December 23, 2021

Carci Industria E Comercio De Aparelhos Cirurgicos E Orto
℅ Bruno Milhoci
Regulatory Affairs Specialist
PR Servicos Regulatorios Administrativos Ltda
Rua Alice Aem Saadi, 855/ 2404
Ribeirao Preto, SP 14096-570
Brazil

Re: K202788
Trade/Device Name: Sonomed IV, Sonomed V
Regulation Number: 21 CFR 890.5300
Regulation Name: Ultrasonic Diathermy
Regulatory Class: Class II
Product Code: IMI
Dated: February 19, 2021
Received: February 19, 2021

Dear Bruno Milhoci:

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,

for Amber Ballard, PhD
Assistant Director, Neurodegenerative Devices Team
DHT5B: Division of Neuromodulation
and Physical Medicine Devices
OHT5: Office of Neurological
and Physical Medicine Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K202788

Device Name
Sonomed IV
Sonomed V

Indications for Use *(Describe)*
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

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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Sonomed IV / Sonomed V

510(k) Summary

Administrative information

Sponsor	CARCI Indústria e Comércio de Aparelhos Cirúrgicos e Ortopédicos Ltda. R. Padre Machado, 82– São Paulo – SP – Brazil Telephone: +55 (11) 5621 2791
Contact Person and Preparer	Bruno Milhoci de Souza Regulatory Affairs Specialist Passarini Regulatory Affairs E-Mail: bruno@rapassarini.com.br Telephone + 55 (16) 3421 8488
Data Prepared	SEPT-15-2020
DEVICE NAME AND CLASSIFICATION	
Trade/ Proprietary Name	Sonomed V and Sonomed IV
Common Name	Ultrasonic Therapy
Primary Classification Name	Ultrasonic Diathermy for Use In Applying Therapeutic Deep Heat
Primary Classification regulation	21 CFR 890.5300
Primary Product Code	IMI
Classification Panel	Physical Medicine
Reviewing Branch	Physical Medicine
PREDICATE DEVICE INFORMATION	
Predicate Manufacturer	Ibramed
Predicate Trade Name	Sonopulse
Predicate 510(k)	K130888

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

Subject Device Description

The SONOMED apparatus is ultrasound equipment for therapy, which has been developed in accordance with the safety standards IEC 60601-1, IEC 60601-2 and IEC 60601-2-5, class II, type BF, which makes it a safe apparatus of high reliability for the therapist and the patient.

SONOMED is medical electric equipment which provides therapeutic ultrasound treatment. Ultrasound is a mechanic stimulus directed to the body through ultrasonic beam emitted by a transducer/applicator, better known as head. This ultrasound is produced in the head through a piezoelectric crystal and is transmitted to the body through the aluminum surface of the head and a contact agent (gel). Depending on how the ultrasound beam passes through the tissues, its energy is gradually and selectively absorbed being transformed into heat, among other effects. This increase in temperature causes biological changes in the tissues as for instance increase in micro circulation, a reduced perception of pain, a reduction in inflammatory activity and an increase in the reestablishing rate of delicate tissues. The higher the ultrasound frequency, the more superficial will be its absorption.

Technological Characteristics

Ultrasound in physiotherapy has successfully and efficiently been used in orthopedics and traumatology for quite a long time.
With this background, Carci developed state-of-the-art ultrasound equipment with multifrequency transducer in 1 MHz and 3 MHz for precise and adequate treatment, in conformity with the type of tissue involved.

Table 5.1

	K number/ Manufacturer	Indications for use statement
Subject Device	Carci	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
Predicate device	K130888 Ibramen	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

Table 5.2 SE comparison

Trade Name information/ Manufacturer	Subject Device		Predicate Device	Equivalient discussion
	Sonomed IV	Sonomed V	K130888/ Sonopulse	
	Carci	Carci	Ibramed	
Regulation Number	890.5300	890.5300	890.5300	Same
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	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	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	Same
Product Code	IMI	IMI	IMI	The subject device and the predicate has the same classification of the ultrasound, but the predicate has mode functions
Console/Generator Dimensions (L x W x H cm)	31 x 18 x 6	31 x 18 x 6	Not available	Equivalent
Treatment Head Dimensions (L x W x H cm)	15 cm x 5 cm x 4 cm	15 cm x 5 cm x 4 cm	Not available	Equivalent
Console/Generator Weight (kg)	1.2 Kg	1.2 Kg	Not available	Equivalent
Treatment Head Weight (kg)	252 Grams	252 Grams	Not available	Equivalent
Power Supply	100 - 240V 50/60Hz	100 - 240V 50/60Hz	(AC Line) 100-240V ~50/60Hz	Same
Leakage Current	49 µA (Normal) 86 µA (single fault)	49µA (Normal) 86 µA (single fault)	Not available	Equivalent
Crystal Material	PZT	PZT	Not available	Equivalent
Technology of ultrasound generation	Piezoelectric	Piezoelectric	Piezoelectric	Same
Treatment Mode(s)	Pulsed, continuous	Pulsed, continuous	Pulsed, continuous	Same
Beam Type (collimated or divergent)	Collimated	Collimated	Pulsed, continuous	Same
Transducer Diameter (cm)	5cm² = 2,52cm	5cm² = 2,52cm	7cm² = 2,98 cm	Equivalent
Acoustic Working Frequency and Accuracy (MHz)	1MHZ± 5%	1MHZ± 5% 3.3MHz± 5%	1MHZ± 5% 3.3MHz± 5%	Frequencies of the devices are similar within the error margin. All the frequencies are covered by the

				regulation number 890.5300
Effective Radiating Area and Accuracy (cm2)	3,2 cm² ±10%	3,2 cm² ±10%	Not available	The effective area of all products are similar
Beam Nonuniformity Ratio (not to exceed 8*) and Accuracy	2.8:1	2.8:1	Not available	Similar.
Output Mode: (Continuous Wave/Amplitude – Modulated Wave)	Continuous Pulsed	Continuous Pulsed	Continuous Pulsed	Same
Maximum Timer Setting and Accuracy (not to exceed 30 min*)	20 minutes	20 minutes	30 minutes	The subject device has a lower treatment time.
Beam Maximum Intensity and Accuracy (W/cm2)	0,1 to 2,0 W/cm² (continuous mode) 0,1 to 3,0 W/cm² (Pulsed)	0,1 to 2,0 W/cm² (continuous mode) 0,1 to 3,0 W/cm² (Pulsed)	Not available	Similar.
Maximum Value of the Output Power (Rated Output Power) and Accuracy (W)	6,4W ± 20%	6,4W ± 20%	Not available	The maximum power of the predicate is higher but the Beam maximum intensity is the same 2.0w/cm² for the continuous mode.
Maximum Value of the Effective Intensity and Accuracy (Not to exceed 3 W/cm2 *)	0,1 to 2,0 W/cm² (continuous mode) 0,1 to 3,0 W/cm² (Pulsed)	0,1 to 2,0 W/cm² (continuous mode) 0,1 to 3,0 W/cm² (Pulsed)	Not available	Similar.
Peak Temperature Rise vs. Time and Tissue Depth to Maximum Treatment Time (for fixed Treatment Head Placement) (deg C)	Head in the air Elevation of temperature raise 18 ºC for 20 minutes, 1 MHz, 6.4W Elevation of temperature raise 19 ºC for 20 minutes, 3.3 MHz, 6.4W Effective depth 3cm for 1MHz and 1cm for 3MHz	Head in the air Elevation of temperature raise 18 ºC for 20 minutes, 1 MHz, 6.4W Elevation of temperature raise 19 ºC for 20 minutes, 3.3 MHz, 6.4W Effective depth 3cm for 1MHz and 1cm for 3MHz	Not available	Not available for comparison
Maximum Patient Contact Surface Temperature of Treatment Head under Simulated or Actual Use Conditions for all Operating Conditions (Continually operated for maximum	Head in the MMT 32 ºC for 1MHz continuous use 6.4W 36 ºC for 3.3MHz continuous use 6.4W	Head in the MMT 32 ºC for 1MHz continuous use 6.4W 36 ºC for 3.3MHz continuous use 6.4W	Not available	Not available for comparison

treatment time) (deg C)				
Penetration Depth (cm)	1Mhz 5cm 3.3MHz 2cm	1Mhz 5cm 3.3MHz 2cm	1Mhz 5cm 3.3MHz 2cm	Same

Discussion:

The subject device and the predicate device have similar intended use, principles of operation, and output characteristics. Of note:

- Treatment time: the predicate has a higher treatment time, if the practitioner needs more than 20 minutes the treatment could be restarted.
- Piezoelectric Material: They have the same Zirconia ceramic piezoelectric family.
- Maximum Value of the Output Power: The output power of the predicate is higher, as the ERA is larger, the output density power is equal.
- Penetration depth: The subject device and the sonopulse has the same penetration depth

Non-Clinical Performance Data:

The Sonomed was tested in accordance with these standards:

- *IEC 60601-1 - Medical electrical equipment - Part 1: General requirements for basic safety and essential performance*
- *IEC 60601-1-2 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests*
- *IEC 60601-2-5 Medical electrical equipment – Part 2-5: Particular requirements for the basic safety and essential performance of ultrasonic physiotherapy equipment*
- *IEC 62304 Medical device software – Software life cycle processes*

- *ISO 10993-1 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process*

Clinical performance Data:

No clinical data were included in this submission.

Conclusion:

The documentation submitted in this premarket notification demonstrates that the subject devices have comparable features and performance and, therefore, are substantially equivalent to the identified predicate device.