April 23, 2022

Joe Xu
QA
WAT Medical Technology Inc.
Room703-711, No.2 North Taoyuan Road
Ningbo, Zhejiang 315600
China

Re: K220503
Trade/Device Name: TENS device-EmeTerm 2, Model: YF-ZTY-E2
Regulation Number: 21 CFR 882.5890
Regulation Name: Transcutaneous Electrical Nerve Stimulator For Pain Relief
Regulatory Class: Class II
Product Code: GZJ
Dated: February 11, 2022
Received: February 22, 2022

Dear Joe Xu:

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,

Pamela Scott
Assistant Director, Neuromodulation Psychiatry Devices
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

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)*
K220503

Device Name
TENS device-EmeTerm 2, Model: YF-ZTY-E2

Indications for Use *(Describe)*
TENS device-EmeTerm 2 is a wearable device for the treatment of nausea and vomiting caused by motion sickness and pregnancy.

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

Prepared in accordance with the requirements of 21 CFR Part 807.92

Prepared Date: April 23, 2022

1. Submitter's Information

The submitter of this pre-market notification is:

Name:	WAT Medical Technology Inc.
Address:	Room703-711, No.2 North Taoyuan Road, 315600, Ningbo, Zhejiang Province, P.R.C
Contact person:	Joe Xu
E-mail:	joexu@watmedical.com
Tel:	+86 151 6268 2168

2. Device Identification

Trade/Device Name:	TENS device-EmeTerm 2
Models:	YF-ZTY-E2
Common name:	Stimulator, Nerve, Transcutaneous, For Pain Relief
Regulation Number:	21 CFR 882.5890
Regulation Name:	Transcutaneous Electrical Nerve Stimulator For Pain Relief
Regulation Class:	Class II
Panel:	Neurology
Product Code:	GZJ

3. Predicate Device

510(K) number:	K172478
Device Name:	TENS device-EmeTerm
Manufacturer:	YF-ZTY-E1
Common name	Stimulator, Nerve, Transcutaneous, For Pain Relief
Regulation Number:	21 CFR 882.5890
Regulation Name:	Transcutaneous Electrical Nerve Stimulator For Pain Relief
Regulation Class:	Class II
Panel:	Neurology
Product Code:	GZJ

4. Device Description

TENS device-EmeTerm 2 is a single-patient use wearable device, rechargeable, non-invasive device that is worn on the wrist like a watch. It is a non-invasive device that is indicated for the over-the-counter use in the relief of mild to moderate nausea and vomiting, motion sickness, mild to moderate nausea and vomiting associated with pregnancy.

TENS device-EmeTerm 2 includes a Rubber wristband with two electrodes. The two electrodes must be placed at the center of the inner wrist, about 2 to 3cm from the wrist crease. The electrodes in the wristband provide relief of nausea and vomiting through electrical stimulation of the median nerve on the ventral side of the patient's wrist.

5. Indication for use

TENS device-EmeTerm 2 is a wearable device for the treatment of nausea and vomiting caused by motion sickness and pregnancy.

6. Technological Characteristics Comparison

Compared to the predicate device, the subject device has the same intended use, similar product design, and similar performance as the predicate device, the main differences of the proposed TENS device-EmeTerm 2 and device EmeTerm would be appearance, external form, electrode surface and power supply method. the summarized comparison information is listed in the following table:

SE Comparisons	**Subject Device**	**Predicate Device K172478**	**Similarities/ Differences**
Device name, Model	TENS device-EmeTerm 2 Model: YF-ZTY-E2	TENS device-EmeTerm Model: YF-ZTY-E1	N/A
Manufacturer	WAT Medical Technology Inc.	WAT Medical Technology Inc.	N/A
Classification	Class II	Class II	Same
Product code	GZJ	GZJ	Same
Indication for use	TENS device-EmeTerm 2 is a wearable device for the treatment of nausea and vomiting caused by motion sickness and pregnancy.	TENS device-EmeTerm is a wearable device for the treatment of nausea and vomiting caused by motion sickness and pregnancy.	Same

Power source		Rechargeable 3.7V DC. 80mAh Lithium battery	3.7V DC. 140mAh Lithium battery	Note No.1
Follow Current		Yes	Yes	Same
Voltage Overload Detection		Yes	Yes	Same
Adjustable Intensity		5	5	Same
Channel		9	1	Note No.2
Operation Tips	Start	Yes	Yes	Same
	Low Battery	Yes	Yes	Same
	Work	Yes	Yes	Same
User Control		Touch screen and one home button	ON/OFF button on front of device	Note No.3
Patient override control method		Click the touch screen to enter the electric stimulation mode. It can be adjusted gears by swiping up or down.	On/Off and gear adjust button on front of device	Note No.4
Indicator displays		Screen	Unit functioning Electrical connection	Note No.5
Timer Setting		Yes	Yes	Same
Waveform		AC Sharp Wave	AC Sharp Wave	Same
Pulse width		100 us (±10%)	100 us (±10%)	Same
Pulse period		500 us (±10%)	500 us (±10%)	Same
Frequency (Hz)		33Hz (±3Hz)	33Hz (±0.5%)	Same
Maximum output voltage (V): @1000 ohms		39V (±3V)	38.2V (±0.5%)	Note No.6
Maximum output current (mA): @1000 ohms		6mA root mean square value of the current (I_{rms}); 40mA peak current.	6mA root mean square value of the current (I_{rms}); 40mA peak current.	Same
Stimulating Surface Areas		2.6	2.709	Note No.7

(cm²)			
Maximum phase charge (μC) @1000Ω	1.8	1.78	Note No.8
Maximum Current Density, (mA/cm², r.m.s.) @1000Ω	4.30	4.30	Same
Maximum Average Power Density, (W/cm²) @1000Ω	0.00002	0.00002	Same
Maximum Average Current (average absolute value, mA) @1000Ω	0.5	0.5	Same
Maximum Charge Density (uC/ cm²) @1000Ω	1.3	1.28	Note No.9
Net Charge (μC) per pulse	0	0	Same

Note No. 1 The battery is different, we have performed testing on battery according to IEC 62133, the difference between two batteries will not affect the safety and effectiveness of the product.

Note No. 2 The two products have the same core part. Emeterm 2 only adds 8 personal computer interaction interfaces, and Emeterm 2 has been validated performance, the results show that the difference will not affect the security and effectiveness of the product.

Note No. 3 The difference of control methods will not affect the safety and effectiveness of the product.

Note No. 4 The difference of control methods will not affect the safety and effectiveness of the product.

Note No. 5 The difference of Indicator displays will not affect the safety and effectiveness of the product.

Note No.6	3% difference couldn't have effect on the product's function, also testing has been done in order to prove that the 1% differences will not affect the safety and effectiveness of our products.
Note No.7	Different dimensions caused by different product design, which will not affect the device's safety and effectiveness.
Note No.8	1% difference couldn't have effect on the product's function, also testing has been done in order to prove that the 1% differences will not affect the safety and effectiveness of our products.
Note No.9	1% difference couldn't have effect on the product's function, also testing has been done in order to prove that the 1% differences will not affect the safety and effectiveness of our products.

7. Performance Data

Clinical test:

Clinical testing is not required.

Non-clinical data

The subject device performed:

Safety and Performance:

IEC 60601-1:2012 Medical electrical equipment -Part 1: General requirements for basic safety and essential performance

IEC 60601-1-11:2015 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 60601-2-10:2015 Medical electrical equipment - Part 2-10: Particular requirements for the basic safety and essential performance of nerve and muscle stimulators

EMC:

IEC 60601-1-2 :2014 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance-Collateral Standard: Electromagnetic disturbances -Requirements and tests

Biocompatibility:

1. ISO 10993-5:2009 Biological evaluation of medical devices - Part 5: Tests for in vitro
2. ISO 10993-10:2010 Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization.

Software verification & validation:

Guidance for the Content of Premarket Submissions for Software Contained in Medical Device

8. Conclusion

The conclusions drawn from the nonclinical tests demonstrate that the device is as safe, as effective, and performs as well as the Predicate device (K172478).