June 17, 2021

Shenzhen Dongdixin Technology Co., Ltd.
Siping Yuan
Floor 1-2, No.3 Building, Fanshen Xusheng
Industrial Estate Xilixiaobaimang 518108
Nanshan District Shenzhen, Guangdong
China

Re: K210364
Trade/Device Name: Migraine TENS Digital Pain Reliever
Regulation Number: 21 CFR 882.5891
Regulation Name: Transcutaneous electrical nerve stimulator to treat headache
Regulatory Class: Class II
Product Code: PCC
Dated: February 3, 2021
Received: February 8, 2021

Dear Siping Yuan:

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,

Patrick Antkowiak
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

Device Name
Migraine TENS Digital Pain Reliever
Model: LT1103, LT1103-P

Indications for Use *(Describe)*

Migraine TENS Digital Pain Reliever LT1103
- 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.

Migraine TENS Digital Pain Reliever LT1103-P
- 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.

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510(k) SUMMARY

as required by section 21 CFR 807.92

Migraine TENS Digital Pain Reliever

Date of Submission: 05/28/2021

Submitter's Name: Shenzhen Dongdixin Technology Co., Ltd.

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Contact: Siping Yuan

1. Proposed Device:

Device Name: Migraine TENS Digital Pain Reliever

Model: LT1103, LT1103-P

Device classification Name:	stimulator, nerve, electrical, transcutaneous, for migraine
Regulation Description:	Transcutaneous electrical nerve stimulator to treat headache.
Regulation Medical Specialty:	Neurology
Review Panel:	Neurology
Regulation Number:	882.5891
Product Code:	PCC
Device Class:	II

2. Predicate Device:

Legally Marketed Device:	Cefaly® Dual
510(k) Number:	K201895
Manufacturer:	CEFALY Technology

3. Device Description:

The Migraine TENS Digital Pain Reliever is a neurostimulator that is applied to the forehead using a self-adhesive electrode positioned bilaterally over the supratrochlearis and supraorbitalis nerves. Supratrochlearis and supraorbitalis (or supratrochlear and supraorbital) nerves belong to the upper branch of the trigeminal nerve (V1). The device uses electric impulses that are delivered to the supratrochlearis and supraorbitalis nerves to prevent and treat pain in the head area.

The Migraine TENS Digital Pain Reliever is operated by a rechargeable battery. Pressure on the single button allows selecting and starting a stimulation program, which runs automatically. And during ramping up, users could choose comfortable intensity level by pressing the button to lock up the current intensity.

The Migraine TENS Digital Pain Reliever consists of the following elements:

- Main Device
- Charging Station
- Electrode Pads
- USB cable

4. Indications for Use:

Migraine TENS Digital Pain Reliever LT1103

- 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.

Migraine TENS Digital Pain Reliever LT1103-P

- The prophylactic treatment of episodic migraine in patients 18 years of age or older.

5. Comparison of Technological Characteristics with the Predicate Device

Both the subject and Predicate Device utilize the application of electrical current through electrodes placed on the forehead. By releasing the low frequency pulse with a particular frequency and reaching the advanced nerve center of cerebral cortex via nervus supraorbitalis, they can stop or postpone the transmission of headache signal to cerebral center.

Basic technological characteristics, new device vs. Predicate device

		New device	New device	Predicate device	S.E. Discussion
1	**510K#**	**K210364**	**K210364**	**K201895**	**N/A**
2	Device Name and Model	Migraine TENS Digital Pain Reliever Model: LT1103	Migraine TENS Digital Pain Reliever Model: LT1103-P	**Cefaly® Dual**	N/A
3	Manufacturer	Shenzhen Dongdixin Technology Co., Ltd.	Shenzhen Dongdixin Technology Co., Ltd.	CEFALY Technology	N/A
4	Intended for use	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.	The prophylactic treatment of episodic migraine in patients 18 years of age or older.	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.	Equivalent The intended for use of LT1103 is equivalent with predicate device, the intended for use of LT1103-P is covered by the predicate device because LT1103-P contains only one program for prophylactic treatment.
5	Where used	OTC	OTC	OTC	Equivalent
6	Power Source	1 rechargeable LiPo 3.7 V battery	1 rechargeable LiPo 3.7 V battery	1 rechargeable LiPo 3.7 V battery	Equivalent
	-Method of Line current isolation	N/A, battery powered	N/A, battery powered	N/A, battery powered	Equivalent
	- Patient Leakage Current (μA) -Normal condition -Single fault condition	N/A, battery powered	N/A, battery powered	N/A, battery powered	Equivalent
7	Channels	1	1	1	Equivalent
	Synchronous or Alternating?	N/A	N/A	N/A	Equivalent

	Method of Channel Isolation	N/A	N/A	N/A	Equivalent
8	Constant Current? Constant Voltage?	Yes No	Yes No	Yes No	Equivalent
9	Software/Firmware/Micro processor Control?	Yes 2 fixed programs: -1 fixed program for the treatment of migraine attacks(Program 1) -1 fixed program for prophylactic treatment of migraine attacks(Program 2)	Yes 1 fixed program: -1 fixed program for prophylactic treatment of migraine attacks	Yes 2 fixed programs: -1 fixed program for the acute treatment of migraine attacks(Program 1) -1 fixed program for prophylactic treatment of migraine attacks(Program 2)	Equivalent, LT1103 is equivalent with predicate device. LT1103-P has only one program, which is covered by the predicate device.
	Program 1: Max. output current Pulse width Pulse frequency Session duration	 16 mA 250 µs, fixed 100 Hz, fixed 60 minutes	N/A	 16 mA 250 µs, fixed 100 Hz, fixed 60 minutes	Equivalent The program 1 of LT1103 is equivalent with predicate device, while LT1103-P does not have program 1.
	Program 2: Max. output current Pulse width Pulse frequency Session duration	 16 mA 250 µs, fixed 60 Hz, fixed 20 minutes	 16 mA 250 µs, fixed 60 Hz, fixed 20 minutes	 16 mA 250 µs, fixed 60 Hz, fixed 20 minutes	Equivalent
10	Timer Range (minutes)	20 minutes, 60 minutes	20 minutes	20 minutes, 60 minutes	Equivalent
11	Weight (grams.)	14	14	12	Different, but the subject device has passed the testing according to the requirement of IEC60601-1. The difference does not
12	Dimensions (mm) H*W * L	41 mm x 41 mm x 13.4mm	41 mm x 41 mm x 13.4mm	55 mm x 40 mm x 15mm	
13	Housing Materials & Construction	ABS+PC for Main device ABS for Charging station	ABS+PC for Main device ABS for Charging station	Plastic ABS	

					raise any safety or effectiveness issue.
14	Waveform	Biphasic	Biphasic	Biphasic	Equivalent
15	Shape	Rectangular Full compensated Symmetrical	Rectangular Full compensated Symmetrical	Rectangular Full compensated Symmetrical	Equivalent
16	Max Output Voltage (V) ±20%				
17	500Ω	8	8	8	Equivalent
18	2kΩ	32	32	32	
19	10kΩ	60	60	60	
20	Max Output Current (mA) ±20%				
21	500Ω	16	16	16	Equivalent
22	2kΩ	16	16	16	
23	10kΩ	6	6	6	
24	Pulse Width(μsec)	250 μs, fixed	250 μs, fixed	250 μs, fixed	Equivalent
25	Frequency (Hz)	60 Hz, fixed 100 Hz, fixed	60 Hz, fixed	60 Hz, fixed 100 Hz, fixed	Equivalent, the frequency of LT1103 is equivalent with predicate device. LT1103-P has only one program, which is covered by the predicate device.
26	Maximum Current Density (mA/cm^2,500Ω)	2.37	2.37	2.37	Equivalent
27	Maximum Average Power Density, (W/cm^2),500Ω	0.000047	0.000017	0.000047	Equivalent, the Maximum Average Power Density of LT1103 is equivalent with predicate device. LT1103-P has only one

					program, which is covered by the predicate device.

6. Performance Data:

The following performance data are provided in support of the substantial equivalence determination:

6.1 Biocompatibility testing

The biocompatibility evaluation for the subject device was conducted in accordance with the International Standard ISO 10993-1 "Biological Evaluation of Medical Devices − Part 1: Evaluation and Testing Within a Risk Management Process". As dictated by the application and duration of contact with the intact skin, the testing included the following tests:

- Cytotoxicity
- Sensitization
- Irritation

6.2 Electrical safety and electromagnetic compatibility (EMC)

Electrical safety and EMC testing were conducted on the subject device. The system complies with the IEC 60601-1, IEC60601-1-11 and IEC 60601-2-10 standards for safety and the IEC 60601-1-2 standard for EMC.

6.3 Software Verification and Validation Testing

Software verification and validation testing were conducted and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." The software for this device was considered as a "Moderate" level of concern.

6.4 Output waveform Testing

For each program, oscilloscope tracing diagrams describing the electrical output waveform was provided to verify the output specifications of the device according to IEC 60601-2-10.

6.5 Electrode impedance and current distribution testing.

Electrode impedance and current distribution testing were conducted on the electrode.

7. Conclusions

The intended use and basic technological characteristics of the Migraine TENS Digital Pain Reliever LT1103, LT1103-P are significantly equivalent with those of the Predicate device K201895. Any technological differences do not raise new questions regarding safety and effectiveness.