July 15, 2021

WAT Medical Technology (Ningbo) Co., Ltd
Rodney Zhang
Cto
Room703-711, No.2 North Taoyuan Road
Ningbo, Zhejiang 315600
China

Re: K172478
Trade/Device Name: TENS device-EmeTerm, CinvStop
Regulation Number: 21 CFR 882.5890
Regulation Name: Transcutaneous electrical nerve stimulator for pain relief
Regulatory Class: Class II
Product Code: GZJ

Dear Rodney Zhang:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change related to your previous substantial equivalence (SE) determination letter for your device cleared on April 19, 2018. Specifically, FDA is updating this SE letter due to a typo in the clearance date, which was incorrectly dated as April 19, 2019.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact Amber Ballard, OHT5: Office of Neurological and Physical Medicine Devices, by email (Amber.Ballard@fda.hhs.gov) or phone (240-402-9983).

Sincerely,

Jitendra V. Virani -S

For Amber Ballard
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

April 19, 2019

WAT Medical Technology (Ningbo) Co., Ltd
Rodney Zhang
CTO
Room703-711, No.2 North Taoyuan Road
Ningbo, 315600 Cn

Re: K172478
Trade/Device Name: TENS device-EmeTerm, CinvStop
Regulation Number: 21 CFR 882.5890
Regulation Name: Transcutaneous Electrical Nerve Stimulator For Pain Relief
Regulatory Class: Class II
Product Code: GZJ
Dated: March 15, 2018
Received: March 20, 2018

Dear Rodney Zhang:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820);

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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

William J. Heetderks -S
2018.04.19 13:39:37 -04'00'

for Carlos L. Peña, PhD, MS
Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K172478

Device Name
EmeTerm CinvStop

Indications for Use *(Describe)*
The EmeTerm CinvStop 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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Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"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."

WAT Med

510 (k) SUMMARY OF SAFETY AND EFFECTIVENESS

(As Required by 21 CFR 807.92)

1. **Date Prepared [21 CFR 807.92(a)(1)]**

   04/11/2018

2. **Submitter's Information [21 CFR 807.92(a)(1)]**

Company Name:	WAT Medical Technology Inc.
Company Address:	Room703-711, No.2 North Taoyuan Road, 315600, Ningbo, Zhejiang Province, P.R.C
Contact Person:	Rodney Zhang
Phone:	86-574-6506-0811
Email:	13500799711@139.com

3. **Trade Name, Common Name, Classification [21 CFR 807.92(a)(2)]**

Trade Name:	TENS device-EmeTerm
Common Name:	TENS device-EmeTerm
Model No.	YF-ZTY-E1
Product Code:	GZJ
Regulation Number:	21 CFR 882.5890
Device Class:	II

4. **Identification of Predicate Devices(s) [21 CFR 807.92(a)(3)]**

The identification of predicates within this submission is as follow:

Predicate I

Manufacturer:	Woodside Biomedical, Inc.
Trade Name:	ReliefBand Device
Product Code:	GZJ
Classification Name:	Neurology
Regulation Number:	21 CFR 882.5890
Classification:	Class II
FDA 510 (k) #:	K020180

5. Description of the Device [21 CFR 807.92(a)(4)]

TENS device-EmeTerm generates the electric pulses with highly specific waveforms, frequency and amplitude to stimulate the median nerve. The accurate pulse signals provide relief through electrical stimulation of the nerves in the patient's wrist.

There are several names formerly used by proposed product TENS device-EmeTerm. Previous names have been shown within various test reports include: EmeTerm-mo, EmeTerm-mo device for preventing and treating motion sickness, ZHITUYI (hand) and ZHITUYI (shell). The names listed above are all representing the test results of TENS device-EmeTerm.

6. Previous Device Names and Company:

Previous Device Name:
There are several names formerly used by proposed product TENS device-EmeTerm. Previous names have been shown within various test reports include EmeTerm-mo, EmeTerm-mo device for preventing and treating motion sickness, ZHITUYI (hand) and ZHITUYI (shell). The names listed above are all representing the test results of TENS device-EmeTerm.

Previous Company:
The company appears in various test reports is WAT Medical Technology (Ningbo) Co., Ltd, which is the same company as the current WAT Medical Technology Inc.

7. Indication for Use [21 CFR 807.92(a)(5)]

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

8. Non-Clinical Tests and Clinical Tests

Non-Clinical Tests	Electromagnetic Safety Test (IEC 60601-1-2) Electronical Safety Test (IEC 60601-1, IEC 60601-1-11) Biocompatibility: In Vitro Cytotoxicity (ISO 10993-5) Biocompatibility: Skin Irritation (ISO 10993-10) Biocompatibility: Skin Sensitization (ISO 10993-10)
Clinical Tests	N/A

9. Technological Characteristics [21 CFR 807.92(a) and Substantial Equivalence Comparison [21 CFR 807.92(b)(1) and 807.92(b)(2)]

Table 1	**Proposed Device**	**Predicate Device**
Product Name	EmeTerm Device	ReliefBand Device
Product Code	GZJ	GZJ
Regulation No.	21 CFR 882.5891	21 CFR 882.5890
Classification	Class II	Class II
Indication for Use	TENS device-EmeTerm is a wearable device for the treatment of nausea and vomiting caused by motion sickness and pregnancy.	The ReliefBand Devices are indicated for over the counter use in the relief of nausea and vomiting (NV) due to motion sickness, and for the relief of mild to moderate nausea and vomiting associated with pregnancy.
510 (k) Number	N/A	K020180

Table 2		**Proposed Device**	**Predicate Device**
Device Feature			
Device Name		EmeTerm Device	ReliefBand Device
Power Source		One lithium battery	Two 3V lithium coin cells
Follow Current		Yes	Yes
Voltage Overload Detection		Yes	Yes
Adjustable Intensity		5	5
Channel		1	1
Operation Tips	Start	Yes	Yes
	Low Battery	Yes	Yes

	Work	Yes	Yes
User Control		ON/OFF button on front of device	ON/OFF button on front of device
Patient override control method		On/Off and gear adjust button on front of device	On/Off and gear adjust button on front of device
Indicator displays		Unit functioning Electrical connection	Unit functioning Electrical connection
Timer Setting		Yes	Yes
Weight		29.5g	34g
Dimensions		4.48*3.25*1.4cm	3.81*5.08*1.14cm
Waveform		AC Sharp Wave	AC Sharp Wave
Phase Duration (μsec)		300us(±0.5%)	300us(±0.5%)
Phase Interval		10us(±0.5%)	10us(±0.5%)
Pulse Period		500us(±0.5%)	505us(±0.5%)
Frequency (Hz)		33Hz(±0.5%)	33Hz(±0.5%)
Net Charge (μC) per pulse		0	0
Maximum output voltage (V): @1000 ohms		38.2V(±0.5%)	39.8V(±0.5%)
Maximum output current (mA): @1000 ohms		6mA(±0.5%)	6mA(±0.5%)
Maximum phase charge (μC) @1000Ω		1.78	1.8
Maximum Current Density, (mA/cm², r.m.s.) @1000Ω		4.30	4.32

Maximum Average Power Density, (W/cm²) @1000Ω	0.00002	0.00002
Maximum Average Current (average absolute value, mA) @1000Ω	0.5	0.5
Maximum Charge Density (uC/ cm²) @1000Ω	1.28	1.3
Stimulating Surface Areas (cm²)	2.709	2.72

10. Conclusion [21 CFR 807.92(b)(3)]

TENS device-EmeTerm is substantially equivalent to predicate device because both devices use identical technology and same intended use, also testing standards are identical with the predicates. The differences between both devices are insignificant in terms of safety and effectiveness.