June 21, 2019

Jkh Usa, LLC
Bill Quanqin Dai, PhD
Manager
1142 S. Diamond Bar Blvd, #861
Diamond Bar, California 91765

Re: K191151
Trade/Device Name: JKH Stimulator Plus
Regulation Number: 21 CFR 882.5890
Regulation Name: Transcutaneous Electrical Nerve Stimulator For Pain Relief
Regulatory Class: Class II
Product Code: NUH, NGX, NYN, GZJ, IPF, IRT
Dated: May 14, 2019
Received: May 23, 2019

Dear Dr. Bill Quanqin 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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

for Vivek Pinto, PhD
Assistant Director, Acute Injury Devices Team
DHT5B: Division of Neuromodulation
and Rehabilitation Devices
OHT5: Office of Neurological
and Physical Medicine Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K191151

Device Name
JKH Stimulator Plus

Indications for Use *(Describe)*
Over-The-Counter Use:

TENS:
PL-029K5BL, PL-029K15, and PL-029T are 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.

PL-029K5BL, PL-029K15, and PL-029T are also intended for symptomatic relief and management of chronic, intractable pain and relief of pain associated with arthritis.

The device of PL-029K5BL and PL-029K15 may be used during sleep. The device of PL-029K5BL and PL-029K15 is labeled for use only with its own compatible electrodes.

PMS:
PL-029K5BL, PL-029K15, and PL-029T are used 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.

PL-029K5BL, PL-029K15, and PL-029T are also intended to temporarily increase local blood circulation in the healthy muscles of lower extremities.

Heating:
The device of PL-029T is intended for temporary relief of minor aches and pains.

Prescription Use:

TENS:
PL-029K5BL, PL-029K15, and PL-029T are intended for the following use:
- Symptomatic relief and management of chronic, intractable pain
- Adjunctive treatment for post-surgical and post-trauma acute pain
- Relief of pain associated with arthritis

PMS:
PL-029K5BL, PL-029K15, and PL-029T are intended for the following use:
- Temporary relaxation of muscle spasm
- Prevention or retardation of disuse atrophy
- Muscle re-education
- Maintaining or increasing range of motion
- Increase of local blood flow in the treatment area
- Prevention of post-surgical venous thrombosis through immediate stimulation of calf muscles

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."

K191151

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 USA, LLC
Mailing Address: 1142 S. Diamond Bar Blvd, #861, Diamond Bar, CA 91765
Contact Person: Dr. Bill Quanqin Dai
Tel: 909-929-9896
Email: Bill@jkhUSA.com
Date of Preparation: 04/26/2019

2. Subject Device

Trade/Device Name: JKH Stimulator Plus
Common Name: Transcutaneous Electrical Nerve Stimulation (TENS) unit, Powered Muscle Stimulation (PMS) unit, and heating for pain relief, blood circulation, and muscle performance
Regulation Medical Specialty: Neurology
Review Panel: Neurology
Product Code: NUH, NGX, NYN, GZJ, IPF, IRT
Regulation Number: 21 CFR 882.5890
Device Class: II
Use: Over-The-Counter (OTC) and Prescription

3. Predicate device

Trade Name: JKH Stimulator Plus
510(k) Number: K182203
Clearance Date: March 14, 2019
Submitter: JKH USA, LLC

4. Description of Subject Device

The subject device delivers electric pulses generated to the user's body areas such as the back neck and foot through the electrodes. The devices include operating elements, such as the ON/OFF button, intensity increase button, and intensity decrease button, and could be attached and detached to electrodes. The device has multiple program modes of different pulse frequencies, covering TENS and PMS that is also called Electrical Muscle Stimulation (EMS). 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 for temporary relief of minor aches and pains.

The device could be easily operated through its buttons to manually realize its functions, such as turning on/off and increasing/decreasing intensity, providing heat/temperature and displaying/burning calories 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 patches/pads and electrode garments, which could be packaged together with the 510(k)-cleared devices or packaged separately as the replacement electrodes for 510(k)-cleared devices. The exact percentage of ingredients used in the biocompatible

electrode patch/pad is withheld as the trade secret and may be disclosed as requested.

5. Indications for Use

Over-The-Counter Use:

TENS:
PL-029K5BL, PL-029K15, and PL-029T are 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.

PL-029K5BL, PL-029K15, and PL-029T are also intended for symptomatic relief and management of chronic, intractable pain and relief of pain associated with arthritis.

The device of PL-029K5BL and PL-029K15 may be used during sleep. The device of PL-029K5BL and PL-029K15 is labeled for use only with its own compatible electrodes.

PMS:
PL-029K5BL, PL-029K15, and PL-029T are used 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.

PL-029K5BL, PL-029K15, and PL-029T are also intended to temporarily increase local blood circulation in the healthy muscles of lower extremities.

Heating:
The device of PL-029T is intended for temporary relief of minor aches and pains.

Prescription Use:

TENS:
PL-029K5BL, PL-029K15, and PL-029T are intended for the following use:
- Symptomatic relief and management of chronic, intractable pain
- Adjunctive treatment for post-surgical and post-trauma acute pain
- Relief of pain associated with arthritis

PMS:
PL-029K5BL, PL-029K15, and PL-029T are intended for the following use:
- Temporary relaxation of muscle spasm
- Prevention or retardation of disuse atrophy
- Muscle re-education
- Maintaining or increasing range of motion
- Increase of local blood flow in the treatment area
- Prevention of post-surgical venous thrombosis through immediate stimulation of calf muscles

6. Summary of Substantial Equivalence
The following comparison Table 1 summarizes the comparison between the subject device and the predicate device, indicating the intended use and technical characteristics of the subject device are

substantially equivalent to those of the predicate device.

Table 1. Comparison between the subject device and the predicate device

Parameter & Predicate Device(s)	**Subject Device**	**Predicate Device**
510(k) Number	K191151	K182203
Submitter/Manufacturer	JKH USA, LLC	JKH USA, LLC
Device Name/Model	JKH Stimulator Plus, PL-029K5BL, PL-029K15, and PL-029T	JKH Stimulator Plus, PL-029K12 and PL-029K13
Intended Use	Over-The-Counter Use: TENS: PL-029K5BL, PL-029K15, and PL-029T are 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. PL-029K5BL, PL-029K15, and PL-029T are also intended for symptomatic relief and management of chronic, intractable pain and relief of pain associated with arthritis. The device of PL-029K5BL and PL-029K15 may be used during sleep. The device of PL-029K5BL and PL-029K15 is labeled for use only with its own compatible electrodes. PMS: PL-029K5BL, PL-029K15, and PL-029T are used 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. PL-029K5BL, PL-029K15, and PL-029T are also intended to temporarily increase local blood circulation in the healthy muscles of lower extremities. Heating: The device of PL-029T is intended for temporary relief of minor aches and pains. Prescription Use: TENS: PL-029K5BL, PL-029K15, and PL-029T are intended for the following use: - Symptomatic relief and management of chronic, intractable pain - Adjunctive treatment for post-surgical and post-trauma acute pain - Relief of pain associated with arthritis PMS: PL-029K5BL, PL-029K15, and PL-029T are	Over-The-Counter Use: TENS: PL-029K12 and PL-029K13 are 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. PL-029K12 and PL-029K13 are also intended for symptomatic relief and management of chronic, intractable pain and relief of pain associated with arthritis. The device of PL-029K12 may be used during sleep. The device of PL-029K12 is labeled for use only with its own compatible electrodes. PMS: PL-029K12 and PL-029K13 are used 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. PL-029K12 and PL-029K13 are also intended to temporarily increase local blood circulation in the healthy muscles of lower extremities. Heating: The device of PL-029K13 is intended for temporary relief of minor aches and pains. Prescription Use: PL-029K12 and PL-029K13 are intended for the following use: - Symptomatic relief and management of chronic, intractable pain - Adjunctive treatment for post-surgical and post-trauma acute pain - Relief of pain associated with arthritis - Temporary relaxation of muscle spasm - Prevention or retardation of disuse atrophy - Muscle re-education - Maintaining or increasing range of motion - Increase of local blood flow in the treatment area - Prevention of post-surgical venous thrombosis through immediate stimulation of calf muscles

		intended for the following use: - Temporary relaxation of muscle spasm - Prevention or retardation of disuse atrophy - Muscle re-education - Maintaining or increasing range of motion - Increase of local blood flow in the treatment area - Prevention of post-surgical venous thrombosis through immediate stimulation of calf muscles	
Prescription or OTC		OTC and Prescription	OTC and Prescription
Power Source(s)		Rechargeable or non-rechargeable battery	Rechargeable or non-rechargeable battery
- Method of Line Current Isolation		Battery Supply	Battery Supply
- Patient Leakage Current: Normal Condition (µA)		N/A	N/A
- Patient Leakage Current: Single Fault Condition (µA)		N/A	N/A
Average DC current through electrodes when device is on but no pulses are being applied (mA)		0	0
Number of Output Modes		PL-029K5BL: 6-8 PL-029K15: 1-4 PL-029T: 8	8
Number of Output		1-2	1
-Synchronous/Alternating?		N/A	N/A
-Method of Channel Isolation		N/A	N/A
Regulated Current or Regulated Voltage?		Voltage	Voltage
Software/Firmware/ Microprocessor Control?		Yes	Yes
Automatic Overload Trip?		No	No
Automatic No-Load Trip?		Yes	Yes
Automatic Shut Off?		Yes	Yes
User Override Control?		Yes	Yes
Indicator Display:	On/Off Status?	Yes	Yes
	Low Battery?	Yes	Yes
	Voltage/ Current Level?	Yes	Yes
Timer Range (minutes)		PL-029K5BL: 10-540 PL-029K15: 10-60 PL-029T: 10-60	PL-029K12: 10-540 PL-029K13: 10-60
Compliance with Voluntary Standards?		Yes	Yes
Compliance with 21 CFR 898?		Yes	Yes
Weight (g)		PL-029K5BL: 40 PL-029K15: 35 PL-029T: 70	PL-029K12: 25 PL-029K13: 105
Dimensions (mm) [L x W x D]		PL-029K5BL: 66x56x18 PL-029K15:70x62x16 PL-029T: 95x55x15	PL-029K12: 69.5x36.8x14 PL-029K13: 88.5x76.5x18.2
Housing Materials and Construction		Silicone & ABS	Silicone & ABS
Functions and design		Electrical stimulation and heat	Electrical stimulation and heat
Maximum skin temperature		43ºC	43ºC
Waveform		Biphasic	Biphasic
Shape		Rectangular	Rectangular

Maximum output voltage (Volts +/- 20%) at 500Ω		PL-029K5BL: 65 PL-029K15: 36 PL-029T: 46	PL-029K12: 57.6 PL-029K13: 46.0
Maximum output voltage (Volts +/- 20%) at 2KΩ		PL-029K5BL: 132 PL-029K15: 72 PL-029T: 92	PL-029K12: 96.0 PL-029K13: 90.4
Maximum output voltage (Volts +/- 20%) at 10kΩ		PL-029K5BL: 180 PL-029K15: 125 PL-029T: 136	PL-029K12: 134 PL-029K13: 124
Maximum output current (mA +/- 20%) at 500Ω		PL-029K5BL: 130 PL-029K15: 72 PL-029T: 92	PL-029K12: 115.2 PL-029K13: 92.0
Maximum output current (mA +/- 20%) at 2KΩ		PL-029K5BL: 66 PL-029K15: 36 PL-029T: 47	PL-029K12: 48.0 PL-029K13: 45.2
Maximum output current (mA +/- 20%) at 10KΩ		PL-029K5BL: 18 PL-029K15: 12.5 PL-029T: 13.6	PL-029K12: 13.4 PL-029K13: 12.4
Pulse Width (μSec)		PL-029K5BL: 50~500 PL-029K15: 100 PL-029T: 104	PL-029K12: 100 PL-029K13: 92
Pulse period (mSec)		PL-029K5BL: 2~1000 PL-029K15: 10~1000 PL-029T: 6~833	PL-029K12: 6.4~840 PL-029K13: 5.6~806
Frequency (Hz)		PL-029K5BL: 1~500 PL-029K15: 1~100 PL-029T: 1.2~167	PL-029K12: 1.2~156.2 PL-029K13: 1.2~178.5
Maximum Phase charge (μC) at 500Ω		PL-029K5BL: 78 PL-029K15: 14.5 PL-029T: 19.3	PL-029K12: 23.0 PL-029K13: 16.9
Maximum average current density (mA/cm^2) at 500Ω		PL-029K5BL: 1.86 PL-029K15: 0.35 PL-029T: 0.40	PL-029K12: 0.21 PL-029K13: 0.34
Maximum average power density (mW/cm^2) at 500Ω		PL-029K5BL: 28 PL-029K15: 1.68 PL-029T: 2.22	PL-029K12: 1.44 PL-029K13: 1.26
Burst Mode	(a) Pulse per burst	N/A	N/A
	(b) Burst per second	N/A	N/A
	(c) Burst-duration (sec)	N/A	N/A
	(d) Duty Cycle	N/A	N/A
ON time (sec)		1~20	3.4~20
OFF time (sec)		0~10	1~2.5
Additional features		N/A	N/A

7. Substantial Equivalence

The differences between the subject device in this submission and the predicate device in K182203 do not raise any new issues of safety or effectiveness, as discussed below.

Both the subject device and the predicate device have the technical specifications that are within the range of other FDA cleared transcutaneous electrical nerve stimulators. For example, the difference of maximum output voltage, maximum output current, maximum phase charge, maximum average current density, and maximum average power density is 7.4V (65V versus 57.6V at 500Ω), 14.8mA (130mA versus 115.2mA at 500Ω), 55μC (78μC versus 23μC at 500Ω), 1.52mA/cm^2 (1.86mA/cm^2 versus 0.34mA/cm^2 at 500Ω), and 26.56 mW/cm^2 (28mW/cm^2 versus 1.44mW/cm^2 at 500Ω), respectively, between the subject device and the predicate device. In addition, the output voltage, output current,

phase charge, average current density, and average power density are set and delivered at a one-by-one level by the user to a strong but comfortable sensation, so the output voltage, output current, phase charge, average current density, and average power density delivered are therapeutically effective with either device. Therefore, the differences of maximum output voltage, maximum output current, maximum phase charge, maximum average current density, and maximum average power density between the subject device and the predicate device does not raise new questions of safety or effectiveness.

The difference of frequencies between the subject device and the predicate device does not raise new types of safety or effectiveness questions because (i) both devices are using standard TENS stimulation frequencies, (ii) random frequency stimulation is within the standard practice for TENS devices and is used in the predicate device, and (iii) the effectiveness of TENS is not dependent on the use of modulated pulse trains such as those generated by the predicate device, and can be equally achieved through the random frequency stimulation as delivered by the subject device. Similarly, the same case could be seen in the predicate K182203: While the K182203-cleared device has a pulse width of 100 µSec, its predicate devices are with pulse widths that range from 70-300 µSec. Therefore, the difference of pulse width also does not raise new issues of safety or effectiveness.

In addition, the subject device PL-029T itself also has a heating mode, and is comparable to the predicate device PL-029K13 that could deliver electrical stimulation and heat separately and simultaneously in K182203. The subject device delivers heat through the substantially equivalent technology to the predicate device, and does not raise new concerns of safety or effectiveness.

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 to the predicate device.

8. Non-Clinical Tests Performed

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) ANSI AAMI ES60601-1 "Medical Electrical Equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601-1)".
(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".
(d) ISO 10993-5 "Biological evaluation of medical devices -- Part 5: Tests for In Vitro Cytotoxicity".
(e) ISO 10993-10 "Biological evaluation of medical devices - Part 10: Tests for Irritation and Skin Sensitization".

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 and garments cleared in the predicate K182203 and other biocompatible electrodes described in this submission could apply to the subject device, such as conductive patches/pads, shoes, belts, wraps, sleeves, socks, insoles, gloves, shirts, shorts, pants, and suits, and will not change the

safety or effectiveness. Concerns of the safe and proper use of the electrodes have been fully addressed through details in the Labeling.

9. Conclusion

The tests and comparison performed 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.