March 8, 2023

ManaMed, Inc.
% Bill Quanqin Dai
Official Correspondent
JKH USA, LLC
14271 Jeffrey Rd. #246
Irvine, California 92620

Re: K222098
Trade/Device Name: ManaSport+
Regulation Number: 21 CFR 890.5300
Regulation Name: Ultrasonic diathermy
Regulatory Class: Class II
Product Code: IMI, PFW
Dated: February 8, 2023
Received: February 9, 2023

Dear Bill Quanqin 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 (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,

Lauren E. Woodard -S

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

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)*
K222098

Device Name
ManaSport+

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.

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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: ManaMed, Inc.
Address: 5240 W. Charleston Blvd.
Las Vegas, NV 89146
Date of Preparation: 03/08/2023

2. Subject Device

Trade/Device Name: ManaSport+
510(k): K222098
Common Name: Ultrasonic Diathermy Device For Use In Applying Therapeutic Deep Heat
Review Panel: Physical Medicine
Product Code: IMI, PFW
Regulation Number: 21 CFR 890.5300
Regulation Name: Ultrasonic diathermy
Device Class: II
Use: Prescription

3. Predicate device

Primary Predicate Device: ManaSport
510(k) Number: K210284
Clearance Date: April 26, 2022
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

The ManaSport+ is an adaptation of the previously cleared ManaSport device, which was cleared under K210284. A wireless control option was added to the ManaSport+ and the subject device was evaluated for home use. 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 for 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. Ultrasound can be used to apply therapeutic deep heat for the treatment of selected medical conditions such as soft tissue injuries, shortened tendons due to past injuries and scar tissues, relief of pain, muscle spasms and joint contractures.

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. Summary of 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 subject device and the predicate device

Parameter & Predicate Device(s)	**Subject Device**	**Primary Predicate Device**	**Predicate Device**	**Equivalence**
510(k)/PMA Number	K222098	K210284	K191568	N/A
Submitter /Manufacturer	ManaMed, Inc	ManaMed, Inc.	ZetrOZ Systems, LLC	N/A
Device Name/Model	ManaSport+	ManaSport	sam 2.0 Long Duration Ultrasound System	N/A
Product Code	IMI, PFW	IMI, PFW	PFW	Identical
Parameter & Predicate Device(s)	Subject Device	Primary Predicate Device	Predicate Device	Equivalence
510(k)/PMA Number	K222098	K210284	K191568	N/A
Submitter /Manufacturer	ManaMed, Inc	ManaMed, Inc.	ZetrOZ Systems, LLC	N/A
Device Name/Model	ManaSport+	ManaSport	sam 2.0 Long Duration Ultrasound System	N/A
Product Code	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 spasms, and joint contractures that may be associated with: • Adhesive capsulitis,	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,	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

	• 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.	• 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. Increased range of motion of contracted joint using heat and stretch techniques.		
Intended Users		Health Care Professionals and lay users (under prescription)	Not Publicly Available	Health Care Professionals and lay users (under prescription)	Identical
Prescription or OTC		Prescription	Prescription	Prescription	Identical
Power Source(s)		120/240 Vac with 5Vdc Input and rechargeable 3.7Vdc battery	Not Publicly Available	120/240 VAC with 5V DC Input Power Jack and Lithium Battery Powered	Identical
Number of Output		1	Not Publicly Available	1-2	Identical
Software /Firmware/ Microprocessor Control?		Yes	Not Publicly Available	Yes	Identical
Automatic No-Load Trip?		Yes	Not Publicly Available	Not Publicly Available	Identical
Automatic Shut Off?		Yes	Not Publicly Available	Not Publicly Available	Identical
User Override Control?		Yes	Not Publicly Available	Not Publicly Available	Identical
Indicator Display:	On/Off Status?	Yes	Not Publicly Available	Not Publicly Available	Identical
	Low Battery?	Yes	Not Publicly Available	Not Publicly Available	Identical
	Voltage / Current Level?	Yes	Not Publicly Available	Not Publicly Available	Identical
Timer Range (minutes)		0-20	Not Publicly Available	0-240	Identical or similar. This does not affect the safety or effectiveness.
Compliance with Voluntary Standards?		Yes	Not Publicly Available	Yes	Identical
Biocompatibility?		Yes	Not Publicly Available	Yes	Identical
Sterility		Non-Sterile	Not Publicly Available	Non-sterile	Identical
Housing construction material		ABS	Not Publicly Available	ABS	Identical
Console/Generator Dimensions (mm) [L x W x H]		140×56×24	Not Publicly Available	61×70.9×18.8	Identical or similar. This does not affect the safety or effectiveness.
Console/Generator Weight (kg)		0.13	Not Publicly Available	0.01	Identical or similar. This does not affect the safety or effectiveness.
Treatment head dimensions (mm) [L x W x H]		30 x 30 x 12	Not Publicly Available	38.1 x 33 x 11.4	Identical or similar. This does not affect the safety or effectiveness.
Treatment Head Weight (kg)		0.031	Not Publicly Available	0.10	Identical or similar. This does not affect the safety or effectiveness.
Functions and design		Ultrasound	Not Publicly Available	Ultrasound	Identical
Frequency (MHz)		1.5	Not Publicly Available	3	Identical or small. The frequency of the subject device is identical to that of the primary predicate device, and smaller than that of the predicate device. Therefore, the frequency does not affect the safety or effectiveness.
Leakage current		<0.3mA	Not Publicly Available	0.3mA	Identical
Crystal material		PZT	Not Publicly Available	Lead Zirconate-Titanate	Identical
Technology of Ultrasound generation		Piezoelectric	Not Publicly Available	Piezoelectric	Identical
Output Mode		Continuous Wave - 100% duty cycle	Not Publicly Available	Continuous Wave - 100% duty cycle	Identical

Ratio of temporal maximum output power to the output power	1:1	Not Publicly Available	Not Publicly Available	Identical

Deviation	± 20%	Not Publicly Available	± 20%	Identical
Maximum Value of the Output Power (W ± 20%)	0.60	Not Publicly Available	Single Applicator: 0.65W ± 20% Dual Applicator: 1.3W ± 20%	Identical or similar. Therefore, the maximum power does not affect the safety or effectiveness.
Temporal average power (W ± 20%)	0.60	Not Publicly Available	Not Publicly Available	Identical or similar. Therefore, the temporal average power does not affect the safety or effectiveness.
Maximum value of the effective intensity (W/cm^2 ± 20%)	0.16	Not Publicly Available	0.264	Identical or similar. Therefore, the maximum effective intensity does not affect the safety or effectiveness.
Beam Maximum Intensity and Accuracy (W/cm^2 ± 20%)	0.16	Not Publicly Available	0.132	Identical or similar. Therefore, the bean maximum intensity does not affect the safety or effectiveness.
Duty factor	100%	Not Publicly Available	100%	Identical
Beam Type	Collimated	Not Publicly Available	Divergent	Identical or similar. This does not affect the safety or effectiveness.
Applicator size	Area: 3.9 or 5 cm^2	Not Publicly Available	Up to two circular Applicators One Applicator: 5 cm2 Two Applicators :10 cm2	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.	Not Publicly Available	44 °C	Identical
Peak Temperature Rise vs. Time and Tissue Depth to Maximum Treatment Time (for fixed Treatment Head Placement) (°C)	7.6°C at 1 cm 3.3°C at 2 cm 1.4°C at 3 cm Max treatment time: 20 min	Not Publicly Available	8°C at 1 cm 6°C at 3 cm 3°C at 5 cm Max treatment time: 4 hours	Identical or similar. This value of the subject device is identical to that of the primary predicate device, and smaller than that of the predicate device. Therefore, it does not affect the safety or effectiveness.
Beam Non-Uniformity Ratio	4 ± 20%	Not Publicly Available	<5 ± 20%	Identical or similar. Therefore, the beam non-uniformity ratio does not affect the safety or effectiveness.
Effective Radiating Area (cm^2)	3.9 or 5 ± 20%	Not Publicly Available	One: 6 cm2 Two:12 cm2 ± 20%	Identical or smaller. Therefore, the effective radiating area does not affect the safety or effectiveness.
Electrical Safety Standards Compliance	IEC 60601-1 IEC 60601-2-5 IEC 60601-1-2 IEC 60601-1-11 IEC 60601-1-6 Wireless Coexistence Cybersecurity	Not Publicly Available	IEC 60601-1 IEC 60601-1-2 IEC 60601-1-11	Identical or similar with IEC 60601- 1-11 and IEC 60601-1-6 added
Wireless Control via Bluetooth App	Yes	Not Publicly Available	No	Different. Although the primary predicate and predicate devices do not have the wireless option, such a wireless option is optional to the subject device. Just like the primary predicate device, the subject device can be operated independently to realize all its features, and completely does not rely on the optional wireless communication to realize any of its features.

7. Substantial Equivalence

The subject and primary predicate device are identical except for the modification made (Home Use & Wireless Option). The home use added to the subject device is supported by IEC 60601-1-11 as well as IEC 60601-1-6, just like the secondary predicate K191568 that has the home use. Although the primary predicate and predicate devices do not have the wireless option, such a wireless option is optional to the subject device. Just like the primary predicate device, the subject device can be operated independently to realize all its features, and completely does not rely on the optional wireless communication to realize any of its features. Supported by the wireless coexistence and cybersecurity, the wireless option does not affect any technical specifications, features, intended use, safety, and effectiveness of the subject device when compared to the primary predicate device.

Therefore, the differences between the subject device and the predicate device do not raise any new issues of safety or effectiveness. Also, those differences do not affect the intended use or alter the fundamental technology of the 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 60601-1-11 "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".
(g) IEC 60601-1-6 "Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability".

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.

9. Clinical Testing

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

10. Conclusion

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