September 21, 2019

JKH USA, LLC
Bill Dai
Manager
1142 S. Diamond Bar Blvd, #861
Diamond Bar, California 91765

Re: K182671
Trade/Device Name: Medi-Direct TENS Pen
Regulation Number: 21 CFR 882.5890
Regulation Name: Transcutaneous Electrical Nerve Stimulator For Pain Relief
Regulatory Class: Class II
Product Code: NUH
Dated: June 6, 2019
Received: August 23, 2019

Dear Bill 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,

Pamela Scott
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)*
K182671

Device Name
Medi-Direct TENS Pen

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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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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 USA, LLC
Mailing Address: 1142 S. Diamond Bar Blvd, #861, Diamond Bar, CA 91765
Contact Person: Bill Quanqin Dai
Tel: 909-929-9896
Email: Bill@jkhUSA.com
Date of Preparation: 06/29/2018

2. Subject Device

Trade/Device Name: Medi-Direct TENS Pen
Common Name: Transcutaneous Electrical Nerve Stimulation (TENS) unit
Regulation Medical Specialty: Neurology
Review Panel: Neurology
Product Code: NUH
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, 2014
Submitter: Shenzhen Jingkehui Electronic Co., Ltd.

Predicate Device: Dolphin Neurostim OTC
510(k) Number: K133789
Clearance Date: March 4, 2015
Submitter: Acumed Medical, Ltd.

4. Description of Subject Device

The subject device is a hand-held and battery-powered unit of TENS. It combines the electrical characteristics of TENS with the point stimulation delivered through the electrodes of a metal contact tip and a metal grounding contact on the device. The device has only one TENS mode of the low frequency (2 Hz), and only one button (Power Button). When the Power Button is held down, the device will turn on and deliver the fixed stimulation output to the user's body skin; when the Power Button is released, the device will turn off and the stimulation output will stop. Therefore, the device is very simple and easy to use.

The device is designed to generate small pulses of electrical current and delivers the pulses to the user's

skin through the metal contact tip such that the underlying nerves and/or muscles are activated for pain relief.

5. Indications for Use

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 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**	**Predicate Device**	**Predicate Device**
510(k) Number	K182671	K162517	K141260	K133789
Submitter/Manufacturer	JKH USA, LLC	JKH Health Co., Ltd.	Shenzhen Jingkehui Electronic Co., Ltd.	Acumed Medical, Ltd.
Device Name/Model	Medi-Direct TENS Pen	PL-029K12	PL-029K	Dolphin Neurostim OTC
Intended Use	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.	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.	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.	The Dolphin Neurostim™ OT C is indicated for temporary relief of pain associated with sore and aching muscles in the back, arms, and legs due to strain from exercise or normal household and work activities.
Prescription or OTC	OTC	OTC	OTC	OTC
Power Source(s)	Battery	Rechargeable battery	Battery	Battery
- Method of Line Current Isolation	Battery Supply	Battery Supply	Battery Supply	Battery Supply
- Patient Leakage Current: Normal Condition (µA)	N/A	N/A	N/A	N/A
- Patient Leakage Current: Single Fault Condition (µA)	N/A	N/A	N/A	N/A
Average DC current through electrodes when device is on but no pulses are being applied (mA)	0	0	0	0
Number of Output	1	1	1	1
-Synchronous/Alternating?	N/A	N/A	N/A	N/A
-Method of Channel Isolation	N/A	N/A	N/A	N/A

Regulated Current or Regulated Voltage?		Voltage	Voltage	Voltage	Voltage
Software/Firmware/ Microprocessor Control?		Yes	Yes	Yes	Yes
Automatic Overload Trip?		No	No	No	No
Automatic No-Load Trip?		No	Yes	No	No
Automatic Shut Off?		No	Yes	Yes	No
User Override Control?		Yes	Yes	Yes	Yes
Indicator Display:	On/Off Status?	No	Yes	Yes	Yes
	Low Battery?	No	Yes	No	Yes
	Voltage/Current Level?	No	Yes	No	No
Timer Range (minutes)		No	10~540	15~60	No
Compliance with Voluntary Standards?		Yes	Yes	Yes	Yes
Compliance with 21 CFR 898?		Yes	Yes	Yes	Yes
Housing Materials and Construction		ABS plastic & metal	ABS, metal, & Silicone	ABS & Silicone	ABS plastic & metal
Waveform		Monophasic	Biphasic	Monophasic	Monophasic & Biphasic
Shape		Rectangular	Rectangular	Rectangular	Rectangular
Maximum output voltage (Volts +/- 20%) at 500Ω		7.1	24~57.6	37.2~71.2	1
Maximum output voltage (Volts +/- 20%) at 2KΩ		27.6	53.6~96	64.8~122	3
Maximum output voltage (Volts +/- 20%) at 10kΩ		132	105~134	96.8~146	6.6
Maximum output current (mA +/- 20%) at 500Ω		14.2	48~115.2	74.4~142.4	2
Maximum output current (mA +/- 20%) at 2KΩ		13.8	26.8~48	32.4~61	1.5
Maximum output current (mA +/- 20%) at 10KΩ		13.2	10.5~13.4	9.7~14.6	0.7
Pulse duration (μSec)		106	100	50~100	213000
Frequency (Hz)		2	1.2~156	1.2~83.3	2.4-3.0
Maximum Phase charge (μC) at 500Ω		1.51	9.6~23	3.7~33	440
Maximum current density (mA/cm^2) at 500Ω		203	1.64~3.26	4.65~8.9	210
Maximum average power density (W/cm^2) at 500Ω		0.00031	0.00004~0.00144	0.00012~0.0031	0.116

As shown in the above comparison table, the maximum output voltage and current of the subject device are within those ranges of the predicate device; the pulse duration, period, frequency, maximum phase charge, and maximum current density of the subject device are smaller or almost the same as those of the predicate device; the maximum average power density of the subject device is within the range of the predicate device. Therefore, the differences do not affect safety or effectiveness.

As demonstrated above, the 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 to the predicate device.

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”.

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.