October 25, 2023

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

Re: K233210
Trade/Device Name: sam CS Long Duration Ultrasound Device
Regulation Number: 21 CFR 890.5300
Regulation Name: Ultrasonic Diathermy
Regulatory Class: Class II
Product Code: PFW
Dated: September 28, 2023
Received: September 28, 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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Lauren E. Woodard -S

for Amber Ballard, PhD
Assistant Director
DHT5B: Division of Neuromodulation
and Rehabilitation 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)*
K233210

Device Name
sam CS Long Duration Ultrasound Device

Indications for Use *(Describe)*
The sam CS Long Duration Ultrasound Device is intended for home use to apply ultrasonic energy to generate deep heat within body tissues and to increase local 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(K) SUMMARY – K233210

Device Trade Name: sam CS 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: October 24, 2023

Classification: 21 CFR 890.5300; Ultrasonic diathermy.
Class: II

Product Code: PFW

Predicate Devices: sam X1 Long Duration Ultrasound Device (K211513)

Indications for Use:

The sam CS Long Duration Ultrasound Device is intended for home use to apply ultrasonic energy to generate deep heat within body tissues and to increase local circulation.

Device Description:

The sam CS Long Duration Ultrasound Device consists of:

- Rechargeable Power Controller and Timer
- Ultrasound Generating Applicators

Single use disposable accessories

- Ultrasonic Coupling Patch

The Power Controller can be used to power the Applicator 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 CS Long Duration Ultrasound Device contains firmware that controls the timing display and inputs from the power button to activate/deactivate the device. There is no control function of this firmware.

The system is intended for prescription home use to apply ultrasonic energy for a long duration (1 hour) to generate deep heat within body tissues and to increase local circulation.

Table 1: Substantial Equivalence Summary

Information	ZetrOZ sam CS Long Duration Ultrasound Device (Subject)	ZetrOZ sam X1 Long Duration Ultrasound Device (K211513)	Comparison (to sam X1)
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 CS Long Duration Ultrasound Device is intended for home use to apply ultrasonic energy to generate deep heat within body tissues and to increase local circulation.	The sam X1 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. The indication statement is a subset of the previous indication for use. The intended use remains the same.
Manufacturer	ZetrOZ	ZetrOZ	Identical
Console/Generator Dimensions (L x W x H cm)	3.4 cm x 3.4 cm x 1.4 cm	3.4 cm x 3.4 cm x 1.4 cm	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)	0.02 kg	0.02 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 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

Information	ZetrOZ sam CS Long Duration Ultrasound Device (Subject)	ZetrOZ sam X1 Long Duration Ultrasound Device (K211513)	Comparison (to sam X1)
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	1 Hour +/- 1 minute	1 Hour +/- 1 minute	Identical
Beam Maximum Intensity and Accuracy (W/cm2)	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% 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
Peak Temperature Rise vs. Time and Tissue Depth to Maximum Treatment Time (for fixed Treatment Head Placement) (deg C)	7°C at 1 cm 4°C at 3 cm 2°C at 5 cm Treatment time: 1 hour	7°C at 1 cm 4°C at 3 cm 2°C at 5 cm Treatment time: 1 hour	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 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

Information	ZetrOZ sam CS Long Duration Ultrasound Device (Subject)	ZetrOZ sam X1 Long Duration Ultrasound Device (K211513)	Comparison (to sam X1)
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 IEC 60601-1-2 IEC 60601-1-11	IEC 60601-1 IEC 60601-1-2 IEC 60601-1-11	Identical
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 – For measurement of battery level	Yes – For measurement of battery level	Identical
Output Channels	Two Independent Power Channels	Two Independent Power Channels	Identical

Substantial Equivalence:
The sam CS Long Duration Ultrasound Device is substantially equivalent to the predicate device with respect to intended use, design, function, and performance. The purpose of this special 510(k) is to adjust the indications for use statement. The output and strength of the signal are identical to the predicate.

Non-Clinical Performance Data:
The sam CS Long Duration Ultrasound Device is in accordance with these recognized consensus standards:
IEC 60601-1 Ed. 3.1 2012 - Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
IEC 60601-1-2 Ed. 4.0 2014-02 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
IEC 60601-1-11 Ed. 2.0 2015-01 Medical electrical equipment – Part 1-11: 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
ISO 10993 Biological evaluation of medical devices - Part 1-Ed. 5-2018: Evaluation and testing within a risk management process; Part 5 Ed. 3-2009: Tests for in vitro cytotoxicity; Part 10 Ed. 3-2010: Tests for irritation and skin sensitization

Clinical Performance Data:
Clinical testing was not necessary to support substantial equivalence of the sam CS device.

Conclusion:
The sam CS Long Duration Ultrasound Device possesses the same intended use and technological characteristics as the predicate device. Therefore, the sam CS Long Duration Ultrasound Device is substantially equivalent to the legally marketed predicate.