November 26, 2019

Tissue Regeneration Technologies LLC
% Jennifer Daudelin
Regulatory Consultant III
M Squared Associates, Inc
575 Eight Avenue, St. Suite 1212
New York, New York 10018

Re: K191961
Trade/Device Name: OrthoGold
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: October 28, 2019
Received: October 29, 2019

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: 2019.11.26 15:16:51 -05'00'

Long Chen
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

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)*
K191961

Device Name
OrthoGold 100

Indications for Use *(Describe)*
The OrthoGold 100™ 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 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.

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.

Section 5: 510(k) Summary K191961

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).

Sponsor: Tissue Regeneration Technologies, LLC
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Woodstock, GA 30188

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Date Prepared: November 25, 2019

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(s):

Manufacturer	Device Name	510(k) Number	Procode	Class
Sanuwave, Inc.	dermaPACE System	DEN160037	PZL	II
Reference Device: Tissue Regeneration Technologies, LLC	OrthoGold 100™	K182682	ISA	I

Indications for Use

The OrthoGold 100™ 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 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.

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	Subject Device OrthoGold 100	Reference Predicate OrthoGold 100	Primary Predicate Device dermaPACE System	Comparison
510(k) Number	**To be assigned**	**K182682**	**DEN160037**	**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	Activation of connective tissue	Intended for 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 dermaPACE System is indicated for adult (22 years and older), diabetic patients presenting with diabetic	Identical

Product Characteristic	Subject Device OrthoGold 100	Reference Predicate OrthoGold 100	Primary Predicate Device dermaPACE System	Comparison
	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.		foot ulcers greater than 30 days in duration and is indicated for use in conjunction with standard diabetic ulcer care.	
Modes of Action	Unfocused pressure pulses		Focused pressure	Similar
Mechanisms of Action	Extracorporeally induced unfocused pressure pulses		Extracorporeally induced focused pressure pulses	Similar
Maximum and Minimum intensity settings	1 to 16		1 to 6	Similar
Number and size of treatment applicator heads	OP155 Size: 230 x ø 70 mm		1 applicator (size not available)	Similar
Operating mode	Continuous		Continuous	Similar
Pulse repeat rate (1/s)	1 - 8 Hz		1-4 Hz	Similar
Number of pulses (min and max)	300 - 1300		500 to Specific Value Not Available	Similar
Maximum operating temperature	Room temperature		Specific Value Not Available	Similar
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	Similar

Performance Data – Clinical

A literature review represents the published literature with the subject device through systematic, comprehensive literature searches and those articles known to the manufacturer. These studies demonstrate the successful clinical use with the OrthoGold technology in 224 diabetic foot ulcers. The studies show significant results in complete wound healing and reduction of wound area. The data from these studies establish the efficacy of the subject device to treat 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 and the safety of the device as shown with the lack of adverse events.

Substantial Equivalence

The OrthoGold 100™ has the same indications for use and similar design features as compared with the predicate systems. The bench testing 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.