October 7, 2025

Xemis Medical Technology (Shenzhen) Co., Ltd.
℅ Jie Yang
Consultant
Chonconn Consulting Co., Ltd.
Room 504, Block C, No. 1029 Nanhai Avenue, Nanshan District
Shenzhen, Guangdong 518067
China

Re: K244041
Trade/Device Name: Ultrasound Therapy Workstation (XMS-UET2)
Regulation Number: 21 CFR 890.5860
Regulation Name: Ultrasound And Muscle Stimulator
Regulatory Class: Class II
Product Code: IMG, GZI, GZJ, IPF, LIH
Dated: December 30, 2024
Received: August 25, 2025

Dear Jie Yang:

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)*

K244041

Device Name

Ultrasound Therapy Workstation (XMS-UET2)

Indications for Use *(Describe)*

This device is intended for use only in adult patients.
Therapeutic Ultrasound
Application of therapeutic deep heat for the treatment of selected sub-chronic and chronic medical conditions such as:
1) Pain relief, muscle spasms and joint contractures.
2) Relief of pain, muscle spasms and joint contractures that may be associated with:
- Adhesive capsulitis
- Bursitis with slight calcification
- Myositis
- Soft tissue injuries
- Shortened tendons due to past injuries and scar tissues

3) Relief of sub-chronic, chronic pain and joint contractures resulting from:
- Capsular tightness
- Capsular scarring

For TENS, Interferential, premodulated (IFC), NMS and Microcurrent:
1) Symptomatic relief of chronic intractable pain
2) Post-traumatic acute pain
3) Post-surgical acute pain

Additionally for NMS, NMS Burst, Hi-Volt and Russian:
1) Relaxation of Muscle spasms
2) Prevention or retardation of disuse atrophy
3) Increasing local blood circulation
4) Muscle re-education
5) Maintaining or increasing range of motion
6) Immediate postsurgical stimulation of calf muscles to prevent venous thrombosis

For DC Continuous Mode
1) Relaxation of muscle spasm

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

Prepared in accordance with the requirements of 21 CFR Part 807.92

Prepared Date: 2025-10-07

1. Submission sponsor

Name: Xemis Medical Technology (Shenzhen) Co., Ltd.
Address: 1101/1102/1201/1202, Unit 1, Building 2, Hongpeng Building, Tiegang Community, Xixiang Street, Baoan, Shenzhen, China
Contact person: Yang Yongfen
Title: RA Engineer
E-mail: yangyongfen@ximisihn.com
Tel: 86-755-23316735

2. Submission correspondent

Name: Chonconn Consulting Co., Ltd.
Address: Room 504, Block C, No. 1029 Nanhai Avenue, Nanshan District, Shenzhen, Guangdong, P.R. China
Contact person: Yang Jie
E-mail: yangjie@chonconn.com
Tel: +86-755 33941160

3. Subject Device Information

Trade/Device Name	Ultrasound Therapy Workstation
Model	XMS-UET2
Common Name	Ultrasound Therapy Workstation
Regulatory Class	Class II
Classification Regulation	21 CFR 890.5860 (Ultrasound and muscle stimulator)
Product codes	IMG, IPF, GZI, GZJ, LIH
Submission type	Traditional 510(K)

4. Predicate Device

	Device name and model	**K number**	**Manufacturer**
Predicate device	ComboRehab	K150436	Shenzhen Dongdixin Technology Co. Ltd.

5. Device Description

The Ultrasound Therapy Workstation (model: XMS-UET2) is an AC-powered device designed to use electrical stimulation and therapeutic ultrasound. Key features include ultrasound output and electrical stimulation output. This device is intended for use in healthcare environments such as hospitals, rehabilitation centers, community health service centers, and clinics.

The device has a color touchscreen display and a control knob with light ring. The screen display shows system information to the user. Both display screen and control knob can assist the user in selecting or adjusting parameters. All controls and indicators are controlled by software.

Three non-invasive therapeutic methods are available: electrotherapy, ultrasound therapy and combination therapy (ultrasound plus electrical stimulation). For each method, the device is configured with protocols and manual operation, which can facilitate users to choose pre-set protocols or adjust parameters to suit individual needs.

6. Indication for use

This device is intended for use only in adult patients.

Therapeutic Ultrasound

Application of therapeutic deep heat for the treatment of selected sub-chronic and chronic medical conditions such as:

1) Pain relief, muscle spasms and joint contractures.

2) Relief of pain, muscle spasms and joint contractures that may be associated with:

- Adhesive capsulitis
- Bursitis with slight calcification
- Myositis
- Soft tissue injuries
- Shortened tendons due to past injuries and scar tissues

3) Relief of sub-chronic, chronic pain and joint contractures resulting from:

- Capsular tightness
- Capsular scarring

For TENS, Interferential, premodulated (IFC), NMS and Microcurrent:

1) Symptomatic relief of chronic intractable pain

2) Post-traumatic acute pain

3) Post-surgical acute pain

Additionally for NMS, NMS Burst, Hi-Volt and Russian:

1) Relaxation of Muscle spasms

2) Prevention or retardation of disuse atrophy

3) Increasing local blood circulation

4) Muscle re-education

5) Maintaining or increasing range of motion

6) Immediate postsurgical stimulation of calf muscles to prevent venous thrombosis

For DC Continuous Mode

1) Relaxation of muscle spasm

7. Comparison to the Predicate Device

Features	Subject Device:	Predicate Device	Comparison
1.510(k) number	K244041	K150436	/
2.Device name, Model	Ultrasound Therapy Workstation XMS-UET2	ComboRehab	/
3.Manufacturer	Xemis Medical Technology (Shenzhen) Co., Ltd.	Shenzhen Dongdixin Technology Co. Ltd	/
Product Code	IMG,GZI,GZJ,IPF,LIH	IMG, IPF, GZJ, GZI, LIH, HCC	Same, See indications for use.
Regulation Number	21 CFR 890.5860	21 CFR 890.5860	Same
Classification	Class II	Class II	Same
Type of use	Prescription	Prescription	Same
Indications for Use	This device is intended for use only in adult patients Therapeutic Ultrasound Application of therapeutic deep heat for the treatment of selected sub-chronic and chronic medical conditions such as: 1) Pain relief, muscle spasms and joint contractures. 2) Relief of pain, muscle spasms and joint contractures that may be associated with: - Adhesive capsulitis - Bursitis with slight calcification - Myositis - Soft tissue injuries - Shortened tendons due to past injuries and scar tissues 3) Relief of sub-chronic, chronic pain and joint contractures resulting from:	Therapeutic Ultrasound Application of therapeutic deep heat for the treatment of selected sub-chronic and chronic medical conditions such as: 1. Pain relief, muscle spasms and joint contractures. 2. Relief of pain, muscle spasms and joint contractures that may be associated with: • Adhesive capsulitis • Bursitis with slight calcification • Myositis • Soft tissue injuries • Shortened tendons due to past injuries and scar tissues 3. Relief of sub-chronic, chronic pain and joint contractures resulting from: • Capsular tightness • Capsular scarring For TENS, Interferential,	Same, The indications of the predicate device cover the subject device. The subject device does not have EMG and EMG triggered Stim indications compared with predicate.

	- Capsular tightness - Capsular scarring For TENS, Interferential, premodulated (IFC), NMS and Microcurrent: 1) Symptomatic relief of chronic intractable pain 2) Post-traumatic acute pain 3) Post-surgical acute pain Additionally for NMS, NMS Burst, Hi-Volt and Russian: 1) Relaxation of Muscle spasms 2) Prevention or retardation of disuse atrophy 3) Increasing local blood circulation 4) Muscle re-education 5) Maintaining or increasing range of motion 6) Immediate postsurgical stimulation of calf muscles to prevent venous thrombosis For DC Continuous Mode 1) Relaxation of muscle spasm	premodulated(IFC), NMS and Microcurrent: 1. Symptomatic relief of chronic intractable pain 2. Post-traumatic acute pain 3. Post-surgical acute pain Additionally for NMS, NMS Burst, Hi-Volt and Russian: 1. Relaxation of Muscle spasms 2. Prevention or retardation of disuse atrophy 3. Increasing local blood circulation 4. Muscle re-education 5. Maintaining or increasing range of motion 6. Immediate postsurgical stimulation of calf muscles to prevent venous thrombosis For DC Continuous Mode Relaxation of muscle spasm For EMG To determine the activation timing of muscles for: 1. Retaining of muscle activation 2. Coordination of muscle activation An indication of the force produced by muscle for control and maintenance of muscle contractions 1. Relaxation muscle training 2. Muscle re-education For EMG triggered Stim 1. Stroke rehab by muscle re-education 2. Relaxation of muscle spasms 3. Prevention or retardation of disuse atrophy 4. Increase local blood circulation 5. Muscle re-education	

		6. Maintaining or increasing range of motion	
Electrotherapy Module			
Electrotherapy mode	NMS (Pulsed mode, burst mode) TENS(Symmetrical, Asymmetrical, Alternating, Symmetrical Burst, Asymmetrical Burst, Alternating Burst, Symmetrical RAAS, Asymmetrical RAAS) high volt Russian interferential (4-pole), premodulated (2-pole interferential), Microcurrent Continuous DC	NMS (Pulsed mode, burst mode) TENS(Symmetrical, Asymmetrical, Alternating, Symmetrical Burst, Asymmetrical Burst, Alternating Burst) high volt interferential (4-pole), premodulated (2-pole interferential), Russian, Microcurrent Direct current	Similar
EMG (Biofeedback)	no	yes	Different, See indications for use.
Basic unit Characteristics			
4. Power Source(s)	AC line	AC line	Same
-Method of Line Current Isolation	Transformer	Transformer	Same
-Leakage current – Normal condition - Single fault condition	75 µA 130 µA	d.c:0. a.c.:76.5 d.c:0. a.c.:132.1	Same
5. Number of output modes	10	10	Same
6. Number of output channel	6	4	Similar
- Synchronous	1&2 or 3&4 or 5&6	1 &2 or 3&4	Similar

or Alternation?			
-Method of Channel Isolation	Through transformers and isolators	Not publicly available	Similar
7.Regulated Current or Regulated Voltage?	Optional Optional	Optional Optional	Same
8. Software/ Firmware/ Microprocessor control?	Yes	Yes	Same
9. Automatic Overload trip	Yes	Yes	Same
10. Automatic no-load trip	Yes	Yes	Same
11. Automatic Shut Off	Yes	Yes	Same
12. Patient override control method	Yes	Yes Patient interrupt switch	Same
13. Indicator display -On/Off status -Low battery - Voltage/Current Level?	 Yes N/A Yes	 Yes Yes Yes	Same
14. Timer range (minutes)	0-60 minutes	0-60 minutes	Same
15.Compliance with voluntary standards	ISO 14971, IEC 60601-1; IEC 60601-1-2; IEC 60601-2-5;	ISO14971, IEC 60601-1, 60601-1-2, IEC 60601-2-10,	Same

	IEC 60601-2-10	IEC60601-2-5, MDD 93/42/EEC,Annex II	
16. Compliance with 21CFR 898	Yes	Yes	Same
17. Weight(lbs.)	9.48	10.36	Similar
18. Dimensions (in.) H*W * L	9.5in*7.5in*16.2 in	10 x 7x15.5	Similar
19. Housing material and construction	Plastic	Plastic	Same
Output specifications			
Waveform	NMS (Pulsed mode, burst mode): Biphasic TENS: Biphasic high volt: Monophasic Russian: Biphasic interferential (4-pole): Biphasic premodulated (2-pole interferential): Biphasic Microcurrent: Monophasic Continuous DC: DC	NMS (Pulsed mode, burst mode): Biphasic TENS: Biphasic high volt: Monophasic Russian: Biphasic interferential (4-pole): Biphasic premodulated (2-pole interferential): Biphasic Microcurrent: Monophasic Continuous DC: DC	Same
Shape	NMS (Pulsed mode, burst mode): Square TENS: Square high volt: Twin spike Russian: Sinusidal interferential (4-pole): Sinusidal premodulated (2-pole interferential): Sinusidal Microcurrent: Square Continuous DC:DC	NMS (Pulsed mode, burst mode): Square TENS: Square high volt: Twin spike Russian: Sinusidal interferential (4-pole): Sinusidal premodulated (2-pole interferential): Sinusidal Microcurrent: Square Continuous DC:DC	Same
Maximum output voltage(V)± 20%	NMS (Pulsed mode, burst mode): 100@500Ω TENS: 100@500Ω	Not publicly available	different for i.NMS mode at 2k Ω

	high volt: 462@500 Ω Russian: 50.2@500Ω interferential (4-pole): 50.2@500Ω premodulated (2-pole interferential): 50.3@500Ω Microcurrent: 0.5@500Ω Continuous DC: 38@500Ω NMS (Pulsed mode, burst mode): 220@2KΩ TENS: 220@2KΩ high volt: 487@2KΩ Russian: 202@2KΩ interferential (4-pole): 202@2KΩ premodulated (2-pole interferential): 202@2KΩ Microcurrent: 2.2@2KΩ Continuous DC: 150@2KΩ Microcurrent: 11@10k Ω high volt: 487@10KΩ NMS, TENS, high volt, Russian, interferential (4-pole), premodulated (2-pole interferential) and Continuous DC are unable to output@10kΩ, indicating no load		ii.Russian mode at 2k Ω iii.Inferential mode at 2k Ω iv.Premodulated mode at 2k Ω v.Continuous DC mode at 2k Ω
Maximum output current(mA) ±20%	NMS (Pulsed mode, burst mode): 200@500Ω TENS: 200@500Ω Russian: 100.4@500Ω interferential (4-pole): 100.4@500Ω premodulated (2-pole interferential): 100.6@500Ω Microcurrent: 1@500Ω Continuous DC: 76@500Ω high volt: 927@500 Ω	Not publicly available	Different for i.Continuous DC mode at 500 Ω ii.Russian mode at 2k Ω iii.Inferential mode at 2k Ω

	NMS (Pulsed mode, burst mode): 110@2KΩ TENS: 110@2KΩ Russian: 101@2KΩ interferential (4-pole): 101@2KΩ premodulated (2-pole interferential): 101@2KΩ Microcurrent: 1.1@2KΩ Continuous DC: 75@2KΩ high volt: 243.5@2kΩ high volt: 48.7@10kΩ Microcurrent: 1.1@10kΩ NMS, TENS, Russian, interferential (4-pole), premodulated (2-pole interferential) and Continuous DC are unable to output@10kΩ, indicating no load		iv.Premodulated mode at 2kΩ v.Continuous DC mode at 2kΩ
Pulse Width	NMS (Pulsed mode, burst mode): 20~400μs TENS: 20~1000μs high volt: 10μs Russian: 50~250μs interferential (4-pole): 50~250μs premodulated (2-pole interferential): 50~250μs Microcurrent: 0.5ms~5s	Not publicly available	Different
Frequency(Hz)	NMS (Pulsed mode, burst mode): 1~250Hz TENS: 1~250Hz high volt: 1~120Hz Russian: 2k~10kHz interferential (4-pole): 2k~10kHz premodulated (2-pole interferential): 2k~10kHz Microcurrent: 0.1~1000Hz Continuous DC: N/A	NMS (Pulsed mode, burst mode): 1~250Hz TENS: 1~250Hz high volt:1~120Hz Russian: Not publicly available interferential (4-pole):2k~10kHz premodulated (2-pole interferential): 2k~10kHz Microcurrent: 0.1~1000Hz Continuous DC: N/A	Different for Russian mode

For interferential modes only: - Beat Frequency(Hz)	Interferential, 4-pole: 1-200Hz Interferential, 2-pole, *Premodulated*: 1-150Hz	Interferential, 4-pole:1-200Hz Interferential, 2-pole, *Premodulated*: 1-200Hz	Similar
For multiphasic waveforms only: - Symmetrical phases?	NMS (Pulsed mode, burst mode): Yes TENS: Yes high volt: No Russian: Yes interferential (4-pole): Yes premodulated (2-pole interferential): Yes Microcurrent: No	NMS (Pulsed mode, burst mode): Yes TENS: Yes high volt: No Russian: Yes interferential (4-pole): Yes premodulated (2-pole interferential): Yes Microcurrent: No	Same
- Phase Duration (include units) (state range, if applicable) (both phases, if asymmetrical)	NMS (Pulsed mode, burst mode): 20~400μs TENS: 20~1000μs high volt: 100μs Russian: 50~250μs interferential (4-pole): 50~250μs premodulated (2-pole interferential): 50~250μs Microcurrent: 0.5ms~5s Continuous DC:N/A	NMS (Pulsed mode, burst mode): 20us-1000us TENS: 20~1000μs high volt:100μs Russian: Not publicly available interferential (4-pole):Not publicly available premodulated (2-pole interferential): Not publicly available Microcurrent: Not publicly available Continuous DC: N/A	Similar
Net Charge (per pulse)	CC mode: Microcurrent: 5000μC @500Ω CV mode: high volt: 5μC @500Ω The rest: Zero	Not publicly available	Different for Microcurrent mode
Symmetry	Symmetric and asymmetric	Symmetric and asymmetric	Same
Method	Balanced	Not publicly available	Same
Maximum Phase Charge(μC)(500Ω)	NMS (Pulsed mode, burst mode): 60 TENS: 100 high volt:5 Russian:15.92 interferential (4-pole): 15.92 premodulated (2-pole	Not publicly available	Different for Microcurrent mode

	interferential): 15.92 Microcurrent: 5000		
Maximum current density(mA/cm²,500Ω)	NMS (Pulsed mode, burst mode): 1.8,0.9 TENS: 2.0,1.4,1.5,1.1 high volt: 0.92 Russian:2.0 interferential (4-pole): 2.8 premodulated (2-pole interferential): 2.0 Microcurrent: 0.028 Continuous DC: 3.2	Not publicly available	Different for i.Russian mode ii.Microcurrent mode
Maximum power density (W/cm²,500 Ω)	NMS (Pulsed mode, burst mode): 0.04,0.01 TENS:0.049,0.025,0.030,0.015 high volt: 0.01 Russian:0.050 interferential (4-pole): 0.101 premodulated (2-pole interferential): 0.050 Microcurrent: 0.00001 Continuous DC:0.128	Not publicly available	Different for i.NMS mode ii.TENS mode iii.High volt mode iv.Russian mode
Burst Mode a. Pulses per burst	NMS (Pulsed mode): N/A NMS (burst mode): 7 TENS: 7 high volt: N/A Russian: N/A interferential (4-pole): N/A premodulated (2-pole interferential): N/A Microcurrent: N/A Continuous DC:N/A	Not publicly available	Same
b. Bursts per second	NMS (Pulsed mode): N/A NMS (burst mode): 1~9 TENS: 1~9 high volt: N/A Russian: 20~100 interferential (4-pole): N/A premodulated (2-pole interferential): N/A Microcurrent: N/A	Not publicly available	Same

	Continuous DC:N/A		
c. Burst duration (ms)	NMS (Pulsed mode): N/A NMS (burst mode): 28~984 ms TENS: 28~984 ms high volt: N/A Russian: 2~25 ms interferential (4-pole): N/A premodulated (2-pole interferential): N/A Microcurrent: N/A Continuous DC:N/A	Not publicly available	Same
d. Duty Cycle [Line (b) x Line (c)]	NMS (Pulsed mode): N/A NMS (burst mode): 2.8%~98.4% TENS: 2.8%~98.4% high volt: N/A Russian: 10%~50% interferential (4-pole): N/A premodulated (2-pole interferential): N/A Microcurrent: N/A Continuous DC:N/A	Not publicly available	Same
ON Time (seconds)	NMS (Pulsed mode): 0~60s TENS(not include burst mode): 0~60s high volt: 0~60s Russian:0~60s interferential (4-pole): N/A premodulated (2-pole interferential): 0~60s Microcurrent: 0~60s Continuous DC:N/A	NMS (Pulsed mode): 0~60s TENS(not include burst mode): 0~60s high volt: 0~60s Russian: 0~60s interferential (4-pole): N/A premodulated (2-pole interferential): 0~60s Microcurrent: 0~60s Continuous DC:N/A	Same
OFF Time (seconds)	NMS (Pulsed mode): 0~60s TENS(not include burst mode): 0~60s high volt: 0~60s Russian:0~60s interferential (4-pole): N/A premodulated (2-pole interferential): 0~60s Microcurrent: 0~60s Continuous DC:N/A	NMS (Pulsed mode): 0~60s TENS(not include burst mode): 0~60s high volt: 0~60s Russian: 0~60s interferential (4-pole): N/A premodulated (2-pole interferential): 0~60s Microcurrent: 0~60s Continuous DC:N/A	Same

Ultrasound Module			
Power Source	AC line	AC line	Same
Maximum Treatment Time:	30 minutes	30 minutes	Same
Frequency	1 MHz or 3 MHz	1 MHz or 3 MHz	Same
Modes	Continuous and Pulsed	Continuous and Pulsed	Same
Pulse Repetition Rate	100Hz, 48Hz, 16Hz	16Hz, 48Hz, 100Hz	Same
Pulse Duration	1.0ms～56.3ms (±5%)	Not publicly available	Different
Temporal Peak/average intensity ration	1～10 (±5%)	1～10	Same
Maximum intensity	2 W/cm² for continuous mode 3 W/cm² for pulsed mode	3 W/cm²	Same
Indication accuracy	± 20 %	± 20 %	Same
Piezoelectric discs	Ultrasound transducer attached to a metal surface and patient contact through the metal	Ultrasound transducer attached to a metal surface and patient contact through the metal	Same
Frequency	1 MHz or 3 MHz	1 MHz or 3 MHz	Same
Effective radiating area	A9050: 4cm² A8040: 4cm² A3010: 1cm²	5 cm² 1 cm²	Similar
Maximum beam non-uniformity ratio	5:1 maximum	5:1 maximum	Same
Beam type	collimated	collimated	Same
Applicator material	AL6061	Not publicly available	Similar
Crystal Material	piezocrystal	piezocrystal	Same
Temporal Max Power (W) for	A3010 (1cm²): 3W±20% A8040 (3cm²)：9W±20% A9050 (4cm²)：12W±20%	1cm²：2W±20% 5cm² : 15W±20%	Similar

pulsed mode			
Temporal Average Power (W) for continuous mode	A3010 (1cm²): 2W±20% A8040 (3cm²): 6W±20% A9050 (4cm²)：8W±20%	Not publicly available	Similar
Instantaneous Peak Power (W)	A3010 (1cm²): 3W±20% A8040 (3cm²)：9W±20% A9050 (4cm²)：12W±20%	1cm²：2W±20% 5cm² : 15W＋20%	Similar
Temporal Max Effective Intensity (W/cm2), peak P/ERA	3W/cm²	3 W/cm² ±20 %	Same
Temporal Average Intensity(W/cm2)	0～2.1W/cm²，±20%	Not publicly available	Similar
Temporal Peak to Average Ratio (Rtpa) for pulsed mode	10.00:1 ±5 % at 10 % Duty Cycle 5.00:1 ±5 % at 20 % Duty Cycle 3.33:1 ±5 % at 30 % Duty Cycle 2.50:1 ±5 % at 40 % Duty Cycle 2.00:1 ±5 % at 50 % Duty Cycle 1.67:1 ±5 % at 60 % Duty Cycle 1.43:1 ±5 % at 70 % Duty Cycle 1.25:1 ±5 % at 80 % Duty Cycle 1.11:1 ±5 % at 90 % Duty Cycle	10.00:1 ±5 % at 10 % Duty Cycle 5.00:1 ±5 % at 20 % Duty Cycle 3.33:1 ±5 % at 30 % Duty Cycle 2.50:1 ±5 % at 40 % Duty Cycle 2.00:1 ±5 % at 50 % Duty Cycle 1.67:1 ±5 % at 60 % Duty Cycle 1.43:1 ±5 % at 70 % Duty Cycle 1.25:1 ±5 % at 80 % Duty Cycle 1.11:1 ±5 % at 90 % Duty Cycle	Similar
Error uncertainties for the ultrasonic frequency	±10%	±10%	Same

There are differences in output parameters between the subject and predicate devices. First, the subject device has additional TENS output modes (i.e., Symmetrical RAAS, Asymmetrical RAAS). These output modes do not raise new questions of safety and effectiveness nor a new intended use.
There are minor differences in maximum output voltage, maximum output current, frequency, and phase duration which do not raise new questions of safety and effectiveness.
The net charge and phase charge for the Microcurrent mode are very large which could increase the risk of skin irritation and burns. Additionally, the device is capable of delivery current densities greater than 2mA/cm2 (i.e., the limit set by IEC 60601-2-10). However, this risk associated with these parameters has been mitigated with labeling revisions which 1) warn users of the risk of skin irritation and burns, 2) instruct device operators to monitor patients for adverse events throughout the duration of treatment, and 3) instruct that the treatment site should be examined after each treatment session to monitor for signs of irritation and/or burns.
Minor differences in the power density do not raise questions of safety and effectiveness since they remain under the 0.25W/cm2 limit set within the FDA guidance document "Guidance Document for Powered Muscle Stimulator 510(k)s."
Lastly, there are minor differences in the ultrasound output parameters which do not raise new questions of safety and effectiveness.

8. Non-clinical tests

The following performance data were provided in support of the substantial equivalence determination.

Biocompatibility testing

Biocompatibility of the subject device was evaluated in accordance with the FDA guidance "Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process" and International Standard ISO 10993-1 "Biological Evaluation of Medical Devices − Part 1: Evaluation and Testing Within a Risk Management Process," as recognized by FDA.

Electrical safety, electromagnetic compatibility (EMC) and performance

Electrical safety, EMC and performance testing were performed to, and passed, the following standards:

- ANSI AAMI ES60601-1 Medical electrical equipment –Part 1: General requirements for basic safety and essential performance
- 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
- IEC 60601-2-5 Particular requirements for the basic safety and essential

performance of ultrasonic physiotherapy equipment

- IEC 60601-2-10 Particular requirements for the basic safety and essential performance of nerve and muscle stimulators

9. Clinical study

Not applicable.

10. Conclusion

Substantial equivalence comparisons, performance testing and compliance with voluntary standards demonstrate that the proposed subject device is substantially equivalent to the predicate device.