510(K) SUMMARY

INMODE RF SYSTEM

510(k) Number K163190

Applicant Name:

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Trade Name: InMode RF System

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

Classification: Class II Medical Device

Predicate Device:

InMode RF System is substantially equivalent to the previously cleared, InMode RF System, also manufactured by InMode MD Ltd.

Device	Manufacturer	510(k) No.
InMode RF System	InMode MD Ltd.	K151793

Device Description:

The InMode RF System (InMode MD Ltd.) is a computerized system generating RF energy with integral temperature and impedance feedback mechanism for procedures requiring electrocoagulation and hemostasis. The InMode RF System constantly monitors the temperature and impedance of the target treatment tissue, automatically adjusting energy delivery to maintain effective and safe tissue heating.

The InMode RF System consists of an AC/DC power supply unit, RF generator, controller and user interface including touch screen. The RF hand piece is connected to the console via a cable and a foot switch activates the energy delivery to the hand piece. The hand piece is comprised of a disposable, single use; internal and external electrodes.

The InMode RF System is compatible with the following hand pieces:

- HP101306A (optional sterile/non-sterile)
- HP172206A (non-sterile)

Device Specifications:

Main Line Frequency (nominal)	50 - 60 Hz
Input Voltage (nominal)	100 - 240 VAC
Electrosurgical Unit dimensions (inch)	14.2’’W x 18.2’’D x 40’’H
Platform weight (lb.)	33
RF Max Output Power (Watt)	20
RF Output Frequency (MHz)	1± 2%

Intended Use/Indication for Use:

The InMode RF System is indicated for use in dermatological and general surgical procedures for electrocoagulation and hemostasis.

Performance Standards:

InMode RF System 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.
- AAMI / ANSI / ISO 11137-1:2006/(R)2010, Sterilization Of Health Care Products - Radiation - Part 1: Requirements For Development, Validation, And Routine Control Of A Sterilization Process For Medical Devices
- AAMI / ANSI / ISO 11137-2:2013, Sterilization Of Health Care Products - Radiation - Part 2: Establishing The Sterilization Dose.
- AAMI / ANSI / ISO 11737-1:2006 (R) 2011, Sterilization Of Health Care Products - Microbiological Methods - Part 1: Determination Of The Population Of Microorganisms On Product.
- AAMI / ANSI / ISO 11737-2:2009/(R) 2014, Sterilization Of Medical Devices - Microbiological Methods - Part 2: Tests Of Sterility Performed In The Definition, Validation And Maintenance Of A Sterilization Process.
- AAMI / ANSI / ISO 11607-1:2006/(R)2010, Packaging For Terminally Sterilized Medical Devices - Part 1: Requirements For Materials, Sterile Barrier Systems And Packaging Systems
- ASTM F1980-07 (Reapproved 2011), Standard Guide For Accelerated Aging Of Sterile Barrier Systems For Medical Devices.

Non-Clinical (Bench) Performance Data:

The InMode RF System with the HP172206A hand piece was utilized in bench performance tests to evaluate the system performance specifications. The tests were performed in a similar manner as to the tests performed with the cleared predicate device. The results of the bench tests demonstrate that the InMode RF System with the HP172206A hand piece performed in a similar way to the predicate device.

Animal Performance Data / Histology Data:

The thermal effects of the InMode RF System with the HP172206A hand piece on the target tissue were evaluated in an *ex-vivo* study. The study was conducted on three different porcine tissue models (muscle, liver & fat) and included a single RF treatment followed by TTC staining analysis. The *ex-vivo* study results show that the InMode RF

System with the HP172206A hand piece is safe for use and effective in achieving the specified indications of dermatological and general electrocoagulation and hemostasis.

Clinical Performance Data:

Not Applicable

Substantial Equivalence:

The subject of this special 510(k) pre-market notification is the InMode RF System. It is composed of the same main device components as its predicate device the InMode RF System FDA cleared under 510(k) file No.K151793 accept for the addition of modified hand piece versions. The components of modified InMode RF System, similarly to cleared, predicate device, generate its mechanism of operation using the same underlying technology for the same intended use. Delivery of monopolar RF energy through each specific hand piece is monitored and controlled by the device ESU. The user interface control panel provides the user with the optimal treatment settings. Using both modified and cleared devices the device user can decide on the optimal treatment settings and adjust these treatment settings through the control panel. Furthermore, the modified device, as the cleared device, introduces similar safety features and comply with same relevant consensus standards.

The device modifications were evaluated under design control activities and in the frame of conformity with relevant consensus standards and all potential hazards were mitigated in a set of performance activities. Performance bench and ex-vivo tests results show that the modified device was able to produce and deliver the desired RF energy according to the design requirements, which are comparable with the predicate device. Labeling material was revised to support the device modifications. All performance activates show that the modifications made to the cleared device do not pose any new safety and effectiveness concerns.

Conclusions:

Based on the comparison to predicate device and on the performance testing, the InMode RF System is substantially equivalent to the predicate InMode RF System for the mentioned indication for use.