JAN - 9 2014

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SECTION 6

510(k) Summary

510 (k) Number: K130888
Date of Submission: June 20, 2013

Submitter: IBRAMED EQUIPAMENTOS MEDICOS
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Common Name:	Ultrasonic Diathermy
Trade Name:	Sonopulse; Sonopulse III
Classification:	Class II
Product Code:	IMI
Classification Panel:	Physical Medicine
Regulation Numbers:	21 CFR 890.5300
Substantial Equivalence:	Sonicator Plus 930, ME 930 K013192

Indications for Use

Therapeutic Ultrasound

- Pain relief
- Reduction of muscle spams
- Localized increase in blood flow
- Increase range of motion of contracted joints using heat and stretch techniques

Device Description

The Sonopulse III offers 1.1 and 3.3MHz ultrasound using a 7cm^2 transducer. The membrane panel provides both tactile and audio feedback when the buttons are pressed. A provides a through set-up routine for the operator. The display will show which treatment has been chosen and when the output is active.

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The Sonopulse offers 1.1 and 3.3MHz ultrasound using a $7cm^2$ or $3cm^2$ transducer. The membrane panel provides both tactile and audio feedback when the buttons are pressed. A provides a through set-up routine for the operator. The display will show which treatment has been chosen and when the output is active.

Device Comparison Table

Features	Subject Devices		Predicate Device
	Sonopulse by Ibramed	Sonopulse III by Ibramed	Sonicator Plus 930 by Mettler K013192
Indications for Use	Therapeutic Ultrasound Pain relief Reduction of muscle spams Localized increase in blood flow Increase range of motion of contracted joints using heat and stretch techniques	Therapeutic Ultrasound Pain relief Reduction of muscle spams Localized increase in blood flow Increase range of motion of contracted joints using heat and stretch techniques	Therapeutic Ultrasound Pain relief Reduction of muscle spams Localized increase in blood flow Increase range of motion of contracted joints using heat and stretch techniques Neuromuscular Stimulation Symptomatic relief of chronic intractable pain, acute post traumatic pain or acute post surgical pain (interferential and premodulated waveforms) Temporary relaxation of muscle spasms (all waveforms) Prevention of post-surgical phlebo-thrombisis through immediate stimulation of calf muscles (all waveforms) Increase blood flow in the treatment area (all waveforms) Prevention or retardation of disuse atrophy in post injury type conditions

			(all waveforms) Muscle re-educations (all waveforms) Maintain or increasing range of motion (all waveforms)
Power Source	(AC Line)100 - 240V~ 50/60Hz	(AC Line)100 - 240V~ 50/60Hz	AC Line
Maximum Treatment Time	30 minutes	30 minutes	30 minutes
Frequency	1.1 MHz ±10% 3.2 MHz ±10%	1.1 MHz ±10% 3.2 MHz ±10%	1.1 MHz ±10% 3.2 MHz ±10%
Modes	Continuous Pulsed-20% and 50% duty cycle	Continuous Pulsed-20% and 50% duty cycle	Continuous Pulsed-20% duty cycle
Pulse Repetition	100Hz 16Hz 48Hz	100Hz 16Hz 48Hz	100Hz ±20%

Substantial Equivalence

The subject and the predicate devices have the same intended use, the same operating principle, and are similar in their hardware configuration.

Technology

The Sonopulse III by Ibramed is a therapeutic ultrasound machine that operates at a 1.1 or 3.3 MHz frequency. The two frequency outputs penetrate to a depth of 5cm and 1 or 2cm respectively.

The Sonopulse by Ibramed is a therapeutic ultrasound machine that operates at a 1.1 or 3.3 MHz frequency. The two frequency outputs penetrate to a depth of 5cm and 1 or 2cm respectively.

Non-Clinical Testing

This submission includes testing results of the Sonopulse and Sonopulse III. Testing was performed in accordance with the IEC tests submitted in the Declaration of Conformity. The subject and predicate devices have all been tested in accordance with the following IEC tests:

IEC 60601-1: The general standard IEC 60601-1 - Medical equipment|medical electrical equipment - Part 1: General requirements for basic safety and essential performance - gives general requirements of the series of standards. It is used as a bench mark for many electrical medical devices. Both the subject and predicate devices comply with this standard.

The standard contains requirements concerning basic safety and essential performance that are generally applicable to medical electrical equipment.

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For certain types of medical electrical equipment, these requirements are either supplemented or modified by the special requirements of a collateral or particular standard. Where particular standards exist, this standard should not be used alone.

IEC 60601-1-2: Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility – Requirements and tests

This collateral standard applies to electromagnetic compatibility of medical electrical equipment and medical electrical systems. The object of this collateral standard is to specify general requirements and tests for electromagnetic compatibility of medical electrical equipment and medical electrical systems. They are in addition to the requirements of the general standard and serve as the basis for particular standards. Both the subject and predicate devices comply with this standard.

IEC 60601-2-5: Medical electrical equipment - Part 2-5: Particular requirements for the basic safety and essential performance of ultrasonic physiotherapy equipment

IEC 60601-2-5 applies to the basic safety and essential performance of ultrasonic physiotherapy equipment employing a single plane unfocused circular transducer per treatment head, producing static beams perpendicular to the face of the treatment head. This standard can also be applied to ultrasonic physiotherapy equipment used for compensation or alleviation of disease, injury or disability. Both the subject and predicate devices comply with this standard.

Conclusion

Based on the data and information presented in this submission, the Sonopulse and Sonopulse III are substantially equivalent to the currently legally marketed Sonicator Plus 930. The differences between the subject and predicate devices do not affect the safety or effectiveness of the proposed device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

January 9, 2014

IBRAMED – Industria Brazileria de EQUIPAMENTOS MEDICOS Ltda
c/o Tara Conrad
TechLink International Consulting
18851 NE 29th Ave. Suite 720
Aventura, Florida 33180 USA

Re: K130888
Trade/Device Name: Sonopulse and Sonopulse III
Regulation Number: 21 CFR 890.5300
Regulation Name: Ultrasonic Diathermy
Regulatory Class: Class II
Product Code: IMI
Dated: December 17, 2013
Received: December 19, 2013

Dear Ms. Conrad:

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. 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); 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 contact 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/MedicalDevices/ResourcesforYou/Industry/default.htm. 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/MedicalDevices/Safety/ReportaProblem/default.htm 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/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Carlos L. Peña -S

Carlos Peña, PhD, MS
Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K130888

Device Name: Sonopulse and Sonopulse III

Indications For Use:

Therapeutic Ultrasound:

- Pain relief
- Reduction of muscle spasms
- Localized increase in blood flow
- Increase range of motion of contracted joints using heat and stretch techniques

Prescription Use __X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of Center for Devices and Radiological Health (CDRH)

Carlos L. Pena -S