July 1, 2020

JKH Health Co., LTD
Pu Jiang
General Manager
4-5F, Building 12, Hengmingzhu Industral Park,
Xinqiao Tongfuyu Industrial Area
Shajing, Baoan
Shenzhen, Guangdong 518104
China

Re: K200561
Trade/Device Name: StimPlus Patch
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: May 12, 2020
Received: June 3, 2020

Dear Pu Jiang:

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:

Timothy Marjenin
Assistant Director
DHT5B: Division of Neuromodulation
and Physical Medicine Devices
OHT5: Office of Neurological
and Physical Medicine Devices
Office of Product Evaluation and Quality
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K200561

Device Name
StimPlus Patch

Indications for Use *(Describe)*

TENS:
PL-029K29, PL-029K30, and PL-029Q 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-029K29, PL-029K30, and PL-029Q are also intended for symptomatic relief and management of chronic, intractable pain and relief of pain associated with arthritis.

PMS:
PL-029K29, PL-029K30, and PL-029Q 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-029K29, PL-029K30, and PL-029Q are also intended to temporarily increase local blood circulation in the healthy muscles of lower extremities.

Heating:
PL-029K30 and PL-029Q is intended for 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: 02/28/2020

2. Subject Device

Trade/Device Name: StimPlus Patch
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, 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: K162517
Clearance Date: April 14, 2017
Submitter: JKH Health Co., Ltd.

Predicate Device: Electronic Pulse Stimulator
510(k) Number: K141260
Clearance Date: September 17, 2014
Submitter: Shenzhen Jingkehui Electronic Co., Ltd.

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 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/light 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 (such as lidocaine, menthol, and/or cannabidiol) used in the biocompatible electrodes is withheld as the trade secret and may be disclosed as requested.

5. Indications for Use

Over-The-Counter Use:

TENS:
PL-029K29, PL-029K30, and PL-029Q 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-029K29, PL-029K30, and PL-029Q are also intended for symptomatic relief and management of chronic, intractable pain and relief of pain associated with arthritis.

PMS:
PL-029K29, PL-029K30, and PL-029Q 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-029K29, PL-029K30, and PL-029Q are also intended to temporarily increase local blood circulation in the healthy muscles of lower extremities.

Heating:
PL-029K30 and PL-029Q is intended for 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 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**	**Primary Predicate Device**	**Predicate Device**	**Equivalence**
510(k) Number	K200561	K162517	K141260	N/A
Submitter/Manufacturer	JKH Health Co., Ltd. (Previous name: Shenzhen Jingkehui Electronic Co., Ltd.)	JKH Health Co., Ltd.	Shenzhen Jingkehui Electronic Co., Ltd.	Identical
Device Name/Model	PL-029K29, PL-029K30, and PL-029Q	PL-029K12 and PL-029K13	PL-029K	N/A

Intended Use	TENS: PL-029K29, PL-029K30, and PL-029Q 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-029K29, PL-029K30, and PL-029Q are also intended for symptomatic relief and management of chronic, intractable pain and relief of pain associated with arthritis. PMS: PL-029K29, PL-029K30, and PL-029Q 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-029K29, PL-029K30, and PL-029Q are also intended to temporarily increase local blood circulation in the healthy muscles of lower extremities. Heating: PL-029K30 and PL-029Q is intended for temporary relief of minor aches and pains.	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. 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.	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.	Identical
Prescription or OTC	OTC	OTC	OTC	Identical
Power Source(s)	Rechargeable or non-rechargeable battery	Rechargeable battery	Non-rechargeable battery	Identical
- Method of Line Current Isolation	Battery Supply	Battery Supply	Battery Supply	Identical
- Patient Leakage Current: Normal Condition (μA)	2.0	2.0	2.0	Identical
- Patient Leakage Current: Single Fault Condition (μA)	<10.0	<10.0	<10.0	Identical
Average DC current through electrodes when device is on but no pulses are being applied (mA)	0	0	0	Identical

Number of Output Modes		PL-029K29: 1-8 PL-029K30: 1-8 PL-029Q: 1-8	8	8	The program modes of the subject device are from those of the predicate device.
Number of Output		1-2	1	1	Identical
-Synchronous/Alternating?		PL-029K29: Synchronous PL-029K30: Synchronous PL-029Q: Synchronous	Synchronous	Synchronous	Identical
-Method of Channel Isolation		1	1	1	Identical
Regulated Current or Regulated Voltage?		Voltage	Voltage	Voltage	Identical
Software/Firmware/ Microprocessor Control?		Yes	Yes	Yes	Identical
Automatic Overload Trip?		No	No	No	Identical
Automatic No-Load Trip?		Yes	Yes	No	Identical
Automatic Shut Off?		Yes	Yes	Yes	Identical
User Override Control?		Yes	Yes	Yes	Identical
Indicator Display:	On/Off	Yes	Yes	Yes	Identical
	Low Battery?	Yes	Yes	No	Identical
	Voltage/ Current Level?	No	No	No	Identical
Timer Range (minutes)		PL-029K29: 10~60 PL-029K30: 10~60 PL-029Q: 10~60	PL-029K12: 10~540 PL-029K13: 10~540	15~60	Identical
Compliance with Voluntary Standards?		Yes	Yes	Yes	Identical
Compliance with 21 CFR 898?		Yes	Yes	Yes	Identical
Dimensions (mm) [L x W x D]		PL-029K29: 150x80x12 PL-029K30: 80x55x20 PL-029Q: 148x81x29	PL-029K12: 69.5x36.8x14 PL-029K13: 88.5x76.5x18.2	117x71x11	The difference of dimension will not affect the safety or effectiveness.
Housing Materials and Construction		Silicone & ABS	Silicone & ABS	Silicone	Identical
Functions and design		PL-029K29: Electrical stimulation PL-029K30: Electrical stimulation and heat PL-029Q: Electrical stimulation and heat	PL-029K12: Electrical stimulation PL-029K13: Electrical stimulation and heat	Electrical stimulation	Identical
Maximum skin temperature		PL-029K29: N/A PL-029K30: 43ºC PL-029Q: 43ºC	PL-029K12: N/A PL-029K13: 43ºC	N/A	Identical
Waveform		Biphasic	Biphasic	Biphasic	Identical
Shape		Rectangular	Rectangular	Rectangular	Identical
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	PL-029K12: 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	71.2	Identical or similar

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	PL-029K12: 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	122	Identical or similar
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	PL-029K12: 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	146	Identical or similar
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 6: 59.2 Mode 7: 81.6 Mode 8: 48.0	PL-029K12: 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 6: 59.2 Mode 7: 81.6 Mode 8: 48.0	142.4	Identical or similar
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	PL-029K12: 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	61	Identical or similar
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	PL-029K12: 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	14.6	Identical or similar
Pulse Width (µSec)	100	100	50~100	Identical or similar
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	PL-029K12: 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	1.2~83.3	Identical or similar
Maximum Phase charge (µC) at 500Ω	Mode 1: This mode cycles the following modes Mode 2: 14.6	PL-029K12: Mode 1: This mode cycles the following modes	33	Identical or similar

		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 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		
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	PL-029K12: 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	8.9	Identical or similar
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	PL-029K12: 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	3.1	Identical or similar
Burst Mode	(a) Pulse per burst	N/A	N/A	N/A	Identical
	(b) Burst per second	N/A	N/A	N/A	Identical
	(c) Burst-duration (sec)	N/A	N/A	N/A	Identical
	(d) Duty Cycle	N/A	N/A	N/A	Identical
ON time (sec)		3.4~20	3.4~20	N/A	Identical
OFF time (sec)		1~2.5	1~2.5	N/A	Identical
Additional features		N/A	N/A	N/A	Identical

7. Substantial Equivalence

As shown in the above table, the subject device and predicate device are identical or similar. The differences between the subject device in this submission and the predicate device in K162517 and K141260 do not raise any new issues of safety or effectiveness, as discussed below.

The program modes of the subject device are from those of the predicate device. Both the subject device and the predicate device have the substantially equivalent technical specifications that are within the range of FDA cleared transcutaneous electrical nerve stimulators. In addition, the output voltage, output current, phase charge, 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, 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 current density, and maximum average power density between the subject device and the predicate device does not raise new questions of safety or effectiveness.

As demonstrated, the ornamental 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.

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.