.0 STERILIZATION, REPROCESSING, SHELF LIFE & USE LIFE INFORMATION

No changes were performed in sterilization processes, reprocessing instructions, shelf life and use life determinations of the subject device in comparison to the predicate device.

14.1 Sterilization information

The InMode Morpheus8 Applicators are comprised of a handle and disposable single-use tip. The tip is provided Gamma-sterilized.

The manufacturer will label the device applicator as "Gamma-sterilized" according to the FDA guidance on "Processing/reprocessing medical devices in health care settings: Validation methods and labeling". Furthermore, the device Instructions for Use will include warnings considering the disposal of the treatment tip following a single-use treatment.

14.2 Reprocessing information

The subject device applicator handle is to be reprocessed in between uses as instructed in the device user manual. The handle should be thoroughly cleaned by the user by using 70% alcohol absorbed pad for at least 30 sec. The user should carefully examine the applicator components prior to their assembly and usage for complete drying and for any visible damage.

The device cleaning instructions were already validated for the predicate device.

14.3 Packaging, Shelf Life and Use Life

The shelf life of the System, excluding the applicator, is (b)(4) and the shelf life of the Morpheus8 Applicators components is (b)(4). The System and Applicators are composed of electronic components and plastic materials. Storage and aging do not have a significant impact on the integrity of these components, therefore (b)(4) respectively are a conservative estimate of device shelf life.

The InMode Morpheus8 Applicators treatment tips are for single use and should be discarded following treatment.

The reuse life of the InMode Morpheus8 Applicators components excluding the treatment tip is defined by the company as two years. The company provides a warranty for (b)(4) matching the reuse life period.

Reuse is limited by the applicator components' life time. The applicator cable may lose integrity during the repeated bending and unbending during treatment, transportation and storage.

The cable life time analysis:

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In conclusion, the critical components of the InMode Morpheus8 Applicators have a life time significantly exceeding the warranty of the device.

Section 15:

Biocompatibility

15.0 Biocompatibility

There was no change in the components' materials composing the Morpheus8 Applicators, nor in the production processes and in post-production processes (sterilization, reprocessing) that might influence the subject device biocompatibility in comparison to predicate device biocompatibility.

15.1 Applicator biocompatible components

The InMode Morpheus8 Applicators includes several components that come in contact with the human body:

- The applicator handle is in direct contact with the operator skin. (b)(4) (b)(4)
- The treatment tip is in direct contact with the patient skin. The tip outer part is (b)(4).
- The micro pin electrodes penetrate the skin upper layers up to a maximal depth of 7.0 mm. The micro pin-electrodes are made of (b)(4) (b)(4) Most of the pins' body is insulated (b)(4) (b)(4)

15.2 Applicator components categorization

The categorization of the applicator components is in accordance with the FDA recognized standard; ISO 10993-1 "Biological evaluation of medical devices, part-1: Evaluation and testing" and the FDA guidance: "Use of international standard ISO-10993, Biological evaluation of medical devices, part-1: Evaluation and testing".

The applicator handle grabbed by the practitioner, should be categorized as surface device, skin for ≤24 h contact duration.

The applicator treatment tip plastic housing can come in direct contact with the practitioner as well as with the patient skin and therefore it should be categorized as surface device, skin for ≤24 h contact duration.

The applicator micro pin electrodes penetrate the upper skin layers (up to 7.0 mm) during the RF local heating treatment. Due to the considerably low penetration depth there is no concern for other tissue breaching and therefore it should be categorized as surface device, skin for ≤24 h contact duration.

15.3 List of materials and their biocompatibility

The following table lists the materials that come in contact with the human body (*Table 15.1)*:

Table 15.1: InMode Morpheus8 Applicators list of materials that directly contact the human body

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The device components that come in direct contact with the user and patient's skin are the applicator handle and the tip heads. All device materials in contact with the patient are identical to the materials used in the FDA-Cleared device (K192695) and therefore are deemed biocompatible as well for the subject device of this 510(k) application.

Conclusively, the InMode Morpheus8 Applicators component materials meet the biocompatibility requirements.

Section 16:

Software

16. Software

16.1 General

The InMode System controller software configuration is based on the InMode System software design (as specified in K180189) with the additional configuration of the Morpheus8 Applicators integration, functionality and control units.

In addition to the main controller software unit, the applicator micro pin electrodes movement mechanism (motor) has its own software unit which is a subunit of the main software and is responsible for the motor operation.

Validation of the InMode System with the Morpheus8 Applicators software units was performed according to clause 14 of IEC 60601-1 Software requirements, IEC 62304:2004 to 62304:2006/A1:2016, Medical device, and Software life-cycle processes standards. The software related documents were composed according to the specific IEEE standards and in accordance with the SW FDA Level of Concern requirements as applied in *FDA Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices, issued May 11, 2005*.

No Off-the-Shelf software is used in the InMode Morpheus8 Applicators software.

The device software version is **(b)(4)** The software revision history log is provided in Appendix 16-1 to this section (InMode Doc No **(b)(4)**

A copy of the software development life cycle procedure is enclosed to this section as Appendix 16-2 (InMode Doc No **(b)(4)** Software Life Cycle Procedure).

16.2 Software classification

The subject device software level of concern is: **(b)(4)** following the *FDA Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices*).

The Software level of concern file is provided in Appendix 16-3 to this section (InMode Doc No. **(b)(4)**.

16.3 Risk Analysis

Risk analysis evaluation was conducted according to ISO 14971 Risk Management Standard. Special considerations were taken in designing the InMode Morpheus8 Applicators for the purpose of achieving its safe and reliable performance.

The Risk Analysis Document, which was developed during the design and development of the InMode Morpheus8 Applicators, is provided in Appendix 16-4 (InMode Doc. No. (b)(4). The different aspects of the device functionality (including software, materials, technical characteristics, etc.), which were evaluated by different sub-teams of the main development team, were integrated into this comprehensive risk analysis. All preventive and/or control actions were implemented or carried out on the InMode Morpheus8 Applicators in order to mitigate the potential device or component failures.

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16.4 Software Requirements and Design Specifications

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The main controller, applicator and applicator motor subset software design, functionality and requirements specifications are described in details at the software requirements specifications (SwRS) and at the software design description (SwDD) documents provided as Appendices 16-5 and 16-6 to this section.

16.5 Software V&V

The software/firmware was tested for functionality and complete integration with the device hardware. The software V&V test plan is provided as Appendix 16-7 to this section (InMode Doc. No. (b)(4) Each software unit was tested and validated as individual and as an integrated part of the system. All of the tests successfully passed. The test plans and results (SwTP) documents are provided in Appendix 16-8 to this section (InMode Doc. No. (b)(4) and (b)(4) for the main controller and applicator SwTP and the applicator motor SwTP, respectively).

16.6 ADDITIONAL SOFTWARE DOCUMENTS

The InMode System with the Morpheus8 Applicator software was further tested for code review in accordance with the requirements set forth in IEC 62304 and applicable standards. The InMode System with the Morpheus8 Applicator Software Code review summary report is provided in Appendix 16-9 (InMode Doc. No. (b)(4) to this section.

Traceability among requirements, specifications, identified hazards and mitigations, and Verification and Validation for the InMode System with the Morpheus8 Applicator and for applicator motor software are provided in Appendix 16-10 (InMode Doc. No. (b)(4) and (b)(4) to this section.

List of remaining software anomalies, annotated with an explanation of the impact on safety or effectiveness, including operator usage and human factors is provided in Appendix 16-11 (InMode Doc. No (b)(4) to this section.

16.7 SOFTWARE DEVELOPMENT ENVIRONMENT DESCRIPTION

In accordance with the *FDA Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices,* 510(k) file submissions of (b)(4) level of concern software medical devices (such as the software of the subject device) should contain in addition to the software development life cycle plan the following documentation:

- An annotated list of the control/baseline documents generated during the software development process and a list or description of software coding standards. The InMode System with the Morpheus8 Applicator Software Coding Standard and Guidelines is provided in Appendix 16-12 (InMode Doc. No. (b)(4) to this section.
- Software configuration management and maintenance plan (SCMP) is provided in Appendix 16-13 (InMode Doc. No. (b)(4) to this section.
- Software development and management plan (SDMP) is provided in Appendix 16-14 (InMode Doc. No. (b)(4) to this section.

16.8 CYBERSECURITY

The InMode System with the Morpheus8 Applicator Cybersecurity policy was designed and developed in accordance with the following FDA Guidance Documents:

- *FDA CDRH Guidance on the Content of Premarket Submissions for Management of Cybersecurity in Medical Devices. Draft, October 2, 2014.*
- *FDA CDRH Guidance on Post market Management of Cybersecurity in Medical Devices, Issued, Dec 28, 2016.*

The InMode RF System with the Morpheus8 Applicator contains the following external system interfaces:

- The InMode System (with the Morpheus8 Applicator) has a dedicated user interface including an LCD touch panel. The software user interface is a dedicated one that does not allow execution of external programs.
- Software updates are performed on the InMode System (with the Morpheus8 Applicator) by inserting a software plug with unique connector, containing application executable code.
- The InMode System (with the Morpheus8 Applicator) is connected to a standard power outlet.
- The InMode System (with the Morpheus8 Applicator) includes Applicator connector.
- There is no device connection to the internet or other external devices.

An analysis of potential vulnerabilities related with the InMode System (with the Morpheus8 Applicator) Cybersecurity control was conducted with no detected vulnerabilities.

The InMode System (with the Morpheus8 Applicator) Cybersecurity Evaluation Report is provided in Appendix 16-15 (InMode Doc. No **(b)(4)**) to this section.

16.9 List of related software documentation

The following software validation documents for the InMode Morpheus8 Applicators software are provided in Appendices 16-1 to 16-11:

Appendix 16-1: Software revision history log

Appendix 16-2: Software development life cycle procedure

Appendix 16-3: Software level of concern file

Appendix 16-4: Risk Analysis Document

Appendix 16-5-1: Main controller and applicator software requirements specifications (SwRS)

Appendix 16-5-2: Applicator motor software requirements specifications (SwRS)

Appendix 16-6-1: Main controller and applicator software design description (SwDD)

Appendix 16-6-2: Applicator motor software design description (SwDD)

Appendix 16-7: software V&V test plan

Appendix 16-8-1: Main controller and applicator test plans and results (SwTP)

Appendix 16-8-2: Applicator motor test plans and results (SwTP)

Appendix 16-9: Code review summary report

Appendix 16-10-1: Main controller and applicator traceability Matrix

Appendix 16-10-2: Applicator motor traceability Matrix

Appendix 16-11: Unresolved Anomalies

Appendix 16-12: Software Coding Standard and Guidelines

Appendix 16-13: Software configuration management and maintenance plan (SCMP)

Appendix 16-14: Software development and management plan (SDMP)

Appendix 16-15: Cybersecurity Evaluation Report

APPENDIX 16-1

Software Revision History Log

(InMode Doc. No. (b)(4))

Morpheus8 Revision History Log

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APPENDIX 16-2

(b)(4) Inv Software Life Cycle Procedure

Approval signatures			
Authorized By	**Position**	**Signature**	**Date**
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Revision History			
Revision	**Description**	**Author**	**Date**
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APPENDIX 16-3

Software Level of Concern File

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APPENDIX 16-4

Risk Analysis Document

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Appendix 16-5

Software Requirements Specifications (SwRS)

Contains:

1. Appendix 16-5-1: Main Controller and Applicator Software Requirements Specifications (SwRS)
2. Appendix 16-5-2: Applicator Motor Software Requirements Specifications (SwRS)

Appendix 16-5-1:

Main Controller and Applicator Software Requirements Specifications (SwRS)

(InMode Doc. No. (b)(4)

Morpheus8 Software Requirements Specifications

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Approval signatures			
Authorized By	Position	Signature	Date
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Revisions

Rev.	Page	Description	Approval	Date
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Appendix 16-5-2:

Applicator Motor Software Requirements Specifications (SwRS)

(InMode Doc. No. (b)(4)

Morpheus8 Applicator Software Requirements Specifications.

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Appendix 16-6

Software Design Description (SwDD)

Contains:

1. **Appendix 16-6-1: Main Controller and Applicator Software Design Description (SwDD)**
2. **Appendix 16-6-2: Applicator Motor Software Design Description (SwDD)**

Appendix 16-6-1:

Main Controller and Applicator Software Design Description (SwDD)

(InMode Doc. No. (b)(4)

MORPHEUS8 SDD

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Approval signatures			
Authorized By	Position	Signature	Date
(b)(4)			

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Revisions

Rev.	Page	Description	Approval	Date
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Appendix 16-6-2:

Applicator Motor Software Design Description (SwDD)

(InMode Doc. No. (b)(4))

Morpheus 8 Applicator Software Design Descriptions

(b)(4)

Approval signatures			
Authorized By	Position	Signature	Date
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Appendix 16-7

Software V&V Test Plan

(InMode Doc. No. (b)(4)

Morpheus8

Software Verification and Validation Plan

(b)(4)

Approval signatures			
Authorized By	Position	Signature	Date
(b)(4)			

Revisions

Rev.	Description	Originator	Date
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Appendix 16-8

Test Plans and Results (SwTP)

Contains:

1. **Appendix 16-8-1: Main Controller and Applicator Test Plans and Results (SwTP)**
2. **Appendix 16-8-2: Applicator Motor Test Plans and Results (SwTP)**

Appendix 16-8-1:

Main Controller and Applicator Test Plans and Results (SwTP)

(InMode Doc. No. (b)(4)

Morpheus8 Software Test Plan and Results

(b)(4)

Approval signatures			
Authorized By	Position	Signature	Date
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Appendix 16-8-2:

Applicator Motor Test Plans and Results (SwTP)

(InMode Doc. No. (b)(4)

1.1.1

Morpheus 8 Applicator Software Test Plan and Results

(b)(4)

Approval signatures			
Authorized By	Position	Signature	Date
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Appendix 16-9

Code Review Summary Report

(InMode Doc. No. (b)(4)

Morpheus8 Hand Piece Code Review

(b)(4)

Approval signatures			
Authorized By	Position	Signature	Date
(b)(4)			

Revisions

Rev.	Description	Originator	Date
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Appendix 16-10

Traceability Matrix

Contains:

1. Appendix 16-10-1: Main Controller and Applicator Traceability Matrix
2. Appendix 16-10-2: Applicator Motor Traceability Matrix

Appendix 16-10-1:

Main Controller and Applicator Traceability Matrix

(InMode Doc. No. (b)(4)

Morpheus8 Traceability Matrix

(b)(4)

Approval signatures			
Authorized By	Position	Signature	Date
(b)(4)			

Revisions

Rev.	Page	Description	Approval	Date
(b)(4)				

(b)(4)

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Appendix 16-10-2:

Applicator Motor Traceability Matrix

(InMode Doc. No. (b)(4)

Morpheus8 applicator Traceability Matrix

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Approval signatures			
Authorized By	Position	Signature	Date
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Revisions

Rev.	Page	Description	Approval	Date
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Appendix 16-11

Unresolved Anomalies

(InMode Doc. No (b)(4)

(b)(4)

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APPENDIX 16-12

Software Coding Standard and Guidelines

(InMode Doc. No. (b)(4)

INMODE CODING STANDARDS AND GUIDELINES

(b)(4)

Approval signatures			
Authorized By	**Position**	**Signature**	**Date**
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APPENDIX 16-13

Software Configuration Management and Maintenance Plan (SCMP)

(InMode Doc. No. (b)(4)

Software Configuration Management Plan

(b)(4)

Approval signatures			
Authorized By	**Position**	**Signature**	**Date**
(b)(4)			

Revisions

Rev.	Page	Description	Approval	Date
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Appendix 16-14

Software Development and Management Plan (SDMP)

(InMode Doc. No. (b)(4))

Morpheus8
Software Development Plan

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Approval signatures			
Authorized By	Position	Signature	Date
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Appendix 16-15

Cybersecurity Evaluation Report

(InMode Doc. No. (b)(4)

Morpheus8

Cybersecurity Evaluation

Report

(b)(4)

Approval signatures			
Authorized By	Position	Signature	Date
(b)(4)			03/03/2020
			03/03/2020
			03/03/2020

Revisions

Rev.	Page	Description	Approval	Date
(b)(4)				

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Section 17:

Electromagnetic Compatibility and Electrical Safety

17. Electromagnetic Compatibility and Electrical Safety

17.1 Compliance to standards

The InMode System with the Morpheus8 Applicators which is the subject of this 510(k) file slightly differs from its predicate device in its increased microneedles penetration depth potential. This modification has no influence on device electrical safety or on its electromagnetic compatibility. (b)(4)

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The InMode System with the Morpheus8 Applicators is in full compliance with the following 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 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

17.2 Test Reports and Certificates

The test certificates demonstrate that the InMode System with the Morpheus8 Applicators complies with the requirements of all of the above-mentioned standards. The test certificates and reports for the InMode System with the Morpheus8 Applicators are provided in Appendix 17-1 to Appendix 17-3. Compliance with these standards was declared in Section 9 of this 510(k) submission.

Appendix 17-1:

IEC 60601-1 Test Report

Test Report issued under the responsibility of:

The Standards Institution of Israel

IEC 60601-1
Medical electrical equipment
Part 1: General requirements for basic safety and essential performance

Report Reference No. ..... :	(b)(4)
Date of issue ..... :	03.10.2019
Total number of pages ..... :	123
CB Testing Laboratory ..... :	(b)(4)
Address ..... :	
Applicant's name ..... :	InMode MD Ltd.
Address ..... :	Tabor House, Industrial Park South Yokneam 20692, POB 44, Israel
Test specification:	
Standard ..... :	IEC 60601-1:2005 (Third Edition) + CORR. 1:2006 + CORR. 2:2007 + A1:2012 (or IEC 60601-1: 2012 reprint)
Test procedure ..... :	(b)(4)
Non-standard test method ..... :	
Test Report Form No. ..... :	(b)(4)
Test Report Form Originator ..... :	
Master TRF ..... :	

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APPENDIX 17-2:

ELECTROMAGNETIC COMPATIBILITY TESTING (IEC 60601-1-2) TEST CERTIFICATE & REPORT

Contains:

Appendix 17-2-1: IEC 60601-1-2 Test certificate

Appendix 17-2-2: IEC 60601-1-2 Test Report

Appendix 17-2-1:

IEC 60601-1-2 Test Certificate

(b)(4)

Appendix 17-2-2:

IEC 60601-1-2 Test Report

(b)(4)

Test Report No. (b)(4)

Applicant: *InMode LTD.*

Equipment Under Test:

RF System

Name: *InMode RF*

Model: *InMode RF with RF Hand pieces*

Issued by:

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APPENDIX 17-3:

PARTICULAR REQUIREMENTS FOR THE BASIC SAFETY AND ESSENTIAL PERFORMANCE OF HIGH FREQUENCY SURGICAL EQUIPMENT AND HIGH FREQUENCY SURGICAL ACCESSORIES (IEC 60601-2-2) TEST REPORT

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TEST REPORT
IEC 60601-2-2
Medical electrical equipment
Part 2: Particular requirements for the basic safety and essential performance of high frequency surgical equipment and high frequency surgical accessories

Report Number..... :	(b)(4)
Date of issue..... :	03.10.2019
Total number of pages ..... :	48
Name of Testing Laboratory preparing the Report ..... :	(b)(4)
Applicant's name ..... :	InMode MD Ltd.
Address..... :	Tabor House, Industrial Park South Yokneam 20692, POB 44, Israel
Test specification:	
Standard ..... :	IEC 60601-2-2: 2017 for use in conjunction with IEC 60601-1:2005, COR1:2006, COR 2:2007, AMD1:2012 or IEC 60601-1:2012
Test procedure..... :	(b)(4)
Non-standard test method ..... :	

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Section 18:

Performance Testing-Bench

18.0 Performance Testing

As mentioned in earlier sections of this 510(k) file submission, the subject device and FDA-Cleared Morpheus8 Applicators (K192695) have identical indications for use but slightly different specifications. The change in specifications focuses on the maximal 24 and 40 pin tip microneedles penetration depth, which is controlled by the software. While the Morpheus8 Applicators (K192695) were previously limited to a penetration depth of 4mm, the current software update enables the Morpheus8 24 and 40 pin tips, which are basically the same tips, a penetration depth variety ranging between 1-7 mm for the 24 tip-head and 2-7 mm for the 40 tip-head. No mechanical or hardware modifications were performed neither in the InMode platform, nor on the Morpheus8 Applicator and 24/40 pin Tips to support this change. The software and user interface were adjusted to fit this change.

In order to ensure that the subject device performs safely and effectively on target tissues to achieve its intended use of electrocoagulation and hemostasis in deeper tissues of up to 5, 6 and 7 mm an *ex-vivo* tissue study was performed by the sponsor.

The purpose of the *ex-vivo* test was to evaluate and compare the fractional coagulation necrosis pattern of target tissues, formed by thermal effect of the InMode System with the Morpheus8 Applicators 24 and 40 pin tip heads in different tissue depths.

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In its study design the sponsor took into consideration the recommendations set forth in the FDA Guidance Document on *Premarket Notification (510(k)) Submissions for*

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Study Objectives:

To evaluate the fractional coagulation necrosis pattern of tissues, formed by the InMode System with the Morpheus8 Applicators 24 and 40 pin tip heads in different tissue depths.

Study Design:

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A tabular representation of the treatment settings is provided in ***Table 18.1***.

Table 18.1: Treatment settings used in the study

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Figure 18-1: InMode System with the Morpheus8 Applicator User Interface Treatment Screen

Materials and Methodology:

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tissues.

Conclusions:

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APPENDIX 18-1

BENCH TEST PROTOCOL

EX-VIVO EVALUATION OF THE FRACTIONAL COAGULATION NECROSIS PATTERN FORMED BY THE INMODE DEVICE WITH MORPHEUS8 APPLICATOR IN DIFFERENT TISSUE DEPTHS

EX-VIVO TEST PROTOCOL

PROTOCOL NO.: (b)(4)
VERSION: (b)(4)
January (b)(4)

InMode Ltd. Tavor House, POB 533, Industrial Park South, Yokneam, 2069206, Israel

Approvals

Name & Position	Signature	Date
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Revision History

Rev.	Date	Originator	Company	Comment
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APPENDIX 18-2

BENCH TEST REPORT

EX-VIVO EVALUATION OF THE FRACTIONAL COAGULATION NECROSIS PATTERN FORMED BY THE INMODE DEVICE WITH MORPHEUS8 APPLICATOR IN DIFFERENT TISSUE DEPTHS

EX-VIVO TEST REPORT

STUDY REPORT NO.: (b)(4)

VERSION (b)(4)

STUDY PROTOCOL NO.: (b)(4)

March 2020

InMode Ltd. Tavor House, POB 533, Industrial Park South, Yokneam, 2069206, Israel

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APPENDIX 1

A COMPUTER-VALIDATED, AIDED DESIGN OF (b)(4) SOFTWARE – VALIDATION REPORT

Tavor Building, Yokneam
P.O.B. 533, Israel, 20692
Tel: (972) 4 9097470
Fax: (972) 4 9097471

Surface Area Measurement Tool Validation Procedure

(b)(4)

Approvals

Approval signatures			
Authorized By	Position	Signature	Date
(b)(4)			

Revisions

Rev.	Description	Updated by	Date
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APPENDIX 2

EVALUATION OF THE (b)(4) BY THE COMPUTER-AIDED DESIGN OF (b)(4) SOFTWARE

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Section 19:

Performance Testing – Animal

Not Applicable

Section 20:

Performance Testing – Clinical

Not Applicable

Section 21:

Other

Not Applicable

A. Stein
REGULATORY AFFAIRS CONSULTING LTD.
Beit Hapa'amon (Box 124)
20 Hata'as St., 4442520 Kfar Saba ISRAEL
Tel: +972-9-767-0002 Fax: +972-9-766-8534
E-mail: ahava@asteinrac.com

K200947/S001

June 10, 2020

510(k) Document Mail Center (WO66-0609)
Office of Device Evaluation
Center for Devices and Radiological Health
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002
U.S.A.

Re: K200947 AINN Response letter for the InMode System with the Morhpeus8 Applicators

Dear Mykhaylo Nosovskyy,

Further to your K200947 AINN hold letter, dated June 07, 2020, enclosed please find our responses. The enclosed response is arranged such that the questions from your e-mail letter are printed in bold lettering with our responses following in regular print.

The e-copy is an exact duplicate of the paper copy.

I trust that the information included in this supplement, will be adequate to allow for its prompt review. If you have any questions or comments, please don't hesitate to contact me at the following telephone no. +972-9-767002, fax no. +972-9-7668534 or by e-mail to amit@asteinrac.com.

Thank you for your cooperation and understanding.

Sincerely yours,

(b)(6)

Amit Goren, PhD,
Senior Regulatory Affairs Consultant,
A. Stein – Regulatory Affairs Consulting Ltd.,
for InMode Ltd.

164

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K200947

Device Name
InMode System with the Morpheus8 Applicators

Indications for Use *(Describe)*
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.

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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Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

Appendix 4.0: Revised Brochure

INMODE

MORPHEUS8

The Deepest Subdermal Fractional Technology

WWW.INMODEMD.COM

MORPHEUS8

MORPHEUS8

The InMode System with the Morpheus8 Applicators employs fractional RF multi-electrode technology for dermatological procedure requiring electrocoagulation and hemostasis.

It is designed to deliver RF energy to the target tissue in a fractional manner, via an array of 12, 24 or 40 pin electrodes arranged on a detachable sterilized disposable tip.

The pin array delivers RF energy to the tissue, resulting in heating of surrounding tissue around the electrodes contact, to temperatures leading to electrocoagulation and hemostasis of micro tissue zones.

BENEFITS

- Advanced design creates extremely uniform effect.
- Little to no thermal damage to dermis.

- Morpheus8 Prime (12 pin) Tip : Dermal and subdermal treatment of small areas difficult to maneuver.
- Morpheus8 T Tip: Superficial (epidermal) treatment.
- Morpheus8 (24 pin) Tip : Dermal and subdermal treatment.
- Morpheus8 Body (40 pin) Tip : Dermal and sub-dermal treatment of large body areas.