DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

February 8, 2017

Shenzhen Dongdixin Technology Co., Ltd.
Truman Shen
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No. 3 Building
Xilibaimang Xusheng
Industrial Estate Nanshan
Shenzhen, 518108 CN

Re: K162479
Trade/Device Name: Smart Pain Reliever, Model LT5019
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: August 15, 2016
Received: January 9, 2017

Dear Truman Shen:

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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Michael J. Hoffmann -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)*

K162479

Device Name
Smart Pain Reliever
Model: LT5019

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.**

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# 510(k) SUMMARY

**as required by section 21 CFR 807.92**

Smart Pain Reliever

**Date of Submission:** 08/15/2016

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

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

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**Contact:** Truman Shen

## 1. Proposed Device:

| | |
|---|---|
| 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:

| No. | Legally Marketed Device: | 510(k) Number: | Manufacturer: |
|---|---|---|---|
| 1 | PulseRelief | K151035 | Philips Consumer Lifestyle |
| 2 | SmartRelief | K131159 | Chattem, Inc. |
| 3 | Compex® Sport Plus “MASSAGE” program | K083140 | Compex S.A. |

## 3. Description of Proposed Device:

LT5019 is designed to be used at home, by adults of all genders.

**Explanation of how the device functions:**

The Smart Pain Reliever includes TENS, EMS (including MASSAGE Program). 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 11 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 8 pre-set EMS programs with different pulse settings. In each program, the intensity of the pulse can be adjusted.

The Smart Pain Reliever device only have one massage program, and this 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 functions of the LT5019 device:**

The Smart Pain Reliever device is controlled by means of an APP on a mobile device (phone or table). 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).

**Table 1: Smart Pain Reliever device controls and indicators**

| Control/Indicator | User interface | Function |
|---|---|---|
| **On/off Button** | Press button (when device is off) | Turn on the device |
| | Press button (when device is on) | Turn off the device (at any time, before, during or after treatment ) |
| **LED indicator** | off | Device off |
| | Green flashing | It means that the device is in standby mode |
| | Orange continuous | It means in treating mode or the battery is being charging |
| | Orange flashing | It means that the device is in paused mode |
| | Green continuous | It means it has connected with APP or the battery is full when charging |

## 4. Proposed Device Intended for Use Statement:

**Device Name:** Smart Pain Reliever, Model: LT5019

**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.

## 5. Technological Characteristics and Substantial Equivalence

Both the LT5019 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 2：Substantial Equivalence Comparison Table**

| | | New device | Predicate device | | | Remark |
|---|---|---|---|---|---|---|
| 1 | 510K# | K162479 | K151035 | K131159 | K083140 | -- |
| 2 | Device Name and Model | Smart Pain Reliever<br>Mode: LT5019 | PulseRelief | SmartRelief | Compex® Sport Plus<br>"MASSAGE" program | -- |
| 3 | Manufacturer | Dongdixin Technology Co., Ltd | Philips Consumer Lifestyle | Chattem, Inc. | Compex S.A. | -- |
| 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 | The OTC TENS/EMS stimulator PulseRelief 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 exerciseor normal household work activities.<br>It should be applied to normal, healthy, dry and clean skin of adult patients, and is to be used for stimulate healthy muscles in | To be used for temporary relief of pain associated with sore and aching muscles due to strain from exercise or normal household and work activities, It is also intended for symptomatic relief and management of chronic, intractable pain and relief of pain associated with arthritis | Compex® Sport Plus is intended to stimulate healthy muscles in order to improve or facilitate muscle performance. | Similar |

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| | | | healthy muscles in order to improve and facilitate muscle performance. | order to improve and facilitate muscle performance. | | | |
| 5 | Power Source | | 3.7V battery supply | 3.7V battery supply | 3V battery supply | NIMH rechargeable battery (4.8V≥ 1200mA/h)（4cells pack of 1.2V） | SE Note 1 |
| | -Method of Line current isolation | | N/A | N/A | N/A | N/A | Same |
| | - Patient Leakage Current (μA)<br>-Normal condition<br>-Single fault condition | | 0uA<br>2.0uA | <10uA<br><50uA | N/A | N/A<br>N/A | SE Note 1 |
| 6 | Average DC current through electrodes when device is on but no pulses are being applied (μA) | | 0 | 0 | 0 | 0 | Same |
| 7 | Number of Output Modes | | 2 (TENS/EMS(including MASSAGE program)) | 2 (TENS/EMS) | 1 (TENS) | 9 modes/programs | SE Note 2 |
| 8 | Number of Output Channels: | Synchronous or Alternati-ng? | N/A | N/A | N/A | Synchronous | SE Note 2 |
| | | Method of Channel Isolation | N/A | N/A | N/A | N/A | Same |
| 9 | Regulated Current | | Current control | Current control | Current control | Current control | Same |

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| | or Regulated Voltage? | | | | | | |
| 10 | Software/Firmware /Micro processor Control? | | Yes | Yes | Yes | Yes | Same |
| 11 | Automatic Overload Trip | | Yes | Yes | No | No | SE Note 2 |
| 12 | Automatic No Load contact Trip | | Yes | Yes | No | Yes | SE Note 2 |
| 13 | Automatic Shut off | | Yes | Yes | Yes | Yes | Same |
| 14 | User Override Control? | | Yes Power on/off button on the device, and power on/off in the APP software | Yes Power on/off button on the device, and power on/off in the APP software | No | Power on/off button | SE Note 2 |
| 15 | Indicator Display: | On/Off Status? | Yes | Yes | Yes | Yes | Same |
| | | Low Battery? | Yes | Yes | No | Yes | SE Note 2 |
| | | Voltage/Current Level? | Yes | Yes | Active/inactive output | Yes | SE Note 2 |
| 16 | Timer Range (minutes) | | 1 ～ 59 minutes and continuous | 1 ～ 59 minutes and continuous | 30 minutes | 3-55.5min | SE Note 2 |
| 17 | Weight (grams.) | | 28grams (main device) | 62 grams (main device) | 20 grams | 350g | SE Note 2 |
| 18 | Dimensions (cm.) H*W * L | | 13x41x67mm(main device) | 2 units, each 54x54x14 (excl electrodes) | 64x38x13[mm] | L142*W99*H36 | SE Note 2 |
| 19 | Housing Materials & Construction | | PC + ABS | PC + ABS | Molded Plastic | / | SE Note 3 |

**Table 3: Output Specification TENS mode**

| | | New device | Predicate device | | Remark |
|---|---|---|---|---|---|
| 1 | 510K# | K162479 | K151035 | K131159 | -- |
| 2 | Device Name | Smart Pain Reliever Mode: LT5019 | PulseRelief | SmartRelief | -- |
| 3 | Waveform | Biphasic | Biphasic | Asymmetrical Biphasic | Similar Note 4 |
| 4 | Shape | Rectangular | Rectangular | Rectangular | Same |
| 5 | Max Output Voltage (V) ±20% | | | | Similar Note 5 |
| 6 | 500Ω | 31.2 | 31 | 30 | |
| 7 | 2kΩ | 69.6 | 69 | 70 | |
| 8 | 10kΩ | 69.6 | 70 | 70 | |
| 9 | Pulse Duration (μsec) | 150~250us | 60~350us | 30-220 μs at 50% of peak amplitude | Similar Note 5 |
| 10 | Frequency (Hz) | 2~100Hz | 1~100Hz | 1~100Hz | Similar Note 5 |
| 11 | Maximum Phase Charge (uC) 500Ω | 30 | 1.6~6.8 | 13.2 | Similar Note 5 |
| 12 | Maximum Current Density 500Ω | 0.32mA/cm$^2$ | 0.002~0.045mA /cm2 | 0.1mA/cm$^2$ | Similar Note 5 |
| 13 | Maximum Average Current (average absolute value), mA, 500Ω | 1.2 | 0.06~1.36 | 2.06 | Similar Note 5 |
| 14 | Maximum Average Power Density, (mW/cm²),500Ω | 1.9 | 0.24~1.69 | 1.5 | Similar Note 5 |

**Table 4: Output Specification EMS mode**

| | | New device | Predicate device | Remark |
|---|---|---|---|---|
| 1 | 510K# | K162479 | K151035 | -- |
| 2 | Device Name or Program Name | Smart Pain Reliever Mode: LT5019 | PulseRelief | -- |
| 3 | Waveform | Biphasic | Biphasic | Same |
| 4 | Shape | Rectangular | Rectangular | Same |
| 5 | Max Output Voltage (V) ±20% | | | Similar Note 5 |
| 6 | 500Ω | 31.2 | 31 | |
| 7 | 2kΩ | 69.6 | 69 | |
| 8 | 10kΩ | 69.6 | 70 | |
| 9 | Pulse Duration (usec) | 200~370us | 150~350us | Similar Note 5 |
| 10 | Frequency (Hz) | 3~75Hz | 40~65Hz | Similar Note 5 |
| 11 | Maximum Phase Charge (uC) 500Ω | 24 | 4.7~10.9 | Similar Note 5 |
| 12 | Maximum Current Density | 0.248mA/cm2 | 0.019~0.037mA /cm2 | Similar |

| | | | | |
|---|---|---|---|---|
| | 500Ω | | | Note 5 |
| 13 | Maximum Average Current (average absolute value), mA, 500Ω | 0.72 | 0.47~0.93 | Similar Note 5 |
| 14 | Maximum Average Power Density, (mW/cm²),500Ω | 1.2 | 0.62~1.15 | Similar Note 5 |

**Table 5：Output Specification MASSAGE mode**

| | | New device | Predicate device | Remark |
|---|---|---|---|---|
| 1 | 510K# | To be assigned | K083140 | -- |
| 2 | Device Name or Program Name | Smart Pain Reliever Mode: LT5019 | Compex® Sport Plus "MASSAGE" program | -- |
| 3 | Waveform | Biphasic | Biphasic | Same |
| 4 | Shape | Rectangular | Rectangular | Same |
| 5 | Max Output Voltage (V) ±20% | | | Similar Note 5 |
| 6 | 500Ω | 31.2 | 60 | |
| 7 | 2kΩ | 69.6 | 136 | |
| 8 | 10kΩ | 69.6 | 137 | |
| 9 | Pulse Duration (usec) | 250us | 200~400us | Similar Note 5 |
| 10 | Frequency (Hz) | 10~80Hz | 2~100Hz | Similar Note 5 |
| 11 | Maximum Phase Charge (uC) 500Ω | 30 | 48 | Similar Note 5 |
| 12 | Maximum Current Density 500Ω | 0.32mA/cm2 | Not available | Similar Note 5 |
| 13 | Maximum Average Power Density, (mW/cm²),500Ω | 1.9 | <12mW/cm2 (microwatt) @500Ω | Similar Note 5 |

**Comparison in Detail(s):**

**Note1:**

Although the "Power Source(s)" and "Patient Leakage Current" of subject device are a little different from the predicate devices, they all comply with IEC 60601-1 requirements. So the differences will not raise any safety issue.

**Note2:**

Although the " Number of Output Modes" "Output Intensity Level", " Method of Channel Isolation", " Timer Range", "Weight" and "Dimensions" of subject device are different from the predicate devices, they are all comply with IEC 60601-1 and IEC 60601-2-10 requirements. So the differences of the function specifications will not raise any safety or effectiveness issue. **Note 3:**

Although the "Housing Materials & Construction" of subject device is different from the predicate devices, they are all comply with ISO 10993-1, ISO 10993-5 and ISO 10993-10 requirements. So the differences of the Housing Materials & Construction will not raise any biological hazard.

**Note4:**

Although the "Waveform" of subject device is different from the predicate devices, the

waveform is the key factors of the Net Charge (per pulse), and all the Net Charge (per pulse) are zero. The "Biphasic" waveform won't create Net Charge (per pulse), and not cause charge accumulation on the skin and cause burns. So the differences of the "Waveform" will not raise any safety or effectiveness issue.

**Note5:**

Although the "Maximum Output Voltage" , "Pulse Duration", "Maximum pulse frequency", , "Maximum Phase Charge", "Maximum Average Current", "Maximum Current Density", "Maximum Average Power Density of subject device", are a little different from the predicate devices, they all comply with the FDA guidance requirement for Transcutaneous Electrical Nerve Stimulator for Pain Relief and FDA guidance requirement for Powered Muscle Stimulator for Muscle Conditioning. So the differences of function specification will not raise any safety or effectiveness issue.

## 6. Performance Date:

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

### 6.1 Biocompatibility testing

The biocompatibility evaluation for the LT5019 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 shell and electrode of 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 LT5019. The system complies with the IEC 60601-1, IEC 60601-1-6, IEC 60601-1-11 and IEC 60601-2-10 standards for safety and the IEC 60601-1-2 standard for EMC, and IEC 62133 for battery safety.

### 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. IEC 62304 was followed.

### 6.4 Usability Testing

Usability testing according to IEC 62366, Applying Human Factors and Usability Engineering to Medical Device, was conducted.

## 7. Conclusions

The intended use and basic technological characteristics of the LT5019 device are equivalent with those of the referenced Predicate device K151035, K083140 and K131159.

The LT5019 device complies with the requirement of IEC60601-1, IEC 60601-2-10, IEC60601-1-2 and IEC60601-1-11. The bench testing and safety report documentation supplied in this submission demonstrates that any differences in their technological characteristics do not raise any new questions of safety or effectiveness.

Moreover, the bench testing include the testing performed to characterize the waveform and stimulus parameters, and the performance testing proved that the ability of the LT5019 device to deliver a stimulus that meets design specifications.

In the other words, those engineering difference do not affect the intended use or alter the fundamental scientific technology of the device.

Thus, the Smart Pain Reliever device (K162479) is substantially equivalent to the predicate devices (K151035, K131159 and K083140).