FDA U.S. FOOD & DRUG ADMINISTRATION

August 28, 2020

Tissue Regeneration Technologies, LLC
% Jennifer Daudelin
Official Correspondent
M Squared Associates, Inc.
575 Eighth Avenue, Suite 1212
New York, New York 10018

Re: K200926
Trade/Device Name: OrthoGold 100
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: August 26, 2020
Received: August 27, 2020

Dear Jennifer Daudelin:

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,

Long H. Chen -S

Digitally signed by Long H. Chen -S
Date: 2020.08.28 17:17:01 -04'00'

Long Chen, Ph.D.
Assistant Director
DHT4A: Division of General Surgery Devices
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and Infection Control Devices
Office of Product Evaluation and Quality
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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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K200926

Device Name

OrthoGold 100

Indications for Use *(Describe)*

The OrthoGold 100™ is indicated to provide acoustic pressure shockwaves in the treatment of superficial partial thickness second degree burns in adults (22 years and older). The OrthoGold 100 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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Section 5: 510(k) Summary

The following information is provided as required by 21 CFR § 807.87 for the 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 safety and effectiveness information upon which the substantial equivalence determination is based.

The safety and effectiveness of the OrthoGold 100™ is based upon a determination of the substantial equivalence as well as the safety and effectiveness of its predicate device(s).

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Date Prepared: April 6, 2020

Proposed Class: II

Proprietary Name: OrthoGold 100™

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

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

Regulation Number: 21 CFR 878.4685

Product Codes: PZL

Predicate Device:

Manufacturer	Device Name	510(k) Number	Procode	Class
Tissue Regeneration Technologies, LLC	OrthoGold 100™	K191961	PZL	II

Indications for Use

The OrthoGold 100™ is indicated to provide acoustic pressure shockwaves in the treatment of superficial partial thickness second degree burns in adults (22 years and older). The OrthoGold 100 is indicated for use in conjunction with standard of care burn treatment(s).

Device Description

The OrthoGold 100™ is a pulsed acoustic wave device. It includes an electrically powered generator to generate transient compressed air 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.

Performance Data – Non-Clinical

The OrthoGold 100™ has been evaluated through non-clinical performance testing. The OrthoGold 100™ was tested for electrical safety and electromagnetic compatibility and pressure field measurements. In addition, probe cover testing and transport verification and validation was also conducted. The testing demonstrated that the OrthoGold 100™ met performance requirements and is substantially equivalent to the predicate device.

The table below compares the OrthoGold 100 characteristics to the predicate devices.

Product Characteristic	Predicate Device OrthoGold 100	Subject Predicate OrthoGold 100	Comparison
510(k) Number	**K191961**	**To be assigned**	**NA**
Indications for Use	Intended for 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 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.	The OrthoGold 100™ is indicated to provide acoustic pressure shockwaves in the treatment of superficial partial thickness second degree burns in adults (22 years and older). The OrthoGold 100 is indicated for use in conjunction with standard of care burn treatment(s).	Both the subject and predicate device are intended to apply acoustic waves to dermal wounds

Product Characteristic	Predicate Device OrthoGold 100	Subject Predicate OrthoGold 100	Comparison
Modes of Action	Unfocused pressure pulses		Similar
Mechanisms of Action	Extracorporeally induced unfocused pressure pulses		Similar
Maximum and Minimum intensity settings	1 to 16		Similar
Number and size of treatment applicator heads	OP155 Size: 230 x ø 70 mm		Similar
Operating mode	Continuous		Similar
Pulse repeat rate (1/s)	1 - 8 Hz		Similar
Number of pulses (min and max)	300 - 1300		Similar
Maximum operating temperature	Room temperature		Similar
Type of acoustic wave generation	Electro hydraulic, spark gap under water caused by discharge of high voltage condensers		Similar

Performance Data –Animal

A study investigated the role of ESWT on the early proinflammatory response using a severe, full-thickness and highly inflammatory cutaneous burn wound in a murine model. Various wound-healing parameters were measured and leukocyte infiltration quantitated. The study demonstrated that ESWT of burn wounds 1hour post wounding significantly blunts some immune responses in the wound and attenuates activity at the wound margin. The authors speculate that ESWT may be a potential therapeutic modality to treat severe wounds wherein excessive inflammatory responses involving increased levels of inflammatory cells, proinflammatory cytokines and proteases may become self-resolving allowing wound healing to progresses by way of normal physiological repair processes. The study supports the safe and effective use of the OrthoGold in second-degree burn.

Performance Data – Clinical

A prospective randomized controlled study of 44 patients (22 patients in each group) demonstrated that treatment with the OrthoGold 100 device in addition to standard of care was safe and effective to treat superficial second-degree burn wounds. Adult patients presenting with superficial second-

degree burns involving the epidermis and extending into the dermis were included in the study. Patients were excluded with first degree burns, second degree deep dermal and third-degree burns. In addition, the exclusion criteria included patients with insulin dependent diabetes mellitus, dialysis dependent renal failure, ongoing systemic therapy for malignancy, dermatologic disease, ongoing corticosteroid therapy, and active drug abuse. The control group included 18 males and 4 females who received standard of care burn treatment, which consisted of wound debridement and daily antiseptic dressing changes. The treatment group included 14 males and 8 females who underwent the same standard of care burn treatment in addition to ESWT administered within 24 hours of burn wound debridement. The ESWT group received a single application of unfocused shock wave therapy to the study burn.

Results showed that the mean time to ≥95% epithelialization of the treated burns was significantly shorter for those treated with the OrthoGold device compared to standard of care alone, 9.6 ± 1.7 days for the ESWT group versus 12.5 ± 2.2 days for the control group ($p<0.0005$). Study patients were monitored carefully during the follow-up period for cardiac, neurological, dermal, thermal, or allergic reactions or adverse events. There were no reported cardiac, neurological, dermal, or allergic reactions. Clinically apparent burn wound infection occurred in both groups, 9% in the ESWT group patients and 14% in the control group patients and did not differ significantly between study groups ($p=0.99$). Postburn bacteremia and other nosocomial infections occurred in 8% and 16% of patients, ESWT and control group respectively, and did not differ significantly between study groups. Limitations of this study include a modest sample size, lack of long-term follow-up, no assessment of quality of life outcomes measures, and no illustrative use of doppler imaging and burn wound histology.

The data from this study establishes the efficacy of the subject device to treat superficial partial thickness second degree burns and the safety of the device as shown with the lack of adverse events.

Substantial Equivalence

The OrthoGold 100™ has the same design features as compared with the predicate system. The bench testing, animal and clinical data demonstrates that the performance characteristics of the OrthoGold 100™ are equivalent to those of the other legally marketed extracorporeal shock wave

devices, and therefore supports a determination of Substantial Equivalence for the proposed indications for use. Different questions of safety and effectiveness were not raised between the subject and predicate devices.