



April 28, 2026

ZetrOZ Systems, LLC
Sabrina Lewis
Quality and Regulatory Director
56 Quarry Rd.
Trumbull, Connecticut 06611

Re: K260076

Trade/Device Name: SAM 3.0 Multi-Hour Continuous Ultrasound Device
Regulation Number: 21 CFR 890.5300
Regulation Name: Ultrasonic diathermy
Regulatory Class: Class II
Product Code: PFW
Dated: January 9, 2026
Received: January 12, 2026

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at <https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system>.

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,


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For 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

Indications for Use

510(k) Number (if known)

K260076

Device Name

SAM 3.0 Multi-Hour Continuous Ultrasound Device

Indications for Use (Describe)

The SAM 3.0 Multi-Hour Continuous 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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510(k) Summary

Device Trade Name: SAM 3.0 Multi-Hour Continuous Ultrasound Device

Manufacturer: ZetrOZ Systems
56 Quarry Road
Trumbull, CT 06611

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

Date Prepared: April 10, 2026

510(k) number: K260076

Classifications: 21 CFR §890.5300; Ultrasonic Diathermy.

Class: II

Product Code: PFW

Primary Predicate: SAM 2.0 Long Duration Ultrasound Device (K223019)

Indications For Use:

The SAM 3.0 Multi-Hour Continuous 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 K223019. The sam 3.0 Multi-Hour Continuous Ultrasound Device consists of ultrasound:

- Power Controller
- Cables
- Applicators
- Coupling Patches

The sam 3.0 Multi-Hour Continuous 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 one time 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.

Differences between SAM 2.0 to SAM 3.0 Multi-Hour Continuous Ultrasound Device generations include applicator and controller changes with simplified hardware and additional features such as extended battery life and improved user feedback including an on an indicator when the applicator is warmed and providing therapeutic heating. The SAM 3.0 has software added to control features that replace solid state IC chips. Due to the larger battery size, the overall thickness of the controller has slightly increased to accommodate the larger battery.

Predicate Device:

ZetrOZ submits the following information in this Premarket Notification to demonstrate that, for the purposes of FDA's regulation of medical devices, SAM 3.0 Multi-Hour Continuous 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 (K223019)

Performance Testing Summary:

The SAM 2.0 Long Duration Ultrasound Device has previously demonstrated clinical performance testing its specific treatment algorithm and operational parameters of 3 MHz, 1.3W, 4 hour, 18,720 Joule continuous therapy. The therapeutic parameters are equivalent to the predicate device which is also produced by the same manufacturer, ZetrOZ Systems. A systematic literature review was conducted on SAM 2.0 in K223019, which applies to the SAM 3.0 device. PubMed, EBSCOhost, Academic Search Complete, Google Scholar and ClinicalTrials.gov were utilized 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 further clinical testing was performed for the substantial equivalence of SAM 3.0.

Summary of non-clinical testing:

Software testing was performed to demonstrate equivalency in operational functionality of the electronics with the addition of software control mechanisms and LED display functionality of the system components.

IEC Testing including IEC 60601-1-11 (2015) AMD 1 2020, 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, IEC 60601-1 ed. 3.2 (2020) Medical electrical equipment - Part 1: General

requirements for basic safety and essential performance, IEC 60601-1-2 ed 4.1 (2020) Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests were performed.

All necessary performance testing was conducted on the SAM 3.0 Multi-Hour Continuous Ultrasound Device to support a determination of substantial equivalence to the manufacturer's SAM 2.0 predicate device.

Substantial Equivalence:

Overall, the subject device is nearly identical in design and intended use to the primary predicate K223019. The SAM 3.0 has added software control function, the addition of new LEDs and larger battery capacity than the predicate K223019. The SAM 3.0 is a stationary ultrasound device that is capable of creating deep heating (>4°C) into the tissue. The subject device and predicate K223019 are nearly identical with respect to design, technology, and application.

Substantial Equivalence Table

Information	ZetrOZ SAM 3.0 Multi-Hour Continuous Ultrasound Device K260076 (Subject Device)	ZetrOZ SAM 2.0 Long Duration Ultrasound Device K223019 (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 for Use	The SAM 3.0 Multi-Hour Continuous 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, 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).	Identical
Manufacturer	ZetrOZ Systems, LLC	ZetrOZ Systems, LLC	Identical
Console/Generator Dimensions(L x W x H cm)	6.10 cm L x 7.09 cm H x 2.34 cm W	6.10 cm L x 7.09 cm H x 1.88 cm W	Similar. The difference in thickness is to accommodate the

Information	ZetrOZ SAM 3.0 Multi-Hour Continuous Ultrasound Device K260076 (Subject Device)	ZetrOZ SAM 2.0 Long Duration Ultrasound Device K223019 (Primary Predicate)	Comparison
			larger battery of the SAM 3.0 device.
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)	0.12 kg	0.10 kg	Similar. The difference in weight is due to the larger capacity battery.
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	<.3 mA	<.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 \pm 20%	3MHz \pm 20%	Identical
Effective Radiating Area and Accuracy (cm²)	One: 6 cm ² Two:12 cm ² \pm 20%	One: 6 cm ² Two:12 cm ² \pm 20%	Identical
Beam Nonuniformity Ratio and Accuracy	BNR: <5:1 \pm 20%	BNR: <5:1 \pm 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
Maximum Energy Delivered (J)	18,720 Joules	18,720 Joules	Identical
Beam Maximum Intensity and Accuracy (W/cm²)	0.132 W/cm ² \pm 20%	0.132 W/cm ² \pm 20%	Identical
Maximum Value of the Output Power (Rated Output Power) and Accuracy (W)	Single Applicator: 0.65W \pm 20% Dual Applicator: 1.3W \pm 20%	Single Applicator: 0.65W \pm 20% Dual Applicator: 1.3W \pm 20%	Identical

Information	ZetrOZ SAM 3.0 Multi-Hour Continuous Ultrasound Device K260076 (Subject Device)	ZetrOZ SAM 2.0 Long Duration Ultrasound Device K223019 (Primary Predicate)	Comparison
Maximum Value of the Effective Intensity and Accuracy	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 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 Conditions (Continually operated for maximum treatment time)	44 °C	44 °C	Identical
Therapeutically Applied	Ultrasound Coupling Patch with Articulating Spacer	Ultrasound Coupling Patch with Articulating Spacer	Identical
Applicator Type	Up to two circular Applicators with 3 MHz output and divergent beam	Up to two circular Applicators with 3 MHz output and divergent beam	Identical
Applicator Type Applicator Emitting Surface Areas (cm²)	Up to two circular Applicators with divergent beam One Applicator : 5 cm ² Two Applicators :10 cm ²	Up to two circular Applicators with divergent beam One Applicator : 5 cm ² Two Applicators :10 cm ²	Identical

Conclusion:

The subject device and the predicate devices have the same intended use, have similar technological characteristics, and are made of similar materials. The data included in this submission demonstrate substantial equivalence to the predicate device listed above. The SAM 3.0 Multi-Hour Continuous Ultrasound Device is as safe, as effective, and performs as well as the predicate device.