September 1, 2023

Softwave./TRT LLC
% Cherita James
Regulatory Consultant
M Squared Associates/a PPG Company
1129 20th St NW, Suite 600
Washington, District of Columbia 20036

Re: K231710
Trade/Device Name: Ow100s
Regulation Number: 21 CFR 878.4685
Regulation Name: Extracorporeal Shock Wave Device For Treatment Of Chronic Wounds
Regulatory Class: Class II
Product Code: PZL
Dated: June 12, 2023
Received: June 12, 2023

Dear Cherita James:

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,

Mark Trumbore -S

Digitally signed by Mark Trumbore -S
Date: 2023.09.01 07:59:58 -04'00'

Mark Trumbore, Ph.D.
Assistant Director
DHT4A: Division of General Surgery Devices
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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)*

Device Name
OW100S

Indications for Use *(Describe)*

The OW100S is indicated to provide acoustic pressure shockwaves in the treatment of chronic, full-thickness diabetic foot ulcers with wound areas measuring no larger than 16 cm2, which extend through the epidermis, dermis, tendon, or capsule, but without bone exposure. The OW100S is indicated for adult (22 years and older), diabetic patients presenting with diabetic foot ulcers greater than 30 days in duration and is indicated for use in conjunction with standard diabetic ulcer care.

The OW100S is indicated to provide acoustic pressure shockwaves in the treatment of superficial partial thickness second degree burns in adults (22 years or older). The OW100S is indicated for use in conjunction with standard of care burn treatment(s).

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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5 510(K) SUMMARY

The following information is provided as required by 21 CFR § 807.87 for Tissue Regeneration Technologies, LLC 510(k) premarket notification. In response to the Safe Medical Devices Act of 1990, the following is a summary of the information upon which the substantial equivalence determination is based.

Sponsor: Tissue Regeneration Technologies, LLC
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Woodstock, GA 30188

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Fax: 703-562-9797
Email: Cherita.James@ProPharmaGroup.com

Date of Submission: June 12, 2023

Proposed Class: II

Proprietary Name: OW100S (model OW100S-US)

Common Name: Acoustic wave device

Classification Name: Extracorporeal shock wave device for treatment of chronic wounds

Regulation Number: Section 878.4685 Extracorporeal shock wave device for treatment of chronic wounds.

Product Codes: PZL

Predicate Device: TRT, OrthoGold 100 (OW 100) K191961 and K200926
Reference Device: OW100S K213120

Device Description

The OW100S is a pulsed acoustic wave device. It includes an electrically powered generator to generate a high voltage spark in water that rapidly expands to create the acoustic waves, which in turn are propagated through a water-filled coupling membrane attached to the hand-held applicator. The hand-held applicator reflects the acoustic waves towards the treatment area through a silicone membrane and ultrasound transmission gel.

The modification to the OrthoGold 100 (OW100) is identified as model OW100S and applicator OP155S includes the addition of a “break circuit” added to the acoustic wave generator which

increases the available pulses per handheld applicator/electrode from 100K pulses to 500K pulses at low energy flux density in the device (increase from 70K to 350K pulses at high energy flux density). As a consequence of this change, there are minor changes to the applicator and its connection, software and water cartridge of the device.
Minor labeling changes are limited to product information and set-up details with regard to attachment and detection of the applicator, and water cartridge handling.

There are no changes to the power output performance, electrode and reflector geometry, total primary electrical energy, energy flux density or penetration as a result of this change.

Indications for Use

The OW100S is indicated to provide acoustic pressure shockwaves in the treatment of chronic, full-thickness diabetic foot ulcers with wound areas measuring no larger than 16 cm^2, which extend through the epidermis, dermis, tendon, or capsule, but without bone exposure. The OW100S is indicated for adult (22 years and older), diabetic patients presenting with diabetic foot ulcers greater than 30 days in duration and is indicated for use in conjunction with standard diabetic ulcer care.

The OW100S is indicated to provide acoustic pressure shockwaves in the treatment of superficial partial thickness second degree burns in adults (22 years or older). The OW100S is indicated for use in conjunction with standard of care burn treatment(s).

Performance Data

The same verification and validation testing was performed for the current device design as the predicate and demonstrated that the OW100S meets the design specifications and is safe and effective for its intended use. All tests required by the verification and validation plan were completed and passed. The OW100S software was validated and demonstrated to be of a Moderate level of concern; while hazard analysis / risk management was performed and demonstrated that all risks are mitigated to an acceptable level. The performance testing demonstrated that the OW100S is substantially equivalent to the predicate device.

The OW100S conforms to the following standards:

Standard	Recognition Number
IEC 61846 First edition 1998-04, ultrasonics - pressure pulse lithotripters - characteristics of fields	9-7
AAMI / ANSI ES60601-1:2005/(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	19-4
IEC 60601-1-2:2014 Edition 4, Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests	19-8
IEC 60601-2-36 Edition 2.0: 2014-04, Medical electrical equipment - Part 2-36: Particular requirements for the safety of equipment for extracorporeally induced lithotripsy	9-119
IEC 60601-1-6 Edition 3.1 2013-10 Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability	5-89
IEC 63045-2020: Ultrasonics - Non-focusing short pressure pulse sources including ballistic pressure pulse sources - Characteristics of fields	N/A
IEC 62304:2006/A1:2016 Medical device software - Software life cycle processes [Including Amendment 1 (2016)]	13-79

Substantial Equivalence

The modified OrthoGold 100 (OW100), identified as OW100S, has the following similarities to those which previously received 510(k) concurrence:

- has the same indicated use,
- uses the same operating principle,
- incorporates the same materials
- incorporates the same basic device design, with the addition of the “break circuit” and minor changes to the applicator, water cartridge, and software

The table below compares the OW100S characteristics to the predicate and reference device.

Product Characteristic	**Subject Device OW100S**	**Reference device OW100S**	**Predicate Device OrthoGold 100 (OW100)**	**Comparison**
510(k) Number	**To be assigned**	**K213120**	**K191961, K200926**	**NA**
Indications for Use	The OrthoGold 100 OW100S is indicated to provide acoustic pressure shockwaves in the treatment of chronic, full-thickness diabetic foot ulcers with wound areas measuring no larger than	The OW100S is intended for: -Relief of minor muscles aches and pains -Temporary increase in local blood circulation	K191961: The OrthoGold 100 is indicated to provide acoustic pressure shockwaves in the treatment of chronic, full-thickness diabetic foot ulcers with wound	OW100S has the same indications and intended use as the OW100 in K191961, K200926

Product Characteristic	Subject Device OW100S	Reference device OW100S	Predicate Device OrthoGold 100 (OW100)	Comparison
	16 cm2, which extend through the epidermis, dermis, tendon, or capsule, but without bone exposure. The OrthoGold 100 OW100S is indicated for adult (22 years and older), diabetic patients presenting with diabetic foot ulcers greater than 30 days in duration and is indicated for use in conjunction with standard diabetic ulcer care. The OrthoGold 100 OW100S is indicated to provide acoustic pressure shockwaves in the treatment of superficial partial thickness second degree burns in adults (22 years or older). The OrthoGold 100 OW100S is indicated for use in conjunction with standard of care burn treatment(s).	-Activation of connective tissue.	areas measuring no larger than 16 cm2, which extend through the epidermis, dermis, tendon, or capsule, but without bone exposure. The OrthoGold 100 is indicated for adult (22 years and older), diabetic patients presenting with diabetic foot ulcers greater than 30 days in duration and is indicated for use in conjunction with standard diabetic ulcer care. K200926:The OrthoGold 100 is indicated to provide acoustic pressure shockwaves in the treatment of superficial partial thickness second degree burns in adults (22 years or older). The OrthoGold 100 is indicated for use in conjunction with standard of care burn treatment(s).	
Modes of Action	Unfocused pressure pulses	Unfocused pressure pulses	Unfocused pressure pulses	identical, no change
Mechanisms of Action	Extracorporeally induced unfocused pressure pulses	Extracorporeally induced unfocused pressure pulses	Extracorporeally induced unfocused pressure pulses	identical, no change
Maximum and Minimum intensity settings	1 to 16	1 to 16	1 to 16	identical, no change
Number and size of treatment applicator heads	OP155S Size: 230 x ø 70 mm	OP155S Size: 230 x ø 70 mm	OP155 Size: 230 x ø 70 mm	identical, no change
Electrode lifetime	E1-E10: 500K sw E11-E16: 350K sw	E1-E10: 500K sw E11-E16: 350K sw	E1-E10: 100K sw E-11-E16: 70K sw	Break circuit and modified water cartridge solution reduce the wear of electrodes over

Product Characteristic	Subject Device OW100S	Reference device OW100S	Predicate Device OrthoGold 100 (OW100)	Comparison
				time, but there is no change to device outputs at selected energy level, and therefore no change to safety/effectiveness in treatment
Cartridge solution and conductivity	Potassium bromide solution 2300µS/cm	Potassium bromide solution 2300µS/cm	Silver chloride solution 600µS/cm	Modified solution to support extended electrode life. no change to device outputs at selected energy level, and therefore no change to safety/effectiveness in treatment
Type of application (e.g., continuous vibration at a fixed frequency);	Continuous at various frequencies	Continuous at various frequencies	Continuous at various frequencies	identical, no change
Maximum and minimum vibration frequency	Frequency of 1 - 8 Hz in steps of 0.5 Hz	Frequency of 1 - 8 Hz in steps of 0.5 Hz	Frequency of 1 - 8 Hz in steps of 0.5 Hz	identical, no change
Driving Power	High voltage 2 - 7 kV Capacitor: 0,2 uF	High voltage 2 - 7 kV Capacitor: 0,2 uF	High voltage 2 - 7 kV Capacitor: 0,2 uF	identical, no change
Power Supply	115 VAC	115 VAC	115 VAC	identical, no change
Maximum penetration depth	37.4 mm at energy level 16	37.4 mm at energy level 16	25.4 mm at energy level 16	similar, higher max.penetration depth due to tolerances and several statistical effects. Geometry of reflector in applicator, which defines acoustic field, remained unchanged
Energy flow density PIIT [mJ/mm2]	0.00020 – 0.04900 at energy level 1 - 16	0.00020 – 0.04900 at energy level 1 - 16	0.00017 - 0.04403 at energy level 1 - 16	similar, values of energy flow density slightly higher due to tolerances and several statistical

Product Characteristic	Subject Device OW100S	Reference device OW100S	Predicate Device OrthoGold 100 (OW100)	Comparison
				effects
Operating mode	Continuous	Continuous	Continuous	identical, no change
Pulse repeat rate (1/s)	1 - 8 Hz	1 - 8 Hz	1 - 8 Hz	identical, no change
Number of pulses (min and max)	500-2000/ session	500-2000/ session	500 - 2000	identical, no change
Maximum operating temperature	Room temperature	Room temperature	Room temperature	identical, no change
Type of acoustic wave generation	Electro hydraulic, spark gap under water caused by discharge of high voltage condensers	Electro hydraulic, spark gap under water caused by discharge of high voltage condensers	Electro hydraulic, spark gap under water caused by discharge of high voltage condensers	identical
Peak compressional acoustic pressure pc [Mpa]	11.20 at energy level 16	11.20 at energy level 16	9.27 at energy level 16	similar, values of peak compressioneal acoustic pressure slightly higher due to tolerances and several statistical effects
Peak rarefactional acoustic pressure pcr[Mpa]	1.22 at energy level 16	1.22 at energy level 16	-1.52 at energy level 16	similar, values of rarefractional acoustic pressure slightly lower due to tolerances and several statistical effects
Description of the spatial distribution of the acoustic pressure and intensity	Unfocused acoustic pressure field, see pressure measurements	Unfocused acoustic pressure field, see pressure measurements	Unfocused acoustic pressure field, see pressure measurements	Similar, no change
Positive peak pressure amplitude (MPa) pc [Mpa]	0.61 – 11.20 at energy level 1 - 16	0.61 – 11.20 at energy level 1 - 16	0.43 - 9.27 at energy level 1 - 16	similar, values of positive peak pressure amplitude slightly higher due to tolerances and several statistical effects
Negative peak pressure amplitude (MPa) pcr[Mpa]	-0.17 to – 1.22MPa at energy level 1 - 16	-0.17 to – 1.22MPa at energy level 1 - 16	-0.17 to -1.52 MPa at energy level 1 - 16	similar, values of negative peak pressure amplitude slightly lower due to tolerances and several statistical

Product Characteristic	Subject Device OW100S	Reference device OW100S	Predicate Device OrthoGold 100 (OW100)	Comparison
				effects
Derived focal acoustic pulse energy (mJ) EbT [mJ]	0.020- 3.370 at energy level 1 - 16	0.020- 3.370 at energy level 1 - 16	0.022 - 2.278 at energy level 1 - 16	similar values of derived focal acoustic pulse energy differ due to tolerances and several statistical effects
Derived pulse - intensity integral, integrated over total temporal integration limits PIIT [mJ/mm2]	0.00020-0.04900 mJ/mm2	0.00020-0.04900 mJ/mm2	0.00017 - 0.04403 mJ/mm2 at energy level 1 - 16	similar, values of derived pulse-intensity integtal slightly higher due to tolerances and several statistical effects
Rise time (ns) (10% - 90%) tr [us]	1.08 – 0.18 at energy level 1 - 16	1.08 – 0.18 at energy level 1 - 16	1.89 - 0.28 at energy level 1 - 16	similar, values of rise time differ due to tolerances and several statistical effects
Compressional pulse duration (µs) tFWHMpc [uS]	0.79 - 0.82 µs at energy level 1 - 16	0.79 - 0.82 µs at energy level 1 - 16	1.23 - 0.77 µs at energy level 1 - 16	similar, values of compressional pulse duration differ due to tolerances and several statistical effects

Clinical Information

Not applicable. Bench and performance testing support the substantial equivalence in this submission.

Conclusion

The OW100S has the same indications for use and similar design features as compared with the Primary predicate device system. The OW100S described in this submission is substantially equivalent to the predicate, OrthoGold 100 (OW100). The proposed device performs as well as the legally marketed predicate devices. Any differences between the subject and predicate devices would not affect the safety or effectiveness, or raise different questions of safety and effectiveness.