APR 2 2013

510(K) SUMMARY

INMODE SR DEVICE

510(k) Number K123860

Applicant Name:

Company Name: InMode MD Ltd.
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Date Prepared: December 6, 2012

Trade Name: InMode SR IPL Device

Classification Name: CFR Classification section 878.4810; (Product code ONF)

Classification: Class II Medical Device

Predicate Device:

The InMode SR IPL device is substantially equivalent to the following predicate devices.

Manufacturer	Device	510(k) No.
Sciton	Profile BBL	K032460

Device Description:
The InMode SR IPL device is designed to deliver optical energy to the skin via a pre-cooled sapphire block. The good optical contact between sapphire block and skin is achieved by using water based gel. The device provides individual adjustment of light fluence and pulse duration to achieve maximum efficiency and safety for each patient. The hand piece has integrated skin cooling to enhance safety and comfort of the treatment.

The InMode SR IPL device consists of an AC/DC power supply unit, water cooling system, controller, user interface including a LCD screen and functional buttons and IPL hand piece. The IPL hand piece is connected to the console via a cable. The hand piece comprises a flash lamp, reflector, water flow tube and cooled sapphire output window (10 x 30 mm).

Following are the InMode SR IPL device specifications:
Wavelength: 515 - 1200 nm
Energy Density (Fluence): 10-30 J/cm^2
Pulse Duration: 4-27 msec
Pulse repetition rate: up to 1 Hz
Spot/scan size: 10 x 30 mm
Skin cooling: Continuous contact cooling

Intended Use/Indication for Use:
The InMode SR IPL Device wavelengths (515-1200nm) are indicated for use for the following treatments:

- The treatment of benign pigmented epidermal lesions, including dyschromia, hyperpigmentation, melasma, ephelides (freckles);
- The treatment of benign cutaneous vascular lesions, including port wine stains, facial, truncal and leg telangiectasias, rosacea, erythema of rosacea, angiomas and spider angiomas, poikilodenna of Civatte, superficial leg veins and venlous malformations.

Performance Standards:

The InMode SR IPL Device has been tested and complies with the following voluntary recognized standards:

- IEC 60601-1, Medical Electrical Equipment - Part 1: General Requirements for Safety, 1988; Amendment 1, 1991-11, Amendment 2, 1995
- IEC 60601-1-2, (Second Edition, 2001), Medical Electrical Equipment - Part 1-2: General Requirements for Safety - Collateral Standard: Electromagnetic Compatibility -- Requirements and Tests
- IEC 60601-1-4 Medical electrical equipment – Part 1-4:General requirements for safety – Collateral Standard: Programmable electrical medical systems
- IEC 60601-2-57 standard; Medical Electrical Equipment – Part 2-57: Particular Requirements for the Basic Safety and Essential Performance of Non-Laser Light Source Equipment Intended for Therapeutic, Diagnostic, Monitoring and Cosmetic/Aesthetic Use

Non-Clinical Performance Data:

Not Applicable

Clinical Performance Data:

Not Applicable

Substantial Equivalence:

The indications for use and technological characteristics of the InMode SR IPL device are substantially equivalent to the indications for use and technological characteristics of the Profile BBL device.

The design and components in the InMode SR IPL device, including the console (with power supply, software, cooling system and control and display panel) and the water-cooled hand piece (with cable and connector to console) are similar to the design and components found in the Profile BBL device.

The performance specifications (including wavelength, fluence, pulse duration, pulse repetition rate, spot size and cooling) in InMode SR IPL device are similar to performance specifications in the Profile BBL device.

Comparison Table 1 – Indication for Use Treatment of Vascular Lesions

Device	**InMode SR**	**Profile BBL**
Company	InMode MD	Sciton
510(k) No.	K123860	K032460
Intended Use	Treatment of benign cutaneous vascular lesions, including port wine stains, facial, truncal and leg telangiectasias, rosacea, erythema of rosacea, engiomas and spider angiomas, poikiloderma of Civatte, superficial leg veins and venous malformations	Treatment of benign cutaneous vascular lesions, including port wine stains, facial, truncal and leg telangiectasias, rosacea, erythema of rosacea, engiomas and spider angiomas, poikiloderma of Civatte, superficial leg veins and venous malformations
Wavelength	515-1200nm 580-1200nm	515-1400nm 560-1400nm 590-1400nm
Energy density	10-30 J/cm^2	10-30 J/cm^2
Pulse duration	5-30ms	10-30ms
Pulse repetition rate	1pps	Up to 1pps
Pulse sequence	Single Pulse	Single pulse
Delay between sub-pulses	N/A	N/A
Spot size	10x30mm	10x50mm maximal, 7mm round minimal
Cooling method	Contact Cooling (10°C-25°C)	Contact Cooling (10°C-35°C)

Comparison Table 2 – Indication for Use Treatment of Pigments Lesions

Device	**InMode SR**	**Profile BBL**

Company	InMode MD	Sciton
510(k) No.	K123860	K032460
Intended Use	Treatment of benign pigmented lesions including dyschromia, hyperpigmentation, melasma, ephelides (freckles)	Treatment of benign pigmented lesions including dyschromia, hyperpigmentation, melasma, ephelides (freckles)
Wavelength	515-1200nm 580-1200nm	515-1400nm 560-1400nm 590-1400nm
Energy density	10-30 J/cm^2	10-30 J/cm^2
Pulse duration	5-30ms	10-30ms
Pulse repetition rate	1pps	Up to 1pps
Pulse sequence	Single Pulse	Single pulse
Delay between sub-pulses	N/A	N/A
Spot size	10x30mm	10x50mm maximal, 7mm round minimal
Cooling method	Contact Cooling (10°C-25°C)	Contact Cooling (10°C-35°C)

The safety features in the InMode SR IPL device are substantially equivalent to the safety features found in the predicate device. Any minor differences in the technological characteristics do not raise new safety or effectiveness concerns. Furthermore, the new InMode SR IPL device underwent performance testing, including software validation testing, electrical and mechanical safety testing according to IEC 60601-1, electromagnetic compatibility testing according to IEC 60601-1-2 and safety and essential performance testing of non-laser light source equipment according to IEC 60601-2-57. These performance tests demonstrated that the minor differences in the device software and specifications meet the system requirements and do not raise new safety or effectiveness concerns.

Consequently, it can be concluded that the InMode SR IPL device is substantially equivalent to the predicate Profile BBL device and therefore, may be legally marketed in the USA.

Conclusions:

Based on the performance testing and comparison to predicate devices, the InMode SR IPL device is substantially equivalent to the predicate device listed above.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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Silver Spring, MD 20993-0002

Inmode MD, Limited
% A. Stein-Regulatory Affairs Consulting, Limited
Ms. Ahava Stein
General Manager
20 Hata'as Street, Suite 102
Kfar Saba, Israel 44425

Letter dated: April 2, 2013

Re: K123860
Trade/Device Name: InMode SR IPL Device
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: Class II
Product Code: ONF
Dated: February 28, 2013
Received: March 07, 2013

Dear Ms. Stein:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (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. 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.

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); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/cdrh/mdr/ for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson -S

Mark N. Melkerson
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

INDICATIONS FOR USE

510(k) Number: K123860

Device Name: InMode SR IPL Device

Intended Use Statement:

The InMode SR IPL Device wavelengths (515-1200nm) are indicated for use for the following treatments:

- The treatment of benign pigmented epidermal lesions, including dyschromia, hyperpigmentation, melasma, ephelides (freckles);
- The treatment of benign cutaneous vascular lesions, including port wine stains, facial, truncal and leg telangiectasias, rosacea, erythema of rosacea, angiomas and spider angiomas, poikiloderma of Civatte, superficial leg veins and venous malformations.

Prescription Use __√__ OR Over-The-Counter Use ___
(Per 21 C.F.R. 801 Subpart D) (Optional Format Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R Ogden -S
2013.03.27 17:05:37 -04'00'
(Division Sign-Off) for MXM
Division of Surgical Devices
510(k) Number K123860

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