June 4, 2025

JKH Health Co., Ltd.
% Bill Dai
Managing Member
Jkh Usa LLC
14271 Jeffrey Rd.
#246
Irvine, California 92620

Re: K240788
Trade/Device Name: Ultrasound Stimulator
Regulation Number: 21 CFR 890.5300
Regulation Name: Ultrasonic Diathermy
Regulatory Class: Class II
Product Code: IMI, PFW
Dated: May 5, 2025
Received: May 5, 2025

Dear Dr. Bill Dai:

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.

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,

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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K240788

Device Name

Ultrasound Stimulator

Indications for Use *(Describe)*

Apply stationary use of ultrasound 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.

Apply continuous movement of ultrasound for:
1. Pain.
2. Pain relief, muscle spasms, and joint contractures.
3. Relief of pain, muscle spasms, and joint contractures that may be associated with:
• Adhesive capsulitis,
• Bursitis with slight calcification,
• Myositis,
• Soft tissue injuries, and
• Shortened tendons due to past injuries and scar tissues.
4. Relief of pain, muscle spasms, and joint contractures resulting from:
• Capsular tightness, and
• Capsular scarring.
5. Localized increase in blood flow.
6. Increased range of motion of contracted joint using heat and stretch techniques.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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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

This 510(k) Summary of safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR 807.92.

1. Submitter's Information

Submitter: JKH Health Co., Ltd.
Address: 3-5F And 11F, Building 14, Tiangong Smart Valley Industrial Park, Fuhai Road, Xiagang Community, Chang'an Town, Dongguan, Guangdong, China
Contact Person: Pu Jiang
Tel: +86-755-27926589
Fax: +86-755-29970323
Email: sales@JKHhealth.com Date of Preparation: June 4, 2025

2. Subject Device

Trade/Device Name: Ultrasound Stimulator
Common Name: Ultrasonic Diathermy For Use In Applying Therapeutic Deep Heat Review
Panel: Physical Medicine
Product Code: IMI, PFW
Regulation Number: 21 CFR 890.5300
Device Class: II
Use: Prescription

3. Predicate device

Primary Predicate Device: ManaSport+
510(k) Number: K222098
Clearance Date: March 8, 2023
Submitter: ManaMed, Inc.

Predicate Device: sam 2.0 Long Duration Ultrasound System
510(k) Number: K191568
Clearance Date: March 6, 2020
Submitter: ZetrOZ Systems, LLC

4. Description of Subject Device

As a portable and rechargeable prescriptive device in the home or clinical/hospital setting, the subject device is intended to apply ultrasound to the patient's treatment site. It is demonstrated ultrasound can be used to apply therapeutic deep heat for the treatment of medical conditions including relief of pain, muscle spasms, and joint contractures.

It is intended to be used for 30 minutes per cycle (up to 4 cycles) in the home or clinical/hospital setting by or under the direction of a medical professional to apply ultrasound to the patient's treatment site. The device automatically alerts the patient in case of improper application or performance. All the control components and the rechargeable battery of the device are protectively housed, and the device is connected to one or two applicators of ultrasound.

The subject device consists of the main device, the applicator, the charger/adapter, the liquid and/or solid ultrasound gel, and the sticky pad. For the best result, use the ultrasound gel and the sticky pad supplied.

If you feel your skin is sensitive to the ultrasound gel and/or pad supplied, please contact your physician or use a different FDA-cleared ultrasound gel and/or pad.

5. Indications for Use

Apply stationary use of ultrasound 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.

Apply continuous movement of ultrasound for:
1. Pain.
2. Pain relief, muscle spasms, and joint contractures.
3. Relief of pain, muscle spasms, and joint contractures that may be associated with:
   - Adhesive capsulitis,
   - Bursitis with slight calcification,
   - Myositis,
   - Soft tissue injuries, and
   - Shortened tendons due to past injuries and scar tissues.
4. Relief of pain, muscle spasms, and joint contractures resulting from:
   - Capsular tightness, and
   - Capsular scarring.
5. Localized increase in blood flow.
6. Increased range of motion of contracted joint using heat and stretch techniques.

6. Substantial Equivalence

The following Table 1 summarizes the comparison between the subject device and the predicate device, indicating the intended use and technical characteristics of the subject device are substantially equivalent to those of the predicate device.

Table 1. Comparison between the predicate device and the subject device

Parameter & Predicate Device(s)	**Subject Device**	**Primary Predicate Device**	**Predicate Device**	**Equivalence**
510(k)/PMA Number	K240788	K222098	K191568	N/A
Submitter /Manufacturer	JKH Health Co., Ltd.	ManaMed, Inc.	ZetrOZ Systems, LLC	N/A
Device Name/Model	Ultrasound Stimulator	ManaSport+	sam 2.0 Long Duration Ultrasound System	N/A
Product Code of Ultrasound	IMI, PFW	IMI, PFW	PFW	Identical
Indications for Use	Apply stationary use of ultrasound 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. Apply continuous movement of ultrasound for: 1. Pain. 2. Pain relief, muscle spasms, and joint contractures. 3. Relief of pain, muscle	Apply stationary use of ultrasound 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. Apply continuous movement of ultrasound for: 1. Pain. 2. Pain relief, muscle spasms, and joint contractures.	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.	Identical

		spasms, and joint contractures that may be associated with: • Adhesive capsulitis, • Bursitis with slight calcification, • Myositis, • Soft tissue injuries, and • Shortened tendons due to past injuries and scar tissues. 4. Relief of pain, muscle spasms, and joint contractures resulting from: • Capsular tightness, and • Capsular scarring. 5. Localized increase in blood flow. 6. Increased range of motion of contracted joint using heat and stretch techniques.	3. Relief of pain, muscle spasms, and joint contractures that may be associated with: • Adhesive capsulitis, • Bursitis with slight calcification, • Myositis, • Soft tissue injuries, and • Shortened tendons due to past injuries and scar tissues. 4. Relief of pain, muscle spasms, and joint contractures resulting from: • Capsular tightness, and • Capsular scarring. 5. Localized increase in blood flow. 6. Increased range of motion of contracted joint using heat and stretch techniques.		
Prescription or OTC		Prescription	Prescription	Prescription	Identical
Power Source(s)		100~240 Vac with 5Vdc Input and rechargeable 3.7Vdc battery	100~240 Vac with 5Vdc Input and rechargeable 3.7Vdc battery	120/240 VAC with 5V DC Input Power Jack and Lithium Battery Powered	Identical
Number of Output		1 or 2	1	1-2	Identical
Software /Firmware/ Microprocessor Control?		Yes	Yes	Yes	Identical
Automatic No-Load Trip?		Yes	Yes	Not Publicly Available	Identical
Automatic Shut Off?		Yes	Yes	Not Publicly Available	Identical
User Override Control?		Yes	Yes	Not Publicly Available	Identical
Indicator Display:	On/Off Status?	Yes	Yes	Not Publicly Available	Identical
	Low Battery?	Yes	Yes	Not Publicly Available	Identical
Timer Range (minutes)		30	20	240	Longer than the primary predicate, and shorter than the predicate. There is an overheating temperature protection enforced to prevent the temperature of the treatment head going over 43°C during the normal use, so the possible range of temperature is lower than 43°C. The tests provided shows this does not affect the safety or effectiveness.
Compliance with Voluntary Standards?		Yes	Yes	Yes	Identical
Biocompatibility?		Yes	Yes	Yes	Identical
Sterility		Non-Sterile	Non-Sterile	Non-Sterile	Identical
Housing construction material		ABS	ABS	ABS	Identical
Console/Generator Dimensions (mm) [L x W x H]		138×62×22	140×56×24	61×70.9×18.8	Similar, and do not affect the safety or effectiveness
Console/Generator Weight (kg)		0.18	0.13	0.01	Similar, and do not affect the safety or effectiveness

Treatment head dimensions (mm) [L x W x H]	61 x 45 x 12	30 x 30 x 12	38.1 x 33 x 11.4	Similar, and do not affect the safety or effectiveness
Treatment Head Weight (kg)	0.047	0.031	0.10	Similar, and do not affect the safety or effectiveness
Functions and design	Ultrasound	Ultrasound	Ultrasound	Identical
Frequency	1.5 MHz ± 10%	1.5	3 MHz ± 20%	Identical
Leakage current	<0.3mA	<0.3mA	0.3mA	Identical
Crystal material	PZT	PZT	Lead Zirconate-Titanate	Identical
Technology of Ultrasound generation	Piezoelectric	Piezoelectric	Piezoelectric	Identical
Output Mode	Continuous Wave - 100% duty cycle	Continuous Wave - 100% duty cycle	Continuous Wave - 100% duty cycle	Identical.
Ratio of temporal maximum output power to the output power	1:1	1:1	Not Publicly Available	Identical
Maximum Value of the Output Power (W ± 20%)	0.60	0.60	Single Applicator: 0.65W ± 20% Dual Applicator: 1.3W ± 20%	Similar
Temporal average power (W ± 20%)	0.60	0.60	Not Publicly Available	Identical
Maximum value of the effective intensity (W/cm^2)	0.15 ± 20%	0.16 ± 20%	0.264 ± 20%	Identical or similar. According to the IEC 61689, the deviation allowed is ± 30%.
Beam Maximum Intensity and Accuracy (W/cm^2)	0.15 ± 20%	0.16 ± 20%	0.132 ± 20%	Identical or similar. According to the IEC 61689, the deviation allowed is ± 30%.
Duty factor	100%	100%	Not Publicly Available	Identical
Beam Type	Collimated	Collimated	Divergent	Identical
Applicator size	Area: 3.9 cm^2	Area: 3.9 cm^2 or 5cm^2	One Applicator: 5 cm^2 Two Applicators: 10 cm^2	Identical
Maximum patient contact surface temperature of the treatment head under simulated or actual use conditions for all operating conditions (continually operated for maximum treatment time) (°C)	Meets IEC 60601-2-5, section 201.11 Protection against excessive temperature and other HAZARDS.	Meets IEC 60601-2-5, section 201.11 Protection against excessive temperature and other HAZARDS.	44 °C	Identical
Peak Temperature Rise vs. Time and Tissue Depth to Maximum Treatment Time (for fixed Treatment Head Placement) (°C)	8.6°C at 1 cm 6.1°C at 2 cm 2.1°C at 3 cm Max treatment time: 30 min per cycle and 4 cycles	7.6°C at 1 cm 3.3°C at 2 cm 1.4°C at 3 cm Max treatment time: 20 min	8°C at 1 cm 6°C at 3 cm 3°C at 5 cm Max treatment time: 4 hours	Identical or similar. There is an overheating temperature protection enforced to prevent the temperature of the treatment head going over 43°C during the normal use, so the possible range of temperature is lower than 43°C. The tests provided shows this does not affect the safety or effectiveness.
Beam Non-Uniformity Ratio	<5	4 ± 20%	<5:1 ± 20%	Identical
Effective Radiating Area (cm^2)	3.9 ± 20%	3.9 or 5 ± 20%	One: 6 cm^2 Two:12 cm^2 ± 20%	Identical

7. Summary of Substantial Equivalence

As shown in the above Table 1, the ultrasound from the subject device is identical or similar to the predicate device. There are no new safety or effectiveness issues concerning the subject device, which offers substantially equivalent technical specifications, features, intended use, safety, and effectiveness to the predicate device.

8. Non-Clinical Tests Performed

Non-clinical tests were performed on the subject device in order to validate the design and to assure conformance with the following voluntary design standards in connection with medical device electrical safety, and electromagnetic compatibility.

(a) ANSI AAMI ES60601-1 "Medical Electrical Equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601-1)".
(b) IEC 60601-1-2 "Medical Electrical Equipment - Part 1-2: General Requirements for Basic Safety and Essential Performance - Collateral standard: Electromagnetic Compatibility - Requirements and Tests".
(c) IEC 60601-2-5 "Medical electrical equipment - Part 2-5: Particular requirements for the basic safety and essential performance of ultrasonic physiotherapy equipment".
(d) ISO 10993-5 "Biological evaluation of medical devices -- Part 5: Tests for In Vitro Cytotoxicity".
(e) ISO 10993-10 "Biological evaluation of medical devices - Part 10: Tests for Irritation and Skin Sensitization".
(f) IEC 60601-1-6 "Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability".
(g) IEC 60601-1-11 "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"

In addition to the compliance of voluntary standards, the verification of software used in the subject device has been carried out according to the FDA Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices, and the bench performance testing for the subject device and ultrasonic gel pad has also been conducted.

The subject device was evaluated to ensure all the non-clinical tests in this submission support a determination of substantial equivalence, including:

- Power output evaluation
- Evaluation of total treatment time
- Electrical safety and EMC evaluation
- Device Operation evaluation
- Powering On/Off
- Usability evaluation
- Biocompatibility evaluation
- Thermal safety evaluation
- Performance evaluation

- Software evaluation

All the non-clinical tests performed above demonstrate the subject device is as safe and as effective as the legally marketed predicate devices. The detailed comparison between the subject device and the predicate devices in the above Table 1 demonstrates the intended use and technical characteristics of the subject device are substantially equivalent to those of the predicate devices.

9. Clinical Testing

Clinical testing was not provided in support of this 510(k) application.

10. Conclusion

The testing and comparison performed demonstrate the subject device is substantially equivalent to the predicate devices. Therefore, the subject device is as safe and effective as the predicate devices that have been legally marketed in the United States.