June 23, 2023

ZetrOZ Systems, LLC
Sabrina Lewis
QAR Director
56 Quarry Road
Trumbull, Connecticut 06611

Re: K223019
Trade/Device Name: sam 2.0 Long Ultrasound Device
Regulation Number: 21 CFR 890.5300
Regulation Name: Ultrasonic diathermy
Regulatory Class: Class II
Product Code: PFW
Dated: May 17, 2023
Received: May 17, 2023

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,

Amber T. Ballard -S

Amber Ballard, PhD
Assistant 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: 06/30/2023
*See PRA Statement below.*

510(k) Number *(if known)*
K223019

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, the local increase in circulation, and the relief of pain associated with limited mobility and function related to soft tissue injuries (e.g., knee osteoarthritis, chronic myofascial pain, and shoulder, elbow and ankle tendinopathy).

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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*"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."*

# 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@zertoz.com

**Date Prepared:** June 23, 2023

**510(k) Number:** K223019

**Classifications:** 21 CFR §890.5300; Ultrasonic diathermy.

**Class:** II

**Product Code:** PFW

**Predicate Device:** sam 2.0 Long Duration Ultrasound Device (K191568)

**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, the local increase in circulation, and the relief of pain associated with limited mobility and function related to soft tissue injuries (e.g., knee osteoarthritis, chronic myofascial pain, and shoulder, elbow and ankle tendinopathy).

**Device Description:**

The device was previously cleared in K191568. The sam 2.0 Long Duration Ultrasound Device consists of ultrasound:

- Power Controller
- Cables
- Applicators
- 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 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 a onetime use Coupling Patches.

The system is intended to apply ultrasonic energy for a long duration (4 hours) to generate deep heat within body tissues. The system is intended for prescription home use after proper instruction from a healthcare professional.

**Predicate Device:**
ZetrOZ submits the following information in this Premarket Notification to demonstrate that, for the purposes of FDA's regulation of medical devices, the sam 2.0 Long Duration Ultrasound Device is substantially equivalent in intended use, design principles, and performance to the following predicate device:

**Primary Predicate:** sam 2.0 Long Duration Ultrasound Device (K191568)

**Performance Testing Summary:**
Clinical performance testing was utilized to support the substantial equivalence of this device. A systematic literature review was conducted using PubMed, EBSCOhost, Academic Search Complete, Google Scholar and ClinicalTrials.gov to identify studies evaluating the effects of the subject device, Sustained Acoustic Medicine (SAM), on the musculoskeletal system of humans. This systematic review and meta-analysis aim to summarize the clinical effects of SAM treatment on musculoskeletal injuries functional outcomes (strength and range of motion), quality of life, pain reduction, and safety profile of the intervention. Cumulatively, these studies demonstrate the efficacy of SAM therapy 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. As evidenced by the study data summarized above, the relief of pain associated with limited mobility and function related to the soft tissue injuries that have been clinically validated include knee osteoarthritis, shoulder, elbow and ankle tendinopathy, and chronic myofascial pain.

No non-clinical performance testing was performed to support the expansion of indications.

**Substantial Equivalence:**
Overall, the subject device is nearly identical in design and intended use to the primary predicate K191568. The notable difference is in that of the indications. The subject device presents an expansion of indications to better align with the clinical literature on SAM. The SAM is a stationary ultrasound device that is capable of creating deep heating (>4°C) into the tissue. The subject device and predicate K191568 are identical with respect to design, technology, and application.

| **Information** | **ZetrOZ sam 2.0 Long Duration Ultrasound Device (Subject Device)** | **ZetrOZ sam 2.0 Long Duration Ultrasound Device (K191568) (Primary Predicate)** | **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 |
| Product Code | PFW | PFW | 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, the local increase in circulation, and the relief of pain associated with limited mobility and function related to soft tissue injuries (e.g., knee osteoarthritis, chronic myofascial pain, and shoulder, elbow and ankle tendinopathy). | 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. | Similar to the Primary Predicate.<br>The device is intended to treat medical conditions such as the relief of pain, the relief of muscle spasms, the treatment of joint contractures, and the local increase in circulation. It also includes medical conditions relief of pain associated with limited mobility and function related to soft tissue injuries including knee osteoarthritis, shoulder, elbow and ankle tendinopathy, and chronic myofascial pain as supported by clinical evidence. |
| 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) | 0.10 kg | 0.10 kg | Identical |
| Treatment Head Weight (kg) | 0.01 kg | 0.01 kg | Identical |
| Power Supply | 120/240 VAC with 5V DC Input Power Jack and LithiumBattery 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 | 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 ($cm^2$) | One: 6 $cm^2$<br>Two:12 $cm^2$ | One: 6 $cm^2$<br>Two:12 $cm^2$ | Identical |

| | | | |
|---|---|---|---|
| | ± 20% | ± 20% | |
| 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 ($W/cm^2$) | 0.132 $W/cm^2$ ± 20% | 0.132 $W/cm^2$ ± 20% | Identical |
| Maximum Value of the Output Power (Rated Output Power) and Accuracy (W) | Single Applicator: 0.65W ± 20%<br><br>Dual Applicator: 1.3W ± 20% | Single Applicator: 0.65W ± 20%<br><br>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 |
| Peak Temperature Rise vs. Time and Tissue Depth to Maximum Treatment Time (for fixed Treatment Head Placement) (deg C) | 8°C at 1 cm<br>6°C at 3 cm<br>3°C at 5 cm<br>Max treatment time: 4 hours | 8°C at 1 cm<br>6°C at 3 cm<br>3°C at 5 cm<br>Max treatment time: 4 hours | Identical |
| Maximum Patient Contact Surface Temperature of Treatment Head under Simulated or Actual Use Conditions for all Operating Conditions (Continually operated for maximum treatment time) (deg C) | 44 °C | 44 °C | Identical |
| 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<br>One Applicator : 5 $cm^2$<br>Two Applicators :10 $cm^2$ | Up to two circular Applicators<br>One Applicator : 5 $cm^2$<br>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 | TPX | identical |
| 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<br>IEC 60601-1-2 | IEC 60601-1<br>IEC 60601-1-2 | Identical |

| | | | |
|---|---|---|---|
| | IEC 60601-1-11 | IEC 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 | Yes | Identical |
| Output Channels | Two Independent Power Channels | Two Independent Power Channels | Identical |

**Conclusion:**

The subject device and the predicate device have the same intended use, technological characteristics, and are made of similar materials. The subject and predicate devices are packaged in similar materials. The data included in this submission demonstrate substantial equivalence to the predicate device listed above. The sam 2.0 Long Duration Ultrasound Device is as safe, as effective, and performs as well as the predicate device.