



February 26, 2024

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

Re: K230782

Trade/Device Name: TENS device-HeadTerm 2 (Model: YF-HT2)
Regulation Number: 21 CFR 882.5891
Regulation Name: Transcutaneous Electrical Nerve Stimulator to Treat Headache
Regulatory Class: Class II
Product Code: PCC
Dated: January 24, 2024
Received: January 25, 2024

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 (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.

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,

The signature is written in a cursive, black ink style. The name 'Xiaorui Tang' is clearly legible. A large, light blue 'FDA' watermark is visible in the background behind the signature.

for: CDR Jitendra Virani, MS
Assistant Director
DHT5B: Division of Neuromodulation
and Rehabilitation Devices
OHT5: Office of Neurological
and Physical Medicine Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)
K230782

Device Name
TENS device-HeadTerm 2

Indications for Use (Describe)

The TENS device-HeadTerm 2 is indicated for the prophylactic treatment of episodic migraine in patients 18 years of age or older.

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

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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: February 26, 2024

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:	+86-574-88132850

2. Device Identification

Trade/Device Name:	TENS device-HeadTerm 2
Models:	YF-HT2
Common name:	Stimulator, Nerve, Electrical, Transcutaneous, For Migraine
Regulation Number:	21 CFR 882.5891
Regulation Name:	Transcutaneous Electrical Nerve Stimulator to treat headache
Regulation Class:	Class II
Panel:	Neurology
Product Code:	PCC

3. Predicate Device

Primary predicate device:	
510(K) number:	K172450
Device Name:	TENS device-HeadTerm, eEspresso
Manufacturer:	WAT Medical Technology Inc.
Common name	Stimulator, Nerve, Electrical, Transcutaneous, For Migraine
Regulation Number:	21 CFR 882.5891
Regulation Name:	Transcutaneous Electrical Nerve Stimulator to treat headache
Regulation Class:	Class II
Panel:	Neurology
Product Code:	PCC

Secondary predicate device:

510(K) number:	K201895
Device Name:	Cefaly® Dual
Manufacturer:	CEFALY Technology
Common name	Stimulator, Nerve, Electrical, Transcutaneous, For Migraine
Regulation Number:	21 CFR 882.5891
Regulation Name:	Transcutaneous Electrical Nerve Stimulator to treat headache
Regulation Class:	Class II
Panel:	Neurology
Product Code:	PCC

4. Device Description

TENS device-HeadTerm 2 offers a drug-free scheme, which introduces electric impulses to act on the supraorbital nerve and supratrochlear nerve, the very nerves that transmit migraine pain, to treat and prevent migraine headaches. TENS device- HeadTerm 2 enables an electronic feedback mechanism to adjust the electrical impulses to the specific requirements of the individual user for personalized efficacy and comfort.

The device could adhere to patient's forehead with conductive paste, the current passing through the electrodes and release current stimulate the nerve underneath patients' forehead skin; the stimulation would alleviate migraine headaches, the product provides the user with 9 gear options, and the user can control the stimulating intensity by selecting one of gear.

5. Indication for use

The TENS device-HeadTerm 2 is indicated for the prophylactic treatment of episodic migraine in patients 18 years of age or older.

6. Technological Characteristics Comparison

Compared to the primary predicate device and secondary predicate device, the subject device has the same intended use, similar product design, and similar performance as the primary predicate device, the main differences between TENS device-HeadTerm 2 and device TENS device-HeadTerm is appearance, external form, battery, and TENS device-HeadTerm 2 is intended for OTC, compared to secondary predicate device "Cefaly® Dual", Cefaly® Dual also changed from prescription to OTC use. The summarized comparison information is listed in the following table:

SE Comparisons	Subject Device	Primary Predicate Device K172450	Secondary predicate device K201895	Similarities/ Differences
Device name, Model	TENS device- HeadTerm 2 Model: YF-HT2	TENS device- HeadTerm Model: YF-HT-W1	Cefaly® Dual	N/A
Manufacturer	WAT Medical Technology Inc.	WAT Medical Technology Inc.	CEFALY Technology	N/A
Classification	Class II	Class II	Class II	Same
Product code	PCC	PCC	PCC	PCC
Indication for use	The TENS device-HeadTerm 2 is indicated for the prophylactic treatment of episodic migraine in patients 18 years of age or older.	The TENS device-HeadTerm is indicated for the prophylactic treatment of episodic migraine in patients 18 years of age or older.	The indications for use of the Cefaly® Dual for an over-the-counter use are: -The acute treatment of migraine with or without aura in patients 18 years of age or older. -The prophylactic treatment of episodic migraine in patients 18 years of age or older.	Note No.1
RX/OTC	OTC	RX	OTC	Note No.2
Power source	3.7V DC 60mAh lithium battery	One 3V lithium coin cells	1 rechargeable LiPo 3.7 V battery	Note No.3
Follow Current	Yes	Yes	Not specific	Same
Voltage Overload Detection	Yes	Yes	Not specific	Same
Adjustable Intensity	ON/OFF button on front of device is used to control the startup and shutdown The "+" and "-" touch key at the top and bottom of the control part, which	ON/OFF button on front of device. The device is equipped with the intensity adjustment function, and users can select the most suitable gears. The	Not specific	Note No.4

		can be used to adjust the stimulation intensity gear.	intensity of device keeps going up after the device is started. After it rises to the suitable intensity, you can make a short press on the control button to lock the current intensity after the buzzer rings once and the indicator lamp flickers once intermittently.		
Channel		1	1	1	Same
Operation Tips	Start	Yes	Yes	Not specific	Same
	Low Battery	No	No	Not specific	Same
	Work	Yes	Yes	Not specific	Same
Time Set		No-Manually Adjust	No-Manually Adjust	Not specific	Same
Automatic overload trip voltage level		Yes	Yes	Not specific	Same
Constant Current		No	No	Not specific	Same
Patient override control method		ON/OFF button on front of device is used to control the startup and shutdown The "+" and "-" touch key at the top and bottom of the control part, which can be used to adjust the stimulation intensity gear.	On/Off and gear adjust button on front of device. The device is equipped with the intensity adjustment function, and users can select the most suitable gears. The intensity of device keeps going up after the device is started. After it rises to the suitable intensity, you can make a short press on the control button to lock the current intensity after the buzzer rings once and the indicator lamp flickers once intermittently.	Not specific	Note No.4
Indicator displays		Unit functioning	Unit functioning	Not specific	Same

	Electrical connection	Electrical connection		
Waveform	AC Symmetric Square Wave	AC Symmetric Square Wave	Biphasic	Same as the primary predicate
Pulse width	250 us (± 20)	250 us (± 20)	250 us	Same
Frequency (Hz)	60Hz (± 1)	60Hz (± 1)	60Hz	Same
Maximum output voltage (V): @500 ohms	8V($\pm 0.5\%$)	8V($\pm 0.5\%$)	Not specific	Same
Maximum output voltage (V): @2000 ohms	32V($\pm 0.5\%$)	32V($\pm 0.5\%$)	Not specific	Same
Maximum output voltage (V): @10000 ohms	60V($\pm 3V$)	60V($\pm 3V$)	Not specific	Same
Maximum output current (mA): @500 ohms	16mA($\pm 0.5\%$)	16mA($\pm 0.5\%$)	16mA	Same
Maximum output current (mA): @2000 ohms	16mA ($\pm 0.5\%$)	16mA ($\pm 0.5\%$)	16mA	Same
Maximum output current (mA): @10000 ohms	6mA ($\pm 0.5\%$)	6mA ($\pm 0.5\%$)	6mA	Same
Maximum phase charge (μC) @500 Ω	3.95	3.95	Not specific	Same
Maximum Current Density, (mA/cm ² , r.m.s.) @500 Ω	2.35	2.35	2.37	Same
Maximum Average Power Density, (W/cm ²) @500 Ω	0.000017	0.000017	0.000047	Same

Maximum Average Current (average absolute value, mA) @500Ω	0.48	0.48	Not specific	Same
Net Charge (μC) per pulse	0	0	0	Same

- Note No. 1 The indication for use of subject device is same as that of primary predicate device. The secondary predicate device Cefaly® Dual has two indications, one for each fixed Programs: Program 1 for acute treatment of migraine, and Program 2 for prophylactic treatment of episodic migraine, the indication for use of subject device is same as Program 2, prophylactic treatment of migraine.
- Note No. 2 Cefaly® Dual was also changed from prescription to over-the-counter (OTC) use based on their device and Human Factor Validation testing, we conducted usability study among 24 participants, which demonstrated that subject device is appropriate for OTC use by the intended patient population.
- Note No. 3 The battery is different, we have performed testing on battery according to IEC 62133-2, the difference between two batteries will not affect the safety and effectiveness of the product compared to the predicate devices.
- Note No. 4 The two products have the same core part. TENS device-HeadTerm 2 provide 9 gears of simulation intensity, the predicate device provides only one simulation intensity, the max output voltage and current, waveform, pulse width, frequency and power density of TENS device-HeadTerm 2 is same to that of predicate device, so the difference will not affect the safety and effectiveness of the product compared to the predicate devices.

All the differences don't affect the safety and effectiveness compared to the predicate devices which is concluded after all the required testing, so no new safety and effectiveness issues relating to the system come into conclusion.

7. Performance Data

Clinical test:

Clinical testing is not required.

Non-clinical data

The subject device performed:

Safety and Performance:

IEC 60601-1:2005+A12:2012 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 60601-2-10:2012+A1:2016 Medical electrical equipment - Part 2-10: Particular requirements for the basic safety and essential performance of nerve and muscle stimulators

IEC 62133-2:2017 Secondary cells and batteries containing alkaline or other non-acid electrolytes - Safety requirements for portable sealed secondary cells, and for batteries made from them, for use in portable applications - Part 2: Lithium systems

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:

ISO 10993-5:2009 Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity

ISO 10993-10:2021 Biological evaluation of medical devices - Part 10: Tests for skin sensitization

ISO 10993-23:2021 Biological evaluation of medical devices - Part 23: Tests for irritation

Software verification:

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

Usability verification:

A total of 24 participants took part in usability study, 15 participants were assigned to group A as they successfully selected themselves as intended users. 5 participants were assigned to group B as they incorrectly selected themselves as intended users but were ruled out as an intended users by the study team and the HCP. 4 participants were assigned to group C as they identified themselves as unintended users but were deemed as intended users by study team and the HCP. All 24 subjects completed the following tasks correctly: equipment wearing, power-on, power-off, intensity adjustment, changing, storage, which prove that subject device can be used correctly by different users, and it is appropriate for the OTC use.

8. Conclusion

The conclusions drawn from the nonclinical tests demonstrate that the device is substantially equivalent to the primary predicate device (K172450) and the secondary predicate device (K201895) in terms of the safety and effectiveness.