



July 9, 2024

Softwave/TRT LLC
Cherita James
Regulatory Consultant
3330 Highway 136 West
Woodstock, Georgia 30175

Re: K233937

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 11, 2024
Received: June 11, 2024

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (<https://www.fda.gov/media/99812/download>) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (<https://www.fda.gov/media/99785/download>).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Long H. Chen -S

Digitally signed by Long H. Chen -

S
Date: 2024.07.09 11:52:38 -04'00'

Long Chen, Ph.D.
Assistant Director
DHT4A: Division of General Surgery Devices
OHT4: Office of Surgical
and Infection Control Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

Submission Number (if known)

K233937

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.

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510(k) SUMMARY

The following information is provided as required by 21 CFR § 807.87 for SoftWaveTRT 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: SoftWaveTRT LLC
3330 Highway 136 West
Woodstock, GA 30175

Contact: Cherita James
M Squared Associates/a PPG Company
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Washington, DC 20036
Ph: 347-536-1463
Email: Cherita.James@ProPharmaGroup.com

Submitted date: July 8, 2024

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, OW100S K231710

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.

Model OW100S and applicator OP155S includes a “break circuit” in 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. Updates to labeling of the OW100S includes revisions to

contraindications/warnings/ cautions which do not raise different questions of safety and effectiveness, as they are in line with currently marketed acoustic wave devices for the same indications for use.

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 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).

Performance Data

The same verification and validation testing is applicable 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 OW100s cleared for Class II indications.

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

Standard	Recognition Number
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 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.

The table below compares the OW100S characteristics to the predicate and reference device. Updates to labeling of the OW100S include revisions to contraindications/warnings/ precautions which do not raise different questions of safety and effectiveness, as they are in line with currently marketed acoustic wave devices for the same indications for use.

Product Characteristic	Subject Device OW100S	Primary Predicate device OW100S	Comparison
510(k) Number	TBD	K231710	NA
Product code	PZL	PZL	Same
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 16 cm ² , 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	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 16 cm ² , 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	OW100S has the same indications and intended use as the OW100S in K231710

Product Characteristic	Subject Device OW100S	Primary Predicate device OW100S	Comparison
	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).	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).	
Modes of Action	Unfocused pressure pulses	Unfocused pressure pulses	identical to primary predicate OW100S, no change
Mechanisms of Action	Extracorporeally induced unfocused pressure pulses	Extracorporeally induced unfocused pressure pulses	identical to primary predicate OW100S, no change
Maximum and Minimum intensity settings	1 to 16	1 to 16	identical to primary predicate OW100S, no change
Number and size of treatment applicator heads	OP155S Size: 230 x ø 70 mm	OP155S Size: 230 x ø 70 mm	identical to primary predicate OW100S, no change
Electrode lifetime	E1-E10: 500K sw E11-E16: 350K sw	E1-E10: 500K sw E11-E16: 350K sw	identical to primary predicate OW100S, no change
Cartridge solution and conductivity	Potassium bromide solution 2300µS/cm	Potassium bromide solution 2300µS/cm	identical to primary predicate OW100S, no change
Type of application (e.g., continuous vibration at a fixed frequency);	Continuous at various frequencies	Continuous at various frequencies	identical to primary predicate OW100S, 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	identical to primary predicate OW100S, no change
Driving Power	High voltage 2 - 7 kV Capacitor: 0,2 uF	High voltage 2 - 7 kV Capacitor: 0,2 uF	identical to primary predicate OW100S, no change
Power Supply	115 VAC	115 VAC	identical to primary predicate OW100S, no change
Maximum penetration depth	37.4 mm at energy level 16	37.4 mm at energy level 16	identical to primary predicate OW100S, no change
Energy flow density PIIT [mJ/mm ²]	0.00020 – 0.04900 at energy level 1 - 16	0.00020 – 0.04900 at energy level 1 - 16	identical to primary predicate OW100S, no change
Operating mode	Continuous	Continuous	identical to primary predicate OW100S, no change
Pulse repeat rate (1/s)	1 - 8 Hz	1 - 8 Hz	identical to primary predicate OW100S, no change

Product Characteristic	Subject Device OW100S	Primary Predicate device OW100S	Comparison
Number of pulses (min and max)	500-2000/ session	500-2000/ session	identical to primary predicate OW100S, no change
Maximum operating temperature	Room temperature	Room temperature	identical to primary predicate OW100S, 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	identical to primary predicate OW100S, no change
Peak compressional acoustic pressure p_c [Mpa]	11.20 at energy level 16	11.20 at energy level 16	identical to primary predicate OW100S, no change
Peak rarefactional acoustic pressure p_{cr} [Mpa]	1.22 at energy level 16	1.22 at energy level 16	identical to primary predicate OW100S, no change
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	identical to primary predicate OW100S, no change
Positive peak pressure amplitude (MPa) p_c [Mpa]	0.61 – 11.20 at energy level 1 - 16	0.61 – 11.20 at energy level 1 - 16	identical to primary predicate OW100S, no change
Negative peak pressure amplitude (MPa) p_{cr} [Mpa]	-0.17 to – 1.22MPa at energy level 1 - 16	-0.17 to – 1.22MPa at energy level 1 - 16	identical to primary predicate OW100S, no change
Derived focal acoustic pulse energy (mJ) E_bT [mJ]	0.020- 3.370 at energy level 1 - 16	0.020- 3.370 at energy level 1 - 16	identical to primary predicate OW100S, no change
Derived pulse -intensity integral, integrated over total temporal integration limits $PIIT$ [mJ/mm ²]	0.00020-0.04900 mJ/mm ²	0.00020-0.04900 mJ/mm ²	identical to primary predicate OW100S, no change
Rise time (ns) (10% - 90%) t_r [μ s]	1.08 – 0.18 at energy level 1 - 16	1.08 – 0.18 at energy level 1 - 16	identical to primary predicate OW100S, no change
Compressional pulse duration (μ s) t_{FWHMpc} [μ s]	0.79 - 0.82 μ s at energy level 1 - 16	0.79 - 0.82 μ s at energy level 1 - 16	identical to primary predicate OW100S, no change

Similarities

The OW100S is identical to the previously cleared OW100S previously cleared under K231710. There are no changes to the power output performance, electrode and reflector geometry, total primary electrical energy, energy flux density or wave penetration as a result of these changes.

User interactions with the device are the same. The change requires no revisions to the recommended treatment parameters when compared to prior submissions.

Differences

K233937

Labeling changes to contraindications, warnings, and precautions

This submission concerns revisions and clarifications in labeling contraindications, warnings, and precautions. The changes are implemented to align the labeling with currently marketed acoustic wave devices for the identical indications for use, as well as to clarify and omit information that was duplicated in these sections in prior submissions. In some instances, text is revised to clarify the intent of the statement, or to present statements more appropriately for instance as a warning rather than precaution.

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 identical design features as compared with the Primary predicate device system. The OW100S described in this submission is, in our opinion, substantially equivalent to the predicate. The proposed device performs as well as the legally marketed predicate device. Any differences between the subject and predicate device would not render the device NSE, affect the safety or effectiveness, or raise different questions of safety and effectiveness.