December 8, 2017

Shenzhen Dongdixin Technology Co.,Ltd.
Siping Yuan
R.A. Specialist
No. 3 Building Xilibaimang Xusheng Industrial Estate, Nanshan
Shenzhen, Guangdong 51808 China

Re: K173462
Trade/Device Name: Wireless Pain Relieve Device, Model LT5018C
Regulation Number: 21 CFR 882.5890
Regulation Name: Transcutaneous Electrical Nerve Stimulator For Pain Relief
Regulatory Class: Class II
Product Code: NUH, NGX, NYN
Dated: October 31, 2017
Received: November 8, 2017

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. 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,

Vivek J. Pinto -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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K173462

Device Name
Wireless Pain Relieve Device
Model: LT5018C

Indications for Use *(Describe)*
TENS: The device is designed to be used for temporary relief of pain associated with sore and aching muscles in the shoulder, waist, back, neck, upper extremities(arm) and lower extremities (leg) due to strain from exercise or normal household work activities. And to be used for the symptomatic relief and management of chronic, intractable pain and relief of pain associated with arthritis.
EMS: The device is designed to be used for stimulate healthy muscles in order to improve and facilitate muscle performance.

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:

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."

510(k) SUMMARY

as required by section 21 CFR 807.92

Wireless Pain Relieve Device

Date of Submission: 10/31/2017

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

Address: No. 3 Building, Xilibaimang Xusheng Industrial Estate Nanshan, Shenzhen, CHINA 518108

E-mail: yuansp@dundex.com

Tel: +86(755) 27652471

FAX: +86(755) 27652674

Contact: Siping Yuan

1. Proposed Device:

Device Name: Wireless Pain Relieve Device

Model: LT5018C

Device classification Name:	Stimulator, Nerve, Transcutaneous, Over-The-Counter
Regulation Description:	Transcutaneous electrical nerve stimulator for pain relief
Regulation Medical Specialty:	Neurology
Review Panel:	Neurology
Regulation Number:	882.5890
Product Code:	NUH
Device Class:	II

Device classification Name:	Stimulator, Muscle, Powered, For Muscle Conditioning
Regulation Description:	Powered muscle stimulator.
Regulation Medical Specialty:	Physical Medicine
Review Panel:	Physical Medicine
Regulation Number:	890.5850
Product Code:	NGX
Device Class:	II

Device classification Name:	Stimulator, Electrical, Transcutaneous, For Arthritis
Regulation Description:	Transcutaneous electrical nerve stimulator for pain relief.
Regulation Medical Specialty:	Neurology
Review Panel:	Neurology
Regulation Number:	882.5890
Product Code:	NYN
Device Class:	II

2. Predicate Device:

Legally Marketed Device:	Smart Pain Reliever LT5019
510(k) Number:	K162479
Manufacturer:	Shenzhen Dondixin Technology Co., Ltd.

3. Description of Proposed Device:

LT5018C is designed to be used at home, by adults of all genders.

Explanation of how the device functions:

The Wireless Pain Relieve Device includes TENS, EMS (including MASSAGE Program) mode. Transcutaneous Electrical Nerve Stimulation (TENS) is a noninvasive, drug free method of controlling pain. EMS works by sending electronic pulses to the muscle needing treatment; this

causes the muscle to exercise passively.

Scientific concepts that from the basis for the device:

TENS uses tiny electrical impulses sent through the skin to nerves to modify your pain perception. TENS does not cure any physiological problem; it only helps control the pain, this activates the underlying sensory nerves. EMS is a product derived from the square waveform (ladder-shaped), through the square wave pattern it is able to work directly on muscle motor neurons, contraction helps to condition the muscle in order to facilitate performance.

For Transcutaneous Electrical Nerve Stimulation (TENS) Self-adhesive electrodes are placed on the skin close to the area of pain. The user can choose 6 pre-set TENS programs with different pulse settings. In each program, the intensity of the pulse can be adjusted.
For Electrical Muscle Stimulation (EMS), the electrodes are placed near the muscle to be stimulated. The user can choose 5 pre-set EMS programs with different pulse settings. In each program, the intensity of the pulse can be adjusted.
There have 3 massage programs, and the massage stimulation program is a stimulation program that is used with the EMS mode of stimulation to facilitate recovery from muscle fatigue and to help recover muscle strength after training sessions and competitions.

The Wireless Pain Relieve Device is controlled by means of an APP on a mobile device (phone or table) and remote control. The communication is done via Bluetooth Low Energy. The APP operates on IOS and Android platforms (IOS 8.0 or greater, Android 5.0 or greater).

4. Description of All Device Modification(s)

Compared with the existing device (LT5019), the following main parts of Wireless Pain Reliever LT5018C have changed:

1) Added the remote control to control the operation of device.
2) Change the dimensional specification.
3) Change the hardware based on the new dimensional of enclosure. But the fundamental scientific technology is not change.

Based on the 21CFR820.30 requirement, this is belong to design change and shall have been evaluated according to the standard IEC60601-1, IEC60601-2-10, and IEC 60601-1-2. We have conducted these standard test and the results is Passed. Meanwhile, for add the remote control; we added the wireless coexistence test and the results display the remote control also safely and effectively.

5. Proposed Device Intended for Use Statement:

Device Name: Wireless Pain Relieve Device, Model: LT5018C

Indications for Use:

- TENS: The device is designed to be used for temporary relief of pain associated with

sore and aching muscles in the shoulder, waist, back, neck, upper extremities(arm) and lower extremities (leg) due to strain from exercise or normal household work activities. And to be used for the symptomatic relief and management of chronic, intractable pain and relief of pain associated with arthritis.

- EMS: The device is designed to be used for stimulate healthy muscles in order to improve and facilitate muscle performance.

6. Technological Characteristics and Substantial Equivalence

Both the LT5018C and Predicate Device utilize the application of electrical current through electrodes placed on the skin for pain control, or electrical muscle stimulation (EMS) the elicitation of muscle contraction using electric impulses. The impulses are generated by the device and delivered through electrodes on the skin in direct proximity to the (painful) muscles to be stimulated.

Basic technological characteristics, new device vs. Predicate device

Table 1： Substantial Equivalence Comparison Table

		New device	Predicate device	S.E. Discussion
1	**510K#**	**To be assigned**	**K162479**	**N/A**
2	Device Name and Model	Wireless Pain Relieve device Mode: LT5018C	Smart Pain Reliever Mode: LT5019	N/A
3	Manufacturer	Shenzhen Dongdixin Technology Co., Ltd	Shenzhen Dongdixin Technology Co., Ltd	Same
4	Intended for use	TENS: The device is designed to be used for temporary relief of pain associated with sore and aching muscles in the shoulder, waist, back, neck, upper extremities (arm) and lower extremities (leg) due to strain from exercise or normal household work activities. And to be used for the symptomatic relief and management of chronic, intractable pain and relief of pain associated with arthritis. EMS: The device is designed to be used for stimulate healthy muscles in order to improve and facilitate muscle performance.	TENS: The device is designed to be used for temporary relief of pain associated with sore and aching muscles in the shoulder, waist, back, neck, upper extremities (arm) and lower extremities (leg) due to strain from exercise or normal household work activities. And to be used for the symptomatic relief and management of chronic, intractable pain and relief of pain associated with arthritis. EMS: The device is designed to be used for stimulate healthy muscles in order to improve and facilitate muscle performance.	Same
5	Power Source	3.7V battery supply	3.7V battery supply	Same
	-Method of Line current isolation	N/A	N/A	Same
	- Patient Leakage Current (μA) -Normal condition	0uA	0uA	Same

	-Single fault condition	2.0uA	2.0uA	
6	Average DC current through electrodes when device is on but no pulses are being applied (μA)	0	0	Same
7	Number of Output Modes	2 (TENS/EMS(including MASSAGE))	2 (TENS/EMS(including MASSAGE))	Same
8	Number of Output Channels			
	Synchronous or Alternating?	N/A	N/A	Same
	Method of Channel Isolation	N/A	N/A	Same
9	Regulated Current or Regulated Voltage?	Current control	Current control	Same
10	Software/Firmware/Micro processor Control?	Yes	Yes	Same
11	Automatic Overload Trip	Yes	Yes	Same
12	Automatic No Load contact Trip	Yes	Yes	Same
13	Automatic Shut off	Yes	Yes	Same
14	User Override Control?	Yes Power on/off button on the device Power on/off on the remote control Power on/off in the APP software	Yes Power on/off button on the device, and Power on/off in the APP software	Similar, the new device added the remote control, doesn't affect the safety and effectiveness.
15	Indicator Display:			
	On/Off Status?	Yes	Yes	Same
	Low Battery?	Yes	Yes	Same
	Voltage/ Current	Yes	Yes	Same

	Level?			

Table 2：Output Specification TENS mode

		New device	Predicate device	S.E. Discussion
1	510K#	To be assigned	K162479	N/A
2	Device Name or Program Name	Wireless Pain Relief Device Mode:LT5018C	Smart Pain Reliever Mode: LT5019	N/A
3	Manufacturer	Shenzhen Dongdixin Technology Co., Ltd	Shenzhen Dongdixin Technology Co., Ltd	Same
4	Waveform	Biphasic	Biphasic	Same
5	Shape	Rectangular	Rectangular	Same
6	Max Output Voltage (V) ±20%			
7	500Ω	31	31.2	Similar, the new device have been evaluated and passed the test according to the requirement of IEC60601-2-10
8	2kΩ	66	69.6	
9	10kΩ	66	69.6	
10	Pulse Duration (μsec)	150~250us	150~250us	Same
11	Frequency (Hz)	2~100Hz	2~100Hz	Same
12	Maximum Phase Charge (uC) 500Ω	31	30	Similar, the new device have been evaluated and passed the test according to the requirement of IEC60601-2-10. The maximum average power density of new device is far lower than 250mW/cm2 as required by the FDA guidance for Powered Muscle Stimulator. The safety and effectiveness of the device is not affected.
13	Maximum Current Density 500Ω	0.48mA/cm^2	0.32mA/cm^2	
14	Maximum Average Current (average absolute value), mA, 500Ω	1.2	1.2	
15	Maximum Average Power Density, (mW/cm^2),500Ω	2.88	1.9	

Table 3：Output Specification EMS mode

		New device	Predicate device	S.E. Discussion
1	510K#	To be assigned	K162479	N/A
2	Device Name or Program Name	Wireless Pain Relief Device Mode:LT5018C	Smart Pain Reliever Mode: LT5019	N/A
3	Manufacturer	Shenzhen Dongdixin Technology Co., Ltd	Shenzhen Dongdixin Technology Co., Ltd	Same
4	Waveform	Biphasic	Biphasic	Same
5	Shape	Rectangular	Rectangular	Same
6	Max Output Voltage (V) ±20%			
7	500Ω	31	31.2	Similar, the new device have been evaluated and passed the test according to the requirement of IEC60601-2-10
8	2kΩ	66	69.6	
9	10kΩ	66	69.6	
10	Pulse Duration (usec)	200~370us	200~370us	Same
11	Frequency (Hz)	3-55 Hz	3~75Hz	Similar, the new device have been evaluated and passed the test according to the requirement of IEC60601-2-10
12	Maximum Phase Charge (uC) 500Ω	44.4	24	Similar, the new device have been evaluated and passed the test according to the requirement of IEC60601-2-10. The maximum average power density of new device is far lower than 250mW/cm2 as required by the FDA guidance for Powered Muscle Stimulator. The safety and effectiveness of the device is not affected.
13	Maximum Current Density 500Ω	0.484mA/cm2	0.248mA/cm2	
14	Maximum Average Current (average absolute value), mA, 500Ω	1.22	0.72	
15	Maximum Average Power Density, (mW/cm²),500Ω	2.93	1.2	

Table 4：Output Specification MASSAGE program

		New device	Predicate device	S.E. Discussion
1	510K#	To be assigned	K162479	N/A
2	Device Name or Program Name	Wireless Pain Relief Device Mode:LT5018C	Smart Pain Reliever Mode: LT5019	N/A
3	Manufacturer	Shenzhen Dongdixin Technology Co., Ltd	Shenzhen Dongdixin Technology Co., Ltd	Same
4	Waveform	Biphasic	Biphasic	Same
5	Shape	Rectangular	Rectangular	Same
6	Max Output Voltage (V) ±20%			Similar, the new device have been evaluated and passed the test according to the requirement of IEC60601-2-10
7	500Ω	31	31.2	
8	2kΩ	66	69.6	
9	10kΩ	66	69.6	
10	Pulse Duration (usec)	50-250us	250us	Similar, the new device have been evaluated and passed the test according to the requirement of IEC60601-2-10
11	Frequency (Hz)	2~90Hz	10~80Hz	
12	Maximum Phase Charge (uC) 500Ω	31	30	Similar, the new device have been evaluated and passed the test according to the requirement of IEC60601-2-10. The maximum average power density of new device is far lower than 250mW/cm2 as required by the FDA guidance for Powered Muscle Stimulator. The safety and effectiveness of the device is not affected.
13	Maximum Current Density 500Ω	0.51mA/cm2	0.32mA/cm2	
14	Maximum Average Power Density, (mW/cm²),500Ω	3.2	1.9	

Discussion

The timer range, weight and dimension of the new device are different from the predicate devices, but the new devices are evaluated and passed the testing according to IEC60601-1 and IEC60601-2-10, this Different does not pose any new questions of safety and effectiveness.

The Housing Material, Max Output Voltage/Current, Maximum Phase Charge, Maximum Current Density and Maximum Average Current/Power Density are similar with the predicate devices, but the new devices are evaluated and passed the testing according to IEC60601-2-10 and compliance with the guidance Document for Powered Muscle Stimulator, this difference doesn't pose any new questions of safety and effectiveness.

7. Performance Data:

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

7.1 Biocompatibility testing

Compared with unmodified device, the material of electrodes for the new product LT5018C is the same material of electrodes (K162479) that got the 510(k) clearance on 2017. The material of enclosure is ABS, and it is the same as the material of enclosure (k130802) that got the 510(k) clearance on 2013. These materials have the same product process and injection process.

7.2 Electrical safety and electromagnetic compatibility (EMC)

Electrical safety and EMC testing were conducted on the LT5018C. The system complies with the IEC 60601-1, IEC 60601-1-11 and IEC 60601-2-10 standards for safety and the IEC 60601-1-2 standard for EMC.

For FCC part 15 RADIO FREQUENCY DEVICES, Subpart C—Intentional Radiators.

7.3 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. IEC 62304 was followed.

8. Conclusions

The LT5018C has the same intended use and technological characteristics as the predicate device Smart Pain Reliever LT5019. Moreover, bench testing and safety report supplied in this submission demonstrates that the difference in the submitted models could maintain the same safety and effectiveness as that of predicate device. In the other words, those engineering difference do not affect the intended use or alter the fundamental scientific technology of the device. Thus, LT5018C is substantially equivalent to the predicate device.