September 13, 2018

WAT Medical Technology Inc.
% Rodney Zhang
CTO
WAT Medical Technology Inc.
Room703-711, No.2 North Taoyuan Road
Ningbo, 315600 China

Re: K172450
Trade/Device Name: TENS device-HeadaTerm, eEspresso
Regulation Number: 21 CFR 882.5891
Regulation Name: Transcutaneous electrical nerve stimulator to treat headache
Regulatory Class: Class II
Product Code: PCC
Dated: August 1, 2017
Received: August 14, 2017

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. 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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

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,

Timothy A. Marjenin -S

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)*
K172450

Device Name
TENS device-HeadaTerm, eEspresso

Indications for Use *(Describe)*
The TENS device-HeadaTerm 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.

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WAT Med

SECTION 1

SUMMARY OF SAFETY AND EFFECTIVENESS

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)]**
   09/11/2018

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:	Dr. 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-HeadaTerm, eEspresso
Common Name:	Transcutaneous electrical nerve stimulator to treat headache
Model No.	YF-HT-W1.
Product Code:	PCC
Regulation Number:	21 CFR 882.5891
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:	STX-Med SPRL
Trade Name:	Cefaly
Product Code:	PCC
Classification Name:	Transcutaneous electrical nerve stimulator to treat headache
Regulation Number:	21 CFR 882.5891
Classification:	Class II
FDA 510 (k) #:	K122566 (Primary), K160237

5. **Description of the Device [21 CFR 807.92(a)(4)]**
   TENS device-HeadaTerm 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-HeadaTerm 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 patients 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, and during ramping up, patients could choose comfortable intensity level by pressing the host key to lock up the current voltage, and the patient contact material is biocompatibility safe. The conductive paste could be replaced once the paste lost its adhesiveness and patients are recommended to replace the conductive paste after 7 times of treatment uses.

6. **Previous Device Names and Company:**

Previous Device Name:

Other names appears in various test reports including but not limit to Biocompatibility reports, electrical safety, EMC are recorded as HeadaTerm-wet, HeadaTerm-wet(shell), HeadaTerm-wet device for preventing and treating primary headache, these names are the previous names being used for proposed products.

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. **Indications for Use [21 CFR 807.92(a)(5)]**

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

8. **Technological Characteristic [21 CFR 807.92(a)(6)]**

By releasing the low frequency pulse with a particular frequency and reaching the advanced nerve center of cerebral cortex via nervus supraorbitalis, they can adjust all signals causing headache which come from the biological and physical channels, so as to stop or postpone the transmission of headache signal to cerebral center.

9. **Clinical Testing and Non-Clinical Testing**

Clinical Testing	Not Applicable
Non-Clinical Testing	Electrical Safety
	Electromagnetic Safety
	Performance of nerve and muscle stimulators
	Performance of Device for Home Use

	Biocompatibility: Cytotoxicity
	Biocompatibility: Irritation
	Biocompatibility: Sensitization

The non-clinical testing conducted are listed above, and all tests come back with "Pass" results which demonstrating the same safety and effectiveness with the predicate device.

10. Substantial Equivalence [21 CFR 807.92(b)(1) and 807.92(b)(2)]

	Proposed Device	**Predicate Device**
Product Name	TENS device-HeadaTerm	CEFALY
Product Code	PCC	PCC
Regulation No.	21 CFR 882.5891	21 CFR 882.5891
Classification	Class II	Class II
Intended Use	The TENS device-HeadaTerm is indicated for the prophylactic treatment of episodic migraine in patients 18 years of age or older.	The Cefaly® device is indicated for the prophylactic treatment of episodic migraine in patients 18 years of age or older.
510 (k) Number	N/A	K160237, K122566
Device Feature		
Device Name	TENS device-HeadaTerm	CEFALY
Power Source	One 3V lithium coin cells	One lithium battery
Follow Current	Yes	Yes
Voltage Overload Detection	Yes	Yes
Adjustable Intensity	ON/OFF button on front of device	ON/OFF button on front of device
Channel	1	1
Start	Yes	Yes

Operation Tips	Low Battery	No	Yes
	Work	Yes	Yes
Software-controlled		No	Yes
Time Set		No – Manually Adjust	No – Manually Adjust
Constant Current		No	No
Automatic overload trip voltage level		Yes	Yes
Patient override control method		On/Off button on front of device	On/Off button on front of device
Indicator displays		Unit functioning Electrical connection	Unit functioning Low battery Electrical connection
Timer Setting		Yes	Yes
Weight		11g	30g
Dimensions		127x35x12mm	160 x 170 x 40 mm
Waveform		AC Symmetric Square Wave	AC Symmetric Square Wave
Phase Duration (µsec)		250us(±20)	250us(±0.5%)
Phase Interval		10us(±0.5%)	10us(±0.5%)
Pulse Period		500us(±0.5%)	505us(±0.5%)
Frequency (Hz)		60Hz(±1)	60Hz(±0.5%)
Net Charge (µC) per pulse		0	0
Maximum output voltage (V):		8.00V(±0.5%)	8.00V(±0.5%)

@500 ohms		
Maximum output voltage (V): @2000 ohms	32V(±0.5%)	32V(±0.5%)
Maximum output voltage (V): @10000 ohms	60V(±3)	60V(±0.5%)
Maximum output current (mA): @500 ohms	16mA(±0.5%)	16mA(±0.5%)
Maximum output current (mA): @2000 ohms	16mA(±0.5%)	16mA(±0.5%)
Maximum output current (mA): @10000 ohms	6mA(±0.5%)	6mA(±0.5%)
Maximum phase charge (μC) @500Ω	3.95	4
Maximum Current Density, (mA/cm², r.m.s.) @500Ω	2.35	2.37
Maximum Average Power Density, (W/cm²) @500Ω	0.000017	0.000017
Maximum Average Current (average absolute value, mA) @500Ω	0.48	0.48
IEC60601-1	Yes	Yes
IEC60601-1-2	Yes	Yes
IEC60601-2-10	Yes	Yes

IEC 60601-1-11	Yes	No

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

TENS device-HeadaTerm are 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.