May 5, 2021

Tissue Regeneration Technologies, LLC
% Cherita James
Regulatory Consultant
M Squared Associates, Inc.
127 West 30th St Floor 9
New York, New York 10001

Re: K210451
Trade/Device Name: OrthoGold 100
Regulation Number: 21 CFR 890.5660
Regulation Name: Therapeutic massager
Regulatory Class: Class I
Product Code: ISA
Dated: February 12, 2021
Received: February 16, 2021

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,

Heather Dean, PhD
Assistant Director, Acute Injury 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)*

K210451

Device Name

OrthoGold 100

Indications for Use *(Describe)*

The OrthoGold 100 is intended for:
- Relief of minor muscle aches and pains
- Temporary increase in local blood circulation
- Activation of connective tissue

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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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.

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: May 4, 2021

Proposed Class: I

Proprietary Name: OrthoGold 100™

Common Name: Therapeutic Massager

Classification Name: Massager, Therapeutic, Electric

Regulation Number: 21 CFR 890.5660
Product Codes: ISA

Predicate Device: Storz Medical D-Actor 200 Vibration Massage System K173692

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.

The technology and performance testing of the OrthoGold 100™ have been cleared previously (K182682). There are no changes to the OrthoGold 100™ regarding device characteristics, software, and device performance since the previous clearance.

Indications for Use

The OrthoGold 100 is intended for:

- Relief of minor muscle aches and pains
- Temporary increase in local blood circulation
- Activation of connective tissue

Performance Data

Verification and validation testing was performed and demonstrated that the OrthoGold 100™ 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 OrthoGold 100™ 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 OrthoGold 100 was tested and demonstrated to conform to the general safety requirements of IEC 60601-1:2005; as well as the electromagnetic compatibility requirements of IEC 60601-1-2:2014 (4th Ed.) and 60601-2-36. In-vitro testing was performed to determine applicator displacement, force and penetration depth and was demonstrated to be equivalent to the AW module of the D-Actor 200 predicate device. In addition, probe cover testing and transport verification and validation was also conducted. The performance testing demonstrated that the OrthoGold 100 is substantially equivalent to the predicate device.

The OrthoGold 100 is compliant with 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
DRAFT IEC 63045 ED1, Ultrasonics - Non-focusing pressure pulse sources - Characteristics of fields	N/A

There are no changes to the standards referenced in the previous submission as this submission present no changes to the previously cleared OrthoGold 100.

Clinical Data

Clinical performance data is not relied upon to eastanblish the substantial equivalence of the subject and predicate device.

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

Product Characteristic	**Subject Device** **OrthoGold 100™**	**Predicate Device** **D-Actor 200**	**Comparison**
510(k) Number	**K210451**	**K173692**	**NA**
Indications for Use	Relief of minor muscle aches and pains Temporary increase in local blood circulation Activation of connective tissue	Relief of minor muscle aches and pains Temporary increase in local blood circulation Activation of connective tissue	Equivalent
Modes of Action	Unfocused pressure pulses	Radial (unfocused) pressure waves, or extracorporeal pulse activation respectively	Similar
Mechanisms of Action	Extracorporeally induced unfocused pressure pulses	Pneumatically generated vibrations + unfocused pressure pulses	Equivalent
Maximum and Minimum intensity settings	1 to 16	1-5 bar	Similar
Number and size of treatment applicator heads	OP155 Size: 230 x ø 70 mm	4: 6mmOD, 15mmOD, 20mmOD, 35mmOD	Similar
Maximum and minimum displacements of applicator heads	Not Applicable	0.6 – 2.0 mm	NA
Type of application (e.g., continuous vibration at a fixed frequency);	Continuous at various frequencies	Continuous at various frequencies	Similar

Product Characteristic	**Subject Device** **OrthoGold 100™**	**Predicate Device** **D-Actor 200**	**Comparison**
Maximum and minimum vibration frequency	Frequency of 1 - 8 Hz in steps of 0.5 Hz	1-21 Hz	Similar
Driving Power	High voltage 2 - 7 kV Capacitor: 0,2 uF	1-5 bar	Similar
Power Supply	115 VAC	500 VA	Similar
Maximum penetration depth	25.4 mm at energy level 16	32mm	Similar
Energy flow density PIIT [mJ/mm2]	0.00017 - 0.04403 at energy level 1 - 16	Values of ultrasonic pulse: 5bar/0.284mJ/mm2 3bar/0.176mJ/mm2	Similar
Operating mode	Continuous	Continuous	Similar
Projectile mass (g)	Not Applicable	3	NA
Pulse repeat rate (1/s)	1 - 8 Hz	1-21 Hz	Similar
Number of pulses (min and max)	500 - 2000	Variable	Similar
Maximum operating temperature	Room temperature	10-40C	Similar
Type of acoustic wave generation	Electro hydraulic, spark gap under water caused by discharge of high voltage condensers	Pneumatic/ballistic	Similar
Peak compressional acoustic pressure pc [Mpa]	9.27 at energy level 16	18.5	Similar
Peak rarefactional acoustic pressure pcr[Mpa]	-1.52 at energy level 16	6.8MPa at 5 bar	Similar

Product Characteristic	Subject Device OrthoGold 100™	Predicate Device D-Actor 200	Comparison
Description of the spatial distribution of the acoustic pressure and intensity	Unfocused acoustic pressure field, see pressure measurements	Specific Value Not Available	Similar
Positive peak pressure amplitude (MPa) pc [Mpa]	0.43 - 9.27 at energy level 1 - 16	5 bar/18.5Mpa 3bar/13.4MPa	Similar
Negative peak pressure amplitude (MPa) pcr[Mpa]	-0.17 to -1.52 MPa at energy level 1 - 16	Values of ultrasonic pulse: 5bar/6.8MPa 3bar/5.0MPa	Similar
Derived focal acoustic pulse energy (mJ) EbT [mJ]	0.022 - 2.278 at energy level 1 - 16	Values of ultrasonic pulse: 5bar/6.5mJ 3bar/2.4mJ	Similar
Derived pulse -intensity integral, integrated over total temporal integration limits PIIT [mJ/mm2]	0.00017 - 0.04403 mJ/mm2 at energy level 1 - 16	Values of ultrasonic pulse 5bar/0.284mJ/mm2 3bar/0.176mJ/mm2	Similar
Rise time (ns) (10% - 90%) tr [us]	1.89 - 0.28 at energy level 1 - 16	Ultrasonic pulse: 2.5µs Sonic pulse: 25µs – 2.5ms	Similar
Compressional pulse duration (µs) tFWHMpc [uS]	1.23 - 0.77 µs at energy level 1 - 16	Ultrasonic pulse: 5.0µs Sonic pulse: 50µs – 5.0ms	Similar

Technological Characteristics and Substantial Equivalence

The OrthoGold 100 has the same indications for use and similar design features as compared with the predicate system. The bench testing demonstrates that the performance characteristics of the OrthoGold 100 are equivalent to those of other legally marketed therapeutic massagers, and therefore supports a determination of Substantial Equivalence for the proposed indications for use. 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.