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

April 14, 2017

JKH Health Co., Ltd.
% Bill Quanqin Dai
1142 S. Diamond Bar Blvd, #861
Diamond Bar, CA 91765

Re: K162517
Trade/Device Name: Electronic Pulse Stimulator
Regulation Number: 21 CFR 882.5890
Regulation Name: Transcutaneous Electrical Nerve Stimulator For Pain Relief
Regulatory Class: Class II
Product Code: NUH, NGX, NYN, IRT
Dated: March 14, 2017
Received: March 21, 2017

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" (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,

Carlos L. Pena -S

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)*
K162517

Device Name
Electronic Pulse Stimulator

Indications for Use *(Describe)*
TENS (Modes 1, 2, 4, 5, 6, 8)
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.

It is also intended for symptomatic relief and management of chronic, intractable pain and relief of pain associated with arthritis.

PMS (also called EMS, Modes 1, 3, 7)
To stimulate healthy muscles in order to improve and facilitate muscle performance. To be used for the improvement of muscle tone and firmness, and for strengthening muscles in the arms, abdomen, legs, and buttocks. Not intended for use in any therapy or for the treatment of any medical conditions or diseases.
It is also intended to temporarily increase local blood circulation in the healthy muscles of lower extremities.

Heating Mode
Temporary relief of minor aches and pains.

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

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: JKH Health Co., Ltd. (Previous name: Shenzhen Jingkehui Electronic Co., Ltd.)
Address: 4-5F, Building 12, Hengmingzhu Industrial Park, Xinqiao Tongfuyu Industrial Area, Shajing, Baoan, Shenzhen, China
Contact Person: Pu Jiang
Tel: +86-755-27926589
Fax: +86-755-29970323
Email: bill@JKHhealth.com
Date of Preparation: 08/30/2016

2. Subject Device

Trade/Device Name: Electronic Pulse Stimulator
Common Name: Transcutaneous Electrical Nerve Stimulation (TENS) unit and Powered Muscle Stimulation (PMS) unit
Regulation Medical Specialty: Neurology
Review Panel: Neurology
Product Code: NUH, NGX, NYN, IRT
Regulation Number: 21 CFR 882.5890
Device Class: II
Use: Over-The-Counter (OTC)

3. Predicate device

Predicate Device: Electronic Pulse Stimulator
510(k) Number: K153520
Clearance Date: May 05, 2016
Submitter: JKH Health Co., Ltd. (Previous name: Shenzhen Jingkehui Electronic Co., Ltd.)

Predicate Device: ezFit Digital Heating TENS
Clearance Date: July 16, 2007
510(k) Number: K070299
Submitter: ezFit Technology, Inc.

4. Description of Subject Device

Electronic Pulse Stimulator delivers electric pulses generated to the user's body areas such as the back neck and foot through the electrodes. The portable and compact device has multiple modes of different pulse frequencies, covering TENS and PMS that is also called Electrical Muscle Stimulation (EMS). It includes operating elements of ON/OFF button, intensity increase button, intensity decrease button, mode selection button, and/or timer selection button, and could be attached and detached to electrodes. In addition, the device may also provide heat/temperature. While used in the heating mode, the device is coupled with electronically controlled electrodes to provide automatic thermal heat to the skin with the maximum temperature of 43 ^{o}C.

The device could be easily operated through its buttons to manually realize its functions, such as

turning on/off, increasing/decreasing intensity, changing mode/timer, and providing heat/temperature if needed. The optional wireless control via a remote or Bluetooth APP could provide a secondary operation way to the user, who could be able to wirelessly realize the functions mentioned above.

The electrodes cleared include the electrode pads and electrode garments, which could be packaged separately and/or together with the subject device.

5. Indications for Use

TENS (Modes 1, 2, 4, 5, 6, 8)
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.

It is also intended for symptomatic relief and management of chronic, intractable pain and relief of pain associated with arthritis.

PMS (also called EMS, Modes 1, 3, 7)
To stimulate healthy muscles in order to improve and facilitate muscle performance. To be used for the improvement of muscle tone and firmness, and for strengthening muscles in the arms, abdomen, legs, and buttocks. Not intended for use in any therapy or for the treatment of any medical conditions or diseases.

It is also intended to temporarily increase local blood circulation in the healthy muscles of lower extremities.

Heating Mode
Temporary relief of minor aches and pains.

6. Summary of Substantial Equivalence

The following comparison Table 1 summarizes the comparison between the subject device and predicate device, indicating the intended use and technical characteristics of the subject device are substantially equivalent to those of the predicate device.

Table 1. Device comparison

	Subject Device	**Subject Device**	**Predicate Device**	**Predicate Device**
510(k) Number	K162517	K162517	K153520	K070299
Submitter/Manufacturer	JKH Health Co., Ltd.	JKH Health Co., Ltd.	JKH Health Co., Ltd.	ezFit Technology, Inc.
Device Name/Model	PL-029K12	PL-029K13	PL-029K6	ezFit Digital Heating TENS
Intended Use	TENS Mode 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. It is also intended for symptomatic relief and management of chronic, intractable pain and relief of pain associated with arthritis.	TENS Mode 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. It is also intended for symptomatic relief and management of chronic, intractable pain and relief of pain associated with arthritis.	TENS 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. It is also intended for symptomatic relief and management of chronic, intractable pain and relief of pain associated with arthritis.	For Transcutaneous Electrical Nerve Stimulation, ezFit Digital Heating TENS (Model No.: HR-661/ UC-101) is intended for Symptomatic relief and management of chronic intractable pain. For powered heating therapy, ezFit Digital Heating TENS (Model No.: HR-661/UC-101) is intended for

	PMS Mode To stimulate healthy muscles in order to improve and facilitate muscle performance. To be used for the improvement of muscle tone and firmness, and for strengthening muscles in the arms, abdomen, legs, and buttocks. Not intended for use in any therapy or for the treatment of any medical conditions or diseases. It is also intended to temporarily increase local blood circulation in the healthy muscles of lower extremities.	PMS Mode To stimulate healthy muscles in order to improve and facilitate muscle performance. To be used for the improvement of muscle tone and firmness, and for strengthening muscles in the arms, abdomen, legs, and buttocks. Not intended for use in any therapy or for the treatment of any medical conditions or diseases. It is also intended to temporarily increase local blood circulation in the healthy muscles of lower extremities. Heating Mode Temporary relief of minor aches and pains	PMS To stimulate healthy muscles in order to improve and facilitate muscle performance. To be used for the improvement of muscle tone and firmness, and for strengthening muscles in the arms, abdomen, legs, and buttocks. Not intended for use in any therapy or for the treatment of any medical conditions or diseases. It is also intended to temporarily increase local blood circulation in the healthy muscles of lower extremities.	Temporary relief of minor aches and pains and muscle spasms
Prescription or OTC	OTC	OTC	OTC	Prescription
Power Source(s)	Rechargeable battery	Rechargeable battery	Rechargeable battery	Rechargeable battery
Functions and design	Electrical stimulation	Electrical stimulation and heat	Electrical stimulation	Electrical stimulation and heat
Heating Setting	N/A	Low and high	N/A	Adjustable (36-42 ^{o}C)
Maximum temperature setting	N/A	43 ^{o}C	N/A	42 ^{o}C
Maximum output voltage (Volts +/- 20%) at 500Ω	Mode 1: This mode cycles the following modes Mode 2: 36.4 Mode 3: 47.6 Mode 4: 57.6 Mode 5: 29.6 Mode 6: 29.6 Mode 7: 40.8 Mode 8: 24.0	Mode 1: This mode cycles the following modes Mode 2: 31.2 Mode 3: 46.0 Mode 4: 42.0 Mode 5: 27.6 Mode 6: 27.6 Mode 7: 40.8 Mode 8: 23.2	Mode 1: This mode cycles the following modes Mode 2: 39.2 Mode 3: 64 Mode 4: 56.8 Mode 5: 33.2 Mode 6: 31.6	Undisclosed
Maximum output voltage (Volts +/- 20%) at 2KΩ	Mode 1: This mode cycles the following modes Mode 2: 80.8 Mode 3: 96.0 Mode 4: 93.6 Mode 5: 66.4 Mode 6: 66.4 Mode 7: 86.4 Mode 8: 53.6	Mode 1: This mode cycles the following modes Mode 2: 68.0 Mode 3: 90.4 Mode 4: 68.8 Mode 5: 60.0 Mode 6: 60.0 Mode 7: 84.0 Mode 8: 50.4	Mode 1: This mode cycles the following modes Mode 2: 82.4 Mode 3: 84 Mode 4: 79.2 Mode 5: 70.4 Mode 6: 67.2	Undisclosed
Maximum output voltage (Volts +/- 20%) at 10kΩ	Mode 1: This mode cycles the following modes Mode 2: 134 Mode 3: 132 Mode 4: 108 Mode 5: 126 Mode 6: 126 Mode 7: 129 Mode 8: 105	Mode 1: This mode cycles the following modes Mode 2: 118 Mode 3: 124 Mode 4: 78.4 Mode 5: 115 Mode 6: 115 Mode 7: 124 Mode 8: 99.2	Mode 1: This mode cycles the following modes Mode 2: 129 Mode 3: 120 Mode 4: 84.8 Mode 5: 121 Mode 6: 124	Undisclosed
Maximum output current (mA +/- 20%) at 500Ω	Mode 1: This mode cycles the following modes Mode 2: 72.8 Mode 3: 95.2 Mode 4: 115.2 Mode 5: 59.2	Mode 1: This mode cycles the following modes Mode 2: 62.4 Mode 3: 92.0 Mode 4: 84.0 Mode 5: 55.2	Mode 1: This mode cycles the following modes Mode 2: 78.4 Mode 3: 128 Mode 4: 113.6 Mode 5: 64.4	Undisclosed

	Mode 6: 59.2 Mode 7: 81.6 Mode 8: 48.0	Mode 6: 55.2 Mode 7: 81.6 Mode 8: 46.4	Mode 6: 63.2	
Maximum output current (mA +/- 20%) at 2KΩ	Mode 1: This mode cycles the following modes Mode 2: 40.4 Mode 3: 48.0 Mode 4: 46.8 Mode 5: 33.2 Mode 6: 33.2 Mode 7: 43.2 Mode 8: 26.8	Mode 1: This mode cycles the following modes Mode 2: 34.0 Mode 3: 45.2 Mode 4: 34.4 Mode 5: 30.0 Mode 6: 30.0 Mode 7: 42.0 Mode 8: 25.2	Mode 1: This mode cycles the following modes Mode 2: 41.2 Mode 3: 42 Mode 4: 39.6 Mode 5: 35.2 Mode 6: 33.6	Undisclosed
Maximum output current (mA +/- 20%) at 10KΩ	Mode 1: This mode cycles the following modes Mode 2: 13.4 Mode 3: 13.2 Mode 4: 10.8 Mode 5: 12.6 Mode 6: 12.6 Mode 7: 12.9 Mode 8: 10.5	Mode 1: This mode cycles the following modes Mode 2: 11.8 Mode 3: 12.4 Mode 4: 7.84 Mode 5: 11.5 Mode 6: 11.5 Mode 7: 12.4 Mode 8: 9.92	Mode 1: This mode cycles the following modes Mode 2: 12.9 Mode 3: 12 Mode 4: 8.5 Mode 5: 12.1 Mode 6: 12.4	Undisclosed
Pulse period (mSec)	6.4~840	5.6~806	10~833	Undisclosed
Frequency (Hz)	Mode 1: This mode cycles the following modes Mode 2: 62.5 Mode 3: 12.8~54.3 Mode 4: 1.19 Mode 5: 104.1 Mode 6: 104.1 Mode 7: 19.8 Mode 8: 156.2	Mode 1: This mode cycles the following modes Mode 2: 73.5 Mode 3: 13.7~59.5 Mode 4: 1.24 Mode 5: 104.1 Mode 6: 104.1 Mode 7: 20.8 Mode 8: 178.5	Mode 1: This mode cycles the following modes Mode 2: 69.4 Mode 3: 13.0~52.1 Mode 4: 1.2 Mode 5: 96.2 Mode 6: 96.2	Undisclosed
Maximum Phase charge (μC) at 500Ω	Mode 1: This mode cycles the following modes Mode 2: 14.6 Mode 3: 19.0 Mode 4: 23.0 Mode 5: 11.8 Mode 6: 11.8 Mode 7: 16.3 Mode 8: 9.6	Mode 1: This mode cycles the following modes Mode 2: 11.5 Mode 3: 16.9 Mode 4: 15.5 Mode 5: 10.2 Mode 6: 10.2 Mode 7: 15.0 Mode 8: 8.54	Mode 1: This mode cycles the following modes Mode 2: 15.1 Mode 3: 25.6 Mode 4: 18.2 Mode 5: 12.8 Mode 6: 10.1	Undisclosed
Maximum current density (mA/cm^2) at 500Ω	Mode 1:This mode cycles the following modes Mode 2: 2.02 Mode 3: 2.64 Mode 4: 3.20 Mode 5: 1.64 Mode 6: 1.64 Mode 7: 3.26 Mode 8: 1.92	Mode 1:This mode cycles the following modes Mode 2: 2.23 Mode 3: 3.29 Mode 4: 3.00 Mode 5: 1.97 Mode 6: 1.97 Mode 7: 2.91 Mode 8: 1.66	Mode 1:This mode cycles the following modes Mode 2: 2.18 Mode 3: 3.56 Mode 4: 3.16 Mode 5: 1.84 Mode 6: 1.76	Undisclosed
Maximum average power density (mW/cm^2) at 500Ω	Mode 1: This mode cycles the following modes Mode 2: 0.92 Mode 3: 0.32~1.37 Mode 4: 0.04 Mode 5: 1.01 Mode 6: 1.01 Mode 7: 0.53 Mode 8: 1.44	Mode 1: This mode cycles the following modes Mode 2: 0.94 Mode 3: 0.38~1.65 Mode 4: 0.03 Mode 5: 1.04 Mode 6: 1.04 Mode 7: 0.46 Mode 8: 1.26	Mode 1: This mode cycles the following modes Mode 2: 1.14 Mode 3: 0.64~2.56 Mode 4: 0.03 Mode 5: 1.13 Mode 6: 0.85	Undisclosed

7. Substantial Equivalence

As shown in the above comparison Table 1, the six modes of the predicate PL-029K6 (K153520) are the first six preset modes in both of the subject devices PL-029K12 and PL-029K13. The seventh and eighth preset modes of PL-029K12 and PL-029K13 have the technical characteristics (such as

maximum output voltage, maximum output current, maximum current density, and maximum average power density) almost the same as the six modes of the predicate device. Also, the changes to the display on the subject device do not affect the safety or effectiveness. Accordingly, the subject devices PL-029K12 and PL-029K13 are substantially equivalent to the predicate device PL-029K6, and the same intended use of PL-029K6 as TENS and PMS could apply to PL-029K12 and PL-029K13.

In addition to the TENS and PMS modes, the subject device PL-029K13 also has a heating mode, and is compared to the predicate device that could deliver electrical stimulation and heat separately and simultaneously in K070299. Similar to the predicate device, the subject device is used for the electrical stimulation or heat; consult with your physician before using electrical stimulation and heat simultaneously. The subject device delivers heat through the same technology as the predicate device, and is viewed as substantially equivalent to the predicate device because of the exact same technology and substantially equivalent indications for use. The differences that exist between the subject and predicate devices are insignificant in the terms of safety or effectiveness.

Design and Technology – The basic design and technology of providing electrical stimulation and heat is the same or similar.
Performance and Specifications – The subject device has similar electrical stimulation and heat performance and specifications to the predicate device.
Indications – The indications are similar.
Prescriptive – The predicate K070299 is for prescription, while the remaining predicate and subject devices are for OTC.

As demonstrated, the differences between the subject and predicate devices 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, safety, and effectiveness as the predicate device.

The same electrode pads and garments cleared from the predicate K153520 could apply to the subject device. Also, other-shape electrode pads and garments with the same components, such as conductive shoes, socks, belts, wraps, , will not change the biocompatibility or safety. Some electrodes used have an additional heating layer inside, compared to the K153520 cleared electrode. This heating layer isolated inside the electrode could not be touched by the user and does not raise any biocompatibility issue. Concerns of the safe and proper use of the electrodes and other accessories have been fully addressed 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 electrode pads, electrode garments, and other accessories of the subject device also meet the requirement of safety.

The skin temperatures were measured at Mode 8 with the largest frequency of 160 Hz among the eight preset modes, the highest Intensity Level 20, and the highest Heat Level 2 for 60 min. The results showed the subject device reached the highest skin temperature of about 41 ^{o}C in 20 min, and then kept stable.

9. Conclusion

The tests performed and the comparison of technical characteristics 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 predicate device that has been legally marketed in the United States.