June 22, 2018

Shenzhen Dongdixin Technology Co.,Ltd.
Siping Yuan
R.A. Specialist
No. 3 Building Xilibaimang Xusheng
Industrial Estate Nansha
Shenzhen, China 518108

Re: K180331
Trade/Device Name: Wireless Pain Relieve Device, Model LT5011C
Regulation Number: 21 CFR 882.5890
Regulation Name: Transcutaneous Electrical Nerve Stimulator For Pain Relief
Regulatory Class: Class II
Product Code: NYN, NUH
Dated: May 15, 2018
Received: May 21, 2018

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 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,

Pamela D. Scott -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)*
K180331

Device Name
Wireless Pain Relieve Device
Model: LT5011C

Indications for Use *(Describe)*
The device is designed to be used for temporary relief of pain associated with sore and aching muscles in the shoulder, waist, back, 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.

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

Wireless Pain Relieve Device

Date of Submission: 02/01/2018

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

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Contact: Siping Yuan

1. Proposed Device:

Device Name: Wireless Pain Relieve Device

Model: LT5011C

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, 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:	Wireless Pain Relieve Device LT5018C
510(k) Number:	K173462
Manufacturer:	Shenzhen Dondixin Technology Co., Ltd.

3. Description of Proposed Device:

LT5011C 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 mode. Transcutaneous Electrical Nerve Stimulation (TENS) is a noninvasive, drug free method of controlling pain.

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.

For Transcutaneous Electrical Nerve Stimulation (TENS) Self-adhesive electrodes are placed on the skin close to the area of pain. The user can choose 23 pre-set TENS programs. In each program, the intensity can be adjusted.

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

4. Description of All Device Modification(s)

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

1) Change the dimensional specification and change the hardware based on the new dimension of enclosure. But the fundamental scientific technology does not change.
2) Remove the EMS program and indications for use of EMS mode.
3) Remove the neck program and indications for use of neck pain.
4) Split the cycle program of unmodified device into four programs for users to choose their comfortable programs and add custom program for users to choose their comfortable programs.

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.

5. Proposed Device Intended for Use Statement:

Device Name: Wireless Pain Relieve Device, Model: LT5011C

Indications for Use:

The device is designed to be used for temporary relief of pain associated with sore and aching muscles in the shoulder, waist, back, 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.

6. Technological Characteristics and Substantial Equivalence

Both the LT5011C and Predicate Device utilize the application of electrical current through electrodes placed on the skin for pain control. 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**	**K173462**	**N/A**
2	Device Name and Model	Wireless Pain Relieve device Mode: LT5011C	Wireless Pain Relieve device Mode: LT5018C	**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 , 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.	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.	Similar, the intended use of LT5011C is fallen within the intended use of predicate device.
5	Power Source	DC 3.7V Li-ion Battery(main device) DC 3.0V, 2 x AAA Batteries (Remote control)	DC 3.7V Li-ion Battery(main device) DC 3.0V, 2 x AAA Batteries (Remote control)	Same
	-Method of Line current isolation	N/A	N/A	Same
	- Patient Leakage Current (μA)			Same

	-Normal condition -Single fault condition	0uA 2.0uA	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	1 (TENS)	2 (TENS/EMS(including MASSAGE))	Different, LT5011C only has TENS mode and LT5011C remove indications for use of EMS mode accordingly.
8	Number of Output Channels			
	Synchronous or Alternating?	Alternating	N/A	Different, LT5011C has two channels and have been evaluated and passed the test according to the requirement of IEC60601-2-10.
	Method of Channel Isolation	By Electrical Circuit and Software	N/A	Different, LT5011C has two channels and have been evaluated and passed the test according to the requirement of IEC60601-1.
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 Power on/off on the remote control Power on/off in the APP software	Same
15	Indicator Display:			
	On/Off Status?	Yes	Yes	Same
	Low Battery?	Yes	Yes	Same
	Voltage/ Current Level?	Yes	Yes	Same
16	Timer Range (minutes)	5-90 minutes	30 minutes	Different, new device have been evaluated and passed the test according to the requirement of IEC60601-2-10. User can set the treatment time according their needs.
17	Weight (grams.)	33grams (Main device) 55 grams (Remote control)	36grams (Main device) 65 grams (Remote control)	Different, the new device have been evaluated and passed the testing according to the requirement of IEC60601-1.
18	Dimensions (cm.) H*W * L	80.5(L)x45(W)x13.5(H)mm (Main device) 127(L)x48.7(W)x24.2(H)mm (Remote control)	360(L)x59(W)x11.5(H)mm (Main device) 115(L)x53(W)x25(H)mm (Remote control)	
19	Housing Materials & Construction	ABS	ABS	Same
20	Compliance with 21 CFR 898	Yes	Yes	Same
21	Compliance with Voluntary Standards?	IEC 60601-1, IEC 60601-1-2, IEC 60601-2-10, IEC 60601-1-11 ISO10993-5/10	IEC 60601-1, IEC 60601-1-2, IEC 60601-2-10, IEC 60601-1-11 ISO10993-5/10	Same

Table 2：Output Specification TENS mode

		New device	Predicate device	S.E. Discussion
1	510K#	To be assigned	K173462	N/A
2	Device Name or Program Name	Wireless Pain Relief Device Mode:LT5011C	Wireless Pain Relief Device Mode:LT5018C	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	30.5	31	Similar, the new device have been evaluated and passed the test according to the requirement of IEC60601-2-10
8	2kΩ	65	66	
9	10kΩ	65	66	
10	Pulse Duration (μsec)	100~200us	150~250us	
11	Frequency (Hz)	2~100Hz	2~100Hz	Same
12	Maximum Phase Charge (uC) 500Ω	24	31	Similar, the new device have been evaluated and passed the test according to the requirement of IEC60601-2-10.
13	Maximum Current Density 500Ω	0.295mA/cm^2	0.48mA/cm^2	
14	Maximum Average Current (average absolute value), mA, 500Ω	1.2	1.2	
15	Maximum Average Power Density, (mW/cm^2),500Ω	1.74	2.88	

Discussion:

The number of output modes, number of output channels, 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 difference does not pose any new questions of safety.

The Max Output Voltage/Current, Pulse Duration, Maximum Phase Charge, Maximum Current Density and Maximum Average Power Density are similar with the predicate devices, but the new devices are evaluated and passed the testing according to IEC60601-2-10, 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 LT5011C is the same material of predicate device (K173462) that got the 510(k) clearance on 2017. The material of enclosure is ABS, and it is the same as the material of predicate device (K173462) that got the 510(k) clearance on 2017. 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 LT5011C. 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.

7.4 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.

8. Conclusions

The LT5011C has the similar intended use and technological characteristics as the predicate device Wireless Pain Relieve Device LT5018C. 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, LT5011C is substantially equivalent to the predicate device.