DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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September 17, 2014

Shenzhen Jingkehui Electronic Co. LTD
c/o Bill Quanqin Dai, Ph.D.
Application Correspondent
513 Piazza Drive, Unit B
Mountain View, CA, 94043

Re: 510(k) Number: K141260
Trade/Device Name: Electronic Pulse Stimulator
Regulation Number: 21 CFR 882.5890
Regulation Name: Neurology
Regulatory Class: Class II
Product Code: NUH
Dated: Aug 16th 2014
Received: Aug 20th 2014

Dear Dr. Dai,

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" (21CFR 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 yours,

Felipe Aguel -S

for Carlos Pena, Ph.D.
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)*
K141260

Device Name

Electronic Pulse Stimulator

Indications for Use *(Describe)*

To be used for temporary relief of pain associated with sore and aching muscles in the shoulder, waist, back, arm, and leg, due to strain from exercise or normal household and work activities.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Felipe Aguel -S Date: 2014.09.17 15:39:53 -04'00'

510(k) Summary

This 510(k) Summary of safety and effectiveness information is being submitted in accordance with the requirements of 21 CFR 807.92.

1. Submitter's Information

Submitter: Shenzhen Jingkehui Electronic Co., Ltd.
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Email: bill@JKHhealth.com
Date of Preparation: 05/12/2014

2. Subject Device

Trade/Device Name: Electronic Pulse Stimulator
Common Name: Transcutaneous electrical nerve stimulator (TENS)
Regulation Description: Transcutaneous electrical nerve stimulator for pain relief
Definition: Temporary relief of pain due to sore/aching muscles
Regulation Medical Specialty: Neurology
Review Panel: Neurology
Product Code: NUH
Regulation Number: 21 CFR 882.5890
Device Class: II
Use: Over-The-Counter

3. Predicate device

Predicate Device: Electronic Pulse Stimulator
510(k) Number: K131921
Use: Over-The-Counter
Submitter: Shenzhen Jingkehui Electronic Co., Ltd.

Predicate Device: IQ Technologies
510(k) Number: K131290
Use: Over-The-Counter
Submitter: IQ Technologies Inc.

4. Description of Subject Device

The subject device is a Transcutaneous Electrical Nerve Stimulator (TENS), intended for the over-the-counter use to temporarily relieve pain in different body areas. The subject device, which is compact, portable, and microprocessor-controlled, delivers a gentle electrical pulse to the user's skin through the electrode pads for pain relief. According to the need of users, the pulse intensity can be adjustable on the front control panel of the device.

5. Intended Use of Subject Device

To be used for temporary relief of pain associated with sore and aching muscles in the shoulder, waist, back, arm, and leg, due to strain from exercise or normal household and work activities.

6. Summary of Substantial Equivalence

The following table summarizes the comparison between the subject device and predicate devices, indicating the technical characteristics of the subject device are substantially equivalent to those of the predicate devices.

Parameter	**Subject Device**	**Subject Device**	**Predicate Device**	**Predicate Device**
510(k) Number	K141260	K141260	K131921	K131290
Device Name/Model	Electronic Pulse Stimulator/PL-029BL	Electronic Pulse Stimulator/PL-029K	Electronic Pulse Stimulator/PL-029	IQ Technologies
Maximum output voltage (Volts +/- 20%) at 500Ω	Mode 1: 41.6 Mode 2: 66.4 Mode 3: 60.8 Mode 4: 35.2 Mode 5: 32.8 Mode 6: This mode cycles the above modes Mode 7: 75.2 Mode 8: 24.0	Mode 1: 46.0 Mode 2: 59.6 Mode 3: 49.2 Mode 4: 64.8 Mode 5: 37.2 Mode 6: This mode cycles the above modes Mode 7: 71.2 Mode 8: 64.0	49.6	Mode 1: 42 Mode 2: 63.2 Mode 3: 64 Mode 4: 34.4 Mode 5: 32 Mode 6: This mode cycles the above modes
Maximum output voltage (Volts +/- 20%) at 2KΩ	Mode 1: 80.0 Mode 2: 100 Mode 3: 83.2 Mode 4: 70.4 Mode 5: 67.2 Mode 6: This mode cycles the above modes Mode 7: 121 Mode 8: 46.4	Mode 1: 86.4 Mode 2: 111 Mode 3: 80 Mode 4: 90.4 Mode 5: 64.8 Mode 6: This mode cycles the above modes Mode 7: 122 Mode 8: 89.6	99.2	Mode 1: 80.8 Mode 2: 94.4 Mode 3: 87.2 Mode 4: 68 Mode 5: 64 Mode 6: This mode cycles the above modes
Maximum output voltage (Volts +/- 20%) at 10kΩ	Mode 1: 125 Mode 2: 128 Mode 3: 84.8 Mode 4: 123 Mode 5: 116 Mode 6: This mode cycles the above modes Mode 7: 134 Mode 8: 85.6	Mode 1: 116 Mode 2: 146 Mode 3: 138 Mode 4: 106 Mode 5: 111 Mode 6: This mode cycles the above modes Mode 7: 136 Mode 8: 96.8	114	Mode 1: 129 Mode 2: 129 Mode 3: 96.8 Mode 4: 128 Mode 5: 119 Mode 6: This mode cycles the above modes
Maximum output current (mA +/- 20%) at 500Ω	Mode 1: 83.2 Mode 2: 132.8 Mode 3: 121.6 Mode 4: 70.4 Mode 5: 65.6 Mode 6: This mode cycles the above	Mode 1: 92.0 Mode 2: 119.2 Mode 3: 98.4 Mode 4: 129.6 Mode 5: 74.4 Mode 6: This mode cycles the above	18	Mode 1: 84 Mode 2: 126.4 Mode 3: 128 Mode 4: 68.8 Mode 5: 64 Mode 6: This mode cycles the

	modes Mode 7: 150.4 Mode 8: 48.0	modes Mode 7: 142.4 Mode 8: 128.0		above modes
Maximum output current (mA +/- 20%) at 2KΩ	Mode 1: 40.0 Mode 2: 50 Mode 3: 41.6 Mode 4: 35.2 Mode 5: 33.6 Mode 6: This mode cycles the above modes Mode 7: 60.5 Mode 8: 23.2	Mode 1: 43.2 Mode 2: 55.5 Mode 3: 40 Mode 4: 45.2 Mode 5: 32.4 Mode 6: This mode cycles the above modes Mode 7: 61 Mode 8: 44.8	3.2	Mode 1: 40.4 Mode 2: 47.2 Mode 3: 43.6 Mode 4: 34 Mode 5: 32 Mode 6: This mode cycles the above modes
Maximum output current (mA +/- 20%) at 10KΩ	Mode 1: 12.5 Mode 2: 12.8 Mode 3: 8.5 Mode 4: 12.3 Mode 5: 11.6 Mode 6: This mode cycles the above modes Mode 7: 13.4 Mode 8: 8.6	Mode 1: 11.6 Mode 2: 14.6 Mode 3: 13.8 Mode 4: 10.6 Mode 5: 11.1 Mode 6: This mode cycles the above modes Mode 7: 13.6 Mode 8: 9.7	0.6	Mode 1: 12.9 Mode 2: 12.9 Mode 3: 9.7 Mode 4: 12.8 Mode 5: 11.9 Mode 6: This mode cycles the above modes
Pulse Width (μSec)	100	50~100	50~140	100
Pulse period (mSec)	6.1~824	12~832	40	10~840
Frequency (Hz)	Mode 1: 69.4 Mode 2: 12.8~53.2 Mode 3: 1.2 Mode 4: 96.2 Mode 5: 96.2 Mode 6: This mode cycles the above modes Mode 7: 19.2 Mode 8: 164.4	Mode 1: 54.3 Mode 2: 35.7 Mode 3: 62.5 Mode 4: 6.7 Mode 5: 83.3 Mode 6: This mode cycles the above modes Mode 7: 19.8 Mode 8: 1.2	86	Mode 1: 69.4 Mode 2: 12.3~54.3 Mode 3: 1.2 Mode 4: 100 Mode 5: 100 Mode 6: This mode cycles the above modes
Maximum Phase charge (μC) at 500Ω	Mode 1: 17.3 Mode 2: 24.4 Mode 3: 24.3 Mode 4: 14.6 Mode 5: 12.6 Mode 6: This mode cycles the above modes Mode 7: 31.3 Mode 8: 9.2	Mode 1: 19.9 Mode 2: 6.0 Mode 3: 4.9 Mode 4: 6.5 Mode 5: 3.7 Mode 6: This mode cycles the above modes Mode 7: 33.0 Mode 8: 25.6	23	Mode 1: 18.1 Mode 2: 27.3 Mode 3: 25.6 Mode 4: 14.9 Mode 5: 12.8 Mode 6: This mode cycles the above modes
Maximum current density (mA/cm^2) at	Mode 1: 3.33 Mode 2: 5.31	Mode 1: 5.75 Mode 2: 7.45	1.4	Mode 1: 3.36 Mode 2: 5.06

500Ω	Mode 3: 4.86 Mode 4: 2.82 Mode 5: 2.62 Mode 6: This mode cycles the above modes Mode 7: 6.02 Mode 8: 1.92	Mode 3: 6.15 Mode 4: 8.10 Mode 5: 4.65 Mode 6: This mode cycles the above modes Mode 7: 8.90 Mode 8: 8.00		Mode 3: 5.12 Mode 4: 2.75 Mode 5: 2.56 Mode 6: This mode cycles the above modes
Maximum average power density (mW/cm^2) at 500Ω	Mode 1: 2.00 Mode 2: 0.83~3.45 Mode 3: 0.07 Mode 4: 1.98 Mode 5: 1.59 Mode 6: This mode cycles the above modes Mode 7: 1.81 Mode 8: 1.45	Mode 1: 3.10 Mode 2: 0.79 Mode 3: 0.95 Mode 4: 0.18 Mode 5: 0.72 Mode 6: This mode cycles the above modes Mode 7: 2.91 Mode 8: 0.12	0.23	Mode 1: 2.11 Mode 2: 0.85~3.75 Mode 3: 0.08 Mode 4: 2.05 Mode 5: 1.64 Mode 6: This mode cycles the above modes

7. Substantial Equivalence

The operational principle of the above predicate device is to generate small pulses of electrical current and deliver the pulses to the user's skin through adhesive electrode pads such that the underlying nerves are activated and the pain associated with sore and aching muscles is temporarily relieved.

Identically, the subject device generates small pulses of electrical current and delivers the pulses to the user's skin through adhesive electrode pads such that the underlying nerves are activated and the pain associated with sore and aching muscles is temporarily relieved.

The comparison between the subject device and predicate devices demonstrates the technical characteristics, specifications, and intended use of the subject device are substantially equivalent to those of the predicate devices.

The differences, such the output voltage and current, between the subject device and the predicate devices are insignificant in terms of safety or effectiveness. The verification and validation tests, such as IEC 60601-1, IEC 60601-1-2, and IEC 60601-2-10, further demonstrate these differences maintain the same safety and effectiveness as those of the 510(k) cleared predicate devices. In other words, these differences do not affect the intended use or alter the fundamental technology of the device. There are no new safety or effectiveness issues concerning the subject device, which offers substantially equivalent technical specifications, features, intended use, and effective results as the predicate devices.

Concerns of the safe and proper use of the biocompatible electrode pads have been fully addressed by making the use conscious of the proper placement of the electrode pads and appropriate operations of the device through details in the labeling.

8. Non-Clinical Tests Performed

The subject device does not conduct, nor rely upon, clinical tests to determine substantial equivalence. Non-clinical tests were performed on the subject device in order to validate the design and to assure

conformance with the following voluntary design standards in connection with medical device electrical safety, and electromagnetic compatibility.

(a) IEC 60601-1 "Medical Electrical Equipment - Part 1: General requirements for basic safety and essential performance".
(b) IEC 60601-1-2 "Medical Electrical Equipment - Part 1-2: General Requirements for Basic Safety and Essential Performance - Collateral standard: Electromagnetic Compatibility - Requirements and Tests".
(c) IEC 60601-2-10 “Medical electrical equipment – Part 2-10: Particular requirements for the basic safety and essential performance of nerve and muscle stimulators”.

In addition to the compliance of voluntary standards, the verification of software used in the subject device has been carried out according to the FDA Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices. The biocompatible electrodes, as the accessory of the subject device, also meet the requirement of safety.

9. Conclusion

The tests performed and the comparison of technical characteristics, specifications, and intended use demonstrate the subject device is substantially equivalent to the predicate device. Therefore, the subject device is as safe and effective as the foregoing identified OTC predicate devices that have been legally marketed in the United States.