March 6, 2020

ZetrOZ Systems, LLC
Sabrina Lewis
Director, Quality Assurance & Regulatory Affairs
Musculoskeletal Clinical Regulatory Advisers, LLC
1050 K Street NW
Suite 1000
Washington, DC 20001

Re: K191568
Trade/Device Name: sam 2.0 Long Duration Ultrasound System
Regulation Number: 21 CFR 890.5300
Regulation Name: Ultrasonic Diathermy
Regulatory Class: Class II
Product Code: PFW
Dated: February 4, 2020
Received: February 4, 2020

Dear Sabrina Lewis:

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,

For Vivek Pinto, PhD
Director
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K191568

Device Name

sam 2.0 Long Duration Ultrasound Device

Indications for Use *(Describe)*

The sam 2.0 Long Duration Ultrasound Device is intended for home use to apply ultrasonic energy to generate deep heat within body tissues for the treatment of selected medical conditions such as the relief of pain, the relief of muscle spasms, the treatment of joint contractures, and the local increase in circulation.

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

Device Trade Name: sam 2.0 Long Duration Ultrasound Device

Manufacturer:
ZetrOZ Systems, LLC
56 Quarry Road
Trumbull, CT 06611

Contact:
Ms. Sabrina Lewis
QAR Director
Phone: 888-202-9831
Email: sabrina@zetroz.com

Date Prepared: March 4, 2020

Classification: 21 CFR §890.5300; Ultrasonic diathermy.

Class: II

Product Code: PFW

Predicate Devices: ZetrOZ Ultrasonic Diathermy Device (K130978)

Indications for Use:

The sam 2.0 Long Duration Ultrasound Device is intended for home use to apply ultrasonic energy to generate deep heat within body tissues for the treatment of selected medical conditions such as the relief of pain, the relief of muscle spasms, the treatment of joint contractures, and the local increase in circulation.

Device Description:

The sam 2.0 Long Duration Ultrasound Device consists of:

- Rechargeable Power Controller and Timer
- Ultrasound Generating Applicators
- Applicator Adaptor Cables

Single use disposable accessories

- Ultrasonic Coupling Patch

The Power Controller and cables can be used to power one or two Applicators simultaneously to generate ultrasonic energy at one frequency (3 MHz) and one power setting (0.65 W) per Applicator. In single Applicator mode, the patient can receive 0.65 W at 3 MHz. In dual Applicator

mode, the patient can receive 1.3 W at 3 MHz. The Applicators are applied to the skin with onetime use Ultrasonic Coupling Patches.

The sam 2.0 Long Duration Ultrasound Device contains firmware for logging usage time. There is no control function of this firmware.

The system is intended for prescription home use to apply ultrasonic energy for a long duration (4 hours) to generate deep heat within body tissues and treat selected medical conditions such as the relief of pain, the relief of muscle spasms, the treatment of joint contractures, and the local increase in circulation.

Substantial Equivalence:
The sam 2.0 Long Duration Ultrasound Device is substantially equivalent to the predicate device cited on the previous page with respect to indications, design, function, and performance.

Information	ZetrOZ sam 2.0 Long Duration Ultrasound Device (Subject)	ZetrOZ Ultrasonic Diathermy Device (K130978)	Comparison
Classification Name	Ultrasonic Diathermy Device	Ultrasonic Diathermy Device	Identical
Service Type	Physical Medicine	Physical Medicine	Identical
Classification	21 CFR 890.5300	21 CFR 890.5300	Identical
Class	II	II	Identical
Indications	The sam 2.0 Long Duration Ultrasound Device is intended for home use to apply ultrasonic energy to generate deep heat within body tissues for the treatment of selected medical conditions such as the relief of pain, the relief of muscle spasms, the treatment of joint contractures, and the local increase in circulation.	The ZTX Ultrasonic Diathermy Device is intended to apply ultrasonic energy to generate deep heat within body tissues for the treatment of selected medical conditions such as the relief of pain, the relief of muscle spasms, the treatment of joint contractures, and the local increase in circulation. The ZTX Device is a prescription use device. The ZTX Device should only be administered and monitored by a licensed healthcare practitioner.	Similar. Removal of the healthcare practitioner requirement.
Manufacturer	ZetrOZ	ZetrOZ	Identical
Console/Generator Dimensions (L x W x H cm)	6.10 cm L x 7.09 cm H x 1.88cm W	6.10 cm L x 7.09 cm H x 1.88cm W	Identical
Treatment Head Dimensions (L x W x H cm)	3.81 cm L x 3.30 cm W x 1.14 cm H	3.81 cm L x 3.30 cm W x 1.14 cm H	Identical
Console/Generator Weight (kg)	0.01 kg	0.01 kg	Identical
Treatment Head Weight (kg)	0.10 kg	0.10 kg	Identical

Information	ZetrOZ sam 2.0 Long Duration Ultrasound Device (Subject)	ZetrOZ Ultrasonic Diathermy Device (K130978)	Comparison
Power Supply	120/240 VAC with 5V DC Input Power Jack and Lithium Battery Powered	120/240 VAC with 5V DC Input Power Jack and Lithium Battery Powered	Identical
Leakage Current	0.3 mA	0.3 mA	Identical
Crystal Material	Lead Zirconate-Titanate	Lead Zirconate-Titanate	Identical
Technology of ultrasound generation (e.g., piezoelectric, magnetoconstructive)	Piezoelectric	Piezoelectric	Identical
Treatment Mode(s)	Two discrete settings of power at same Frequency	Two discrete settings of power at same Frequency	Identical
Beam Type (collimated or divergent)	Divergent	Divergent	Identical
Transducer Diameter (cm)	5 cm	5 cm	Identical
Acoustic Working Frequency and Accuracy (MHz)	3MHz ± 20%	3MHz ± 20%	Identical
Effective Radiating Area and Accuracy (cm2)	One: 6 cm^2 Two:12 cm^2 ± 20%	One: 6 cm^2 Two:12 cm^2 ± 20%	Identical
Beam Nonuniformity Ratio and Accuracy	BNR: <5:1 ± 20%	BNR: <5:1 ± 20%	Identical
Output Mode: (Continuous Wave/Amplitude – Modulated Wave)	Continuous Wave - 100% duty cycle	Continuous Wave - 100% duty cycle	Identical
Maximum Timer Setting and Accuracy	4 Hours +/- 1 minute	4 Hours +/- 1 minute	Identical
Beam Maximum Intensity and Accuracy (W/cm2)	0.132 W/cm^2 ± 20%	0.132 W/cm^2 ± 20%	Identical
Maximum Values of the following Powers and Intensities (max settings)			
Maximum Value of the Output Power (Rated Output Power) and Accuracy (W)	Single Applicator: 0.65W ± 20% Dual Applicator: 1.3W ± 20%	Single Applicator: 0.65W ± 20% Dual Applicator: 1.3W ± 20%	Identical
Maximum Value of the Effective Intensity and Accuracy (Not to exceed 3 W/cm2 *)	0.264 W/cm^2 ± 20%	0.264 W/cm^2 ± 20%	Identical
For Amplitude Modulated Waves	Not Amplitude Modulated	Not Amplitude Modulated	Identical
Temperature Specifications			
Peak Temperature Rise vs. Time and Tissue Depth to Maximum Treatment Time (for fixed Treatment Head Placement) (deg C)	8°C at 1 cm 6°C at 3 cm 3°C at 5 cm Max treatment time: 4 hours	8°C at 1 cm 6°C at 3 cm 3°C at 5 cm Max treatment time: 4 hours	Identical
Maximum Patient Contact Surface Temperature of Treatment Head under Simulated or Actual Use Conditions for all Operating	44 °C	44 °C	Identical

Information	ZetrOZ sam 2.0 Long Duration Ultrasound Device (Subject)	ZetrOZ Ultrasonic Diathermy Device (K130978)	Comparison
Conditions (Continually operated for maximum treatment time) (deg C)			
Therapeutically Applied	Ultrasound Coupling Patch	Ultrasound Coupling Patch	Identical
Applicator Type	Up to two circular Applicators with 3 MHz output	Up to two circular Applicators with 3 MHz output	Identical
Applicator Type Applicator Emitting Surface Areas (cm2)	Up to two circular Applicators One Applicator : 5 cm^2 Two Applicators :10 cm^2	Up to two circular Applicators One Applicator : 5 cm^2 Two Applicators :10 cm^2	Identical
Coupling Bandage	ABS Plastic with integrated coupling medium	ABS Plastic with integrated coupling medium	Identical
Applicator Lens Material	TPX	Ultem	Similar
Environmental – Operating Temperature Range	0˚C to +50˚C (32˚F to +122˚F)	0˚C to +50˚C (32˚F to +122˚F)	Identical
Performance Standards	21 CFR 1050.10	21 CFR 1050.10	Identical
Sterility	Non Sterile	Non Sterile	Identical
Designed to meet Electrical Safety Standards	IEC 60601-1 IEC 60601-1-2 IEC 60601-1-11	IEC 60601-1 IEC 60601-1-2	Similar Added 60601-1-11
Biocompatibility	Yes	Yes	Identical
Mechanical safety	Yes	Yes	Identical
Radiation safety (if not radioactive state as such)	Not Radioactive	Not Radioactive	Identical
Software/Firmware	Yes	No	Similar The sam 2.0 Long Duration Ultrasound Device contains firmware for logging usage time. There is no control function of this firmware.
Output Channels	Two Independent Power Channels	Two Independent Power Channels	Identical

Preclinical Testing:

The sam 2.0 Long Duration Ultrasound device was tested to the performance standards set forth under 21 CFR 1050.10 (April 1, 2012). Third party testing of the electronics was performed to demonstrate compliance to IEC 60601-1:2005+AMD1:2012 (Edition 3.1) Medical electrical equipment - Part 1: General requirements for basic safety and essential performance and IEC 60601-1-2:2014 (Edition 4.0) General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests. Third party testing of the device was performed to demonstrate compliance for home use under IEC 60601-1-11:2015 (Edition 2) General requirements for basic safety and essential performance — Collateral standard: Requirements for medical electrical equipment and medical electrical systems used in the home

healthcare environment. Bench testing experiments demonstrated substantially equivalent diathermic heating effects on an ex vivo bovine muscle model.

Clinical Testing:
Usability data, human factors studies, and literature was provided to support the home use label.

Conclusion:
The purpose of the 510(k) is to receive regulatory clearance to introduce the sam 2.0 Long Duration Ultrasound Device to interstate commerce. Substantial equivalence has been demonstrated to the cited predicate device.