December 22, 2020

Sublimed
% Robert Packard
President
Medical Device Academy, Inc.
345 Lincoln Hill Road
Shrewsbury, Vermont 05738

Re: K202159
Trade/Device Name: actiTENS
Regulation Number: 21 CFR 882.5890
Regulation Name: Transcutaneous Electrical Nerve Stimulator For Pain Relief
Regulatory Class: Class II
Product Code: GZJ, NGX, NYN, IPF
Dated: July 30, 2020
Received: August 3, 2020

Dear Robert Packard:

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,

Amber Ballard, PhD
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K202159

Device Name
actiTENS

Indications for Use *(Describe)*
actiTENS is intended to be used as:
• Transcutaneous Electrical Nerve Stimulator (TENS), used for the following indications:
- Symptomatic relief and management of chronic, intractable pain
- Adjunctive treatment for post-surgical and post-trauma acute pain
- Temporary relief of pain associated with sore and aching muscles due to strain from exercise or normal household and work activities
- Relief of pain associated with arthritis
Programs P1, P2, P3, P4, P5, P6, P7, P8, P10, P11, P12 and P13 correspond to TENS mode.

• Electrical Muscle Stimulation (EMS), used for the following indications:
- Temporary relaxation of muscle spasms
- Prevent or retard disuse atrophy
- Increase of local blood flow in the treatment area
- Re-educate muscles
- Maintain or increase the range of motion
- Prevention of venous thrombosis of the calf muscles immediately after surgery
Program P9 corresponds to EMS mode.

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."

510(k) SUMMARY

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of 21 CFR §807.92:

I. SUBMITTER

SUBLIMED
137 rue de Mayoussard
Moirans, F-38430 France
Tel: +33(0)4-76-93-37-15

Contact Person: Corinne Bulteau
Date Prepared: December 22, 2020

II. DEVICE

Trade/Device Name:	actiTENS
Classification Name:	Transcutaneous Electrical Nerve Stimulator for Pain Relief
Regulation:	21 CFR § 882.5890
Regulatory Class:	Class II
Product Classification Code:	GZJ, NGX, NYN, IPF

III. PREDICATE DEVICE

Predicate Manufacturer:	JKH USA, LLC
Predicate Trade Name:	JKH Stimulator Plus
Predicate 510(k):	K182203

No reference devices were used in this submission.

IV. DEVICE DESCRIPTION

actiTENS is a transcutaneous electrical nerve stimulation (TENS) medical device designed to manage chronic pain in people ages 22 and older.

The compact design and flexible shape of the actiTENS electrical impulse generator allows to fix it for daily use directly to the body of the patient.

The impulse generator is delivered with a separate cradle which allows safely recharging its non-removable battery.

The actiTENS is compatible with a selection of disposable electrodes and compatible connector cables transmit the electrical stimulation impulses to the targeted nerves according to the selected therapy. The electrical stimulation waveforms are biphasic and asymmetric.

The actiTENS is controlled via a downloadable mobile app for iPhone which allows the comfortable and simple selection of the adequate stimulation program.

The actiTENS is intended to be used by the patient at home and also for therapeutic application by medical professionals.

It is available for prescription only.

V. INDICATIONS FOR USE

actiTENS is intended to be used as:
• Transcutaneous Electrical Nerve Stimulator (TENS), used for the following indications:
- Symptomatic relief and management of chronic, intractable pain
- Adjunctive treatment for post-surgical and post-trauma acute pain
- Temporary relief of pain associated with sore and aching muscles due to strain from exercise or normal household and work activities
- Relief of pain associated with arthritis
Programs P1, P2, P3, P4, P5, P6, P7, P8, P10, P11, P12 and P13 correspond to TENS mode.

• Electrical Muscle Stimulation (EMS), used for the following indications:
- Temporary relaxation of muscle spasms
- Prevent or retard disuse atrophy
- Increase of local blood flow in the treatment area
- Re-educate muscles
- Maintain or increase the range of motion
- Prevention of venous thrombosis of the calf muscles immediately after surgery
Program P9 corresponds to EMS mode.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVCE

The table below provides a comparison of indications for use and technological characteristics between the subject device and the predicate device in order to demonstrate substantial equivalence:

Comparison with Predicate Device:

Table 1: Comparison of actiTENS with JKH Stimulator Plus (K182203).

Feature	actiTENS	JKH Stimulator Plus – K182203	Comparison
Indications for Use	**actiTENS is intended to be used as:** • Transcutaneous Electrical Nerve Stimulator (TENS), used for the following indications: - Symptomatic relief and management of chronic, intractable pain - Adjunctive treatment for post-surgical and post-trauma acute pain - Temporary relief of pain associated with sore and aching muscles due to strain from exercise or normal household and work activities - Relief of pain associated with arthritis Programs P1, P2, P3, P4, P5, P6, P7, P8, P10, P11, P12 and P13 correspond to TENS mode. • Electrical Muscle Stimulation (EMS), used for the following indications:	Over-the-Counter Use: TENS (Modes 1, 2, 4, 6, 8): 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 work activities. PL-0219K12 and PL-029K13 are also intended for symptomatic relief an 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 (also called EMS, Modes 1, 3, 7): PL-029K12 and PL-	The subject device is not intended for OTC use, and the prescription use of the subject device is identical to the indications of the predicate model PL-029K12.

	- Temporary relaxation of muscle spasms - Prevent or retard disuse atrophy - Increase of local blood flow in the treatment area - Re-educate muscles - Maintain or increase the range of motion - Prevention of venous thrombosis of the calf muscles immediately after surgery Program P9 corresponds to EMS mode.	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, interactable 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	
Prescription or OTC	Prescription	OTC and Prescription	The subject device does not include OTC indications, but this eliminates the risks associated with OTC use.
Power Source(s)	Rechargeable	Rechargeable or non-rechargeable battery	The subject device is limited to use with the rechargeable lithium-ion battery, but this does not introduce any new risks.
Compliance with Voluntary Standards?	Yes	Yes	Same
Compliance With 21 CFR 898?	Yes	Yes	Same
Functions and design	Electrical stimulation	Electrical stimulation and heat	The subject device does not include the IRT product classification, and this eliminates the risks associated with that function.
Maximum skin temperature	N/A	43°C	The subject device does not include the IRT product classification and does not provide heat

Table 2: Comparison of actiTENS with JKH Stimulator Plus (K182203) with regards to TENS and EMS performance.

	actiTENS		JKH Stimulator Plus – K182203	Comparison
Maximum output voltage (Volts+/- 20%) at 500Ω	P1	30.2	PL- 029K12: 57.6 PL- 029K13: 46.0	Maximum output voltage of the subject device is in the range or below this of the predicate device. These technological differences between the subject and predicate device do not raise new safety and effectiveness questions
	P2	30.2		
	P3	30		
	P4	30.2		
	P5	30.2		
	P6	30		
	P7	30.2		
	P8	30.2		
	P9	29.5		
	P10	29.1		
	P11	29.3		
	P12	30.2		
	P13	30.2		
Maximum output voltage (Volts+/- 20%) at 2KΩ	P1	57.9	PL- 029K12: 96.0 PL- 029K13: 90.4	Maximum output voltage of the subject device is in the range or below this of the predicate device. These technological differences between the subject and predicate device do not raise new safety and effectiveness questions
	P2	57.9		
	P3	57.9		
	P4	57.9		
	P5	57.9		
	P6	57.9		
	P7	57.9		
	P8	57.9		
	P9	57.9		
	P10	57.9		
	P11	57.9		
	P12	57.9		
	P13	57.9		

Maximum output voltage (Volts+/- 20%) at 10KΩ	P1	N/A	PL- 029K12: 134 PL- 029K13: 124	The EIG monitors the impedance of each channel and stop any running program (or refuse to launch one) if the measured impedance is out of a specified range. This feature ensures a proper installation of the EIG, the cables and electrodes. If an electrode peels off, stopping the stimulation program quickly enough prevents the patient from feeling an electric discharge as the attached surface diminishes. The 10 kOhm is at the upper range and the EIG refused to launch a stimulation program, thus the measurement could not be performed
	P2			
	P3			
	P4			
	P5			
	P6			
	P7			
	P8			
	P9			
	P10			
	P11			
	P12			
	P13			
Maximum output current(mA+/- 20%) at 500Ω	P1	60.4	PL- 029K12: 115.2 PL- 029K13: 92.0	Maximum output current of the subject device is in the range or below this of the predicate device. These technological differences between the subject and predicate device do not raise new safety and effectiveness questions
	P2	60.4		
	P3	60		
	P4	60.4		
	P5	60.4		
	P6	60		
	P7	60.4		
	P8	60.4		
	P9	59		
	P10	58.2		
	P11	58.6		
	P12	60.4		
	P13	60.4		

Maximum output current(mA+/- 20%) at 2KΩ	P1	28.95	PL- 029K12: 48.0 PL- 029K13: 45.2	Maximum output current of the subject device is in the range or below this of the predicate device. These technological differences between the subject and predicate device do not raise new safety and effectiveness questions
	P2	28.95		
	P3	28.95		
	P4	28.95		
	P5	28.95		
	P6	28.95		
	P7	28.95		
	P8	28.95		
	P9	28.95		
	P10	28.95		
	P11	28.95		
	P12	28.95		
	P13	28.95		
Maximum output current(mA+/- 20%) at 10KΩ	P1	N/A	PL- 029K12: 13.4 PL- 029K13: 12.4	The EIG monitors the impedanceof each channel and stop any running program (or refuse to launch one) if the measured impedance is out of a specified range. This feature ensures a proper installation of the EIG, the cables and electrodes. If an electrode peels off, stopping the stimulation program quickly enough prevents the patient from feeling an electric discharge as the attached surface diminishes. The 10 kOhm is at the upper range and the EIG refused to launch a stimulation program, thus the measurement could not be performed
	P2			
	P3			
	P4			
	P5			
	P6			
	P7			
	P8			
	P9			
	P10			
	P11			
	P12			
	P13			

Pulse Width (µSec)	P1	197.5	PL- 029K12: 100 PL- 029K13: 92	These technological differences between the subject and predicate device do not raise new safety and effectiveness questions
	P2	147		
	P3	247.5		
	P4	197.5		
	P5	147.5		
	P6	200 or 147		
	P7	147.5		
	P8	modulated 100-200		
	P9	247.5		
	P10	147.5		
	P11	147.5		
	P12	57.5		
	P13	177.5		
Frequency (Hz)	P1	100	PL- 029K12: 156.2 PL- 029K13: 178.5	Frequencies of the subject device is in the range or below this of the predicate device. These technological differences between the subject and predicate device do not raise new safety and effectiveness questions
	P2	80		
	P3	2		
	P4	100		
	P5	100		
	P6	2 or 100		
	P7	100		
	P8	modulated 2-80		
	P9	50		
	P10	80		
	P11	80		
	P12	80		
	P13	10		

Maximum Phase charge (µC) at 500Ω	P1	11.9	PL- 029K12: 23.0 PL- 029K13: 16.9	The maximum phase charge is in the same range than the maximum phase charge of the predicate. Furthermore the highest value for the predicate is over than the intended device. This raises no new safety or effectiveness questions.
	P2	8.9		
	P3	14.9		
	P4	11.9		
	P5	8.9		
	P6	12.0		
	P7	8.9		
	P8	12.1		
	P9	14.6		
	P10	8.6		
	P11	8.6		
	P12	3.5		
	P13	10.7		
Maximum current density (mA/cm2) at 500Ω	P1	3.0	PL- 029K12: 3.26 PL- 029K13: 3.29	The maximum current density is in the same range than the maximum current density of the predicate. Furthermore the highest value for the predicate is over than the intended device. This raises no new safety or effectiveness questions.
	P2	3.0		
	P3	3.0		
	P4	3.0		
	P5	3.0		
	P6	3.0		
	P7	3.0		
	P8	1.7		
	P9	2.9		
	P10	2.9		
	P11	2.9		
	P12	3.0		
	P13	3.0		

Maximum average power density (mW/cm2) at 500Ω	P1	1.78	PL- 029K12: 1.44 PL- 029K13: 1.26	The maximum average power density is in the same range than the maximum average power density of the predicate. This raises no new safety or effectiveness questions.
	P2	1.06		
	P3	0.04		
	P4	1.78		
	P5	1.33		
	P6	1.78		
	P7	1.33		
	P8	1.44		
	P9	1.06		
	P10	0.99		
	P11	1.00		
	P12	0.41		
	P13	0.16		

The subject device and predicate device have equivalent indications for use and technological characteristics, with the exception that the subject device does not include over-the-counter-use (NUH product classification) and the subject device does not include heat as a modality (IRT product classification).

The predicate device claims two main functions: electrical stimulation and heat. The predicate device modalities work independently. Each modality has its own independent therapeutic effect. The subject device claims only the electrical stimulation effect as many devices cleared by the FDA, while the heating modality is exempt from 510(k) clearance. This technological difference between the subject and predicate device does not raise new safety and effectiveness questions. Concerning the maximum output voltage and the maximum output current, the subject device has been developed as a current generator with a maximum setpoint current of 60mA and has been limited by hardware to deliver output voltage of 60V. Thus it delivers a current of 60mA at 60V for 1KΩ. Above this charge the maximum output power will decrease. In each case the maximum output current and maximum output voltage are lower than the predicate. The subject device presents a maximum phase charge lower than the predicate device. In addition, the output voltage, phase charge, current density and average power density depends on the output current that is set by the user. The output current always starts at 0mA and is increased manually by the user with a 0.5mA increment, to achieve a strong but comfortable sensation, so the output voltage, output current, phase charge, current density and average power density delivered are therapeutically effective with the subject device. These technological differences between the subject and predicate device do not raise new safety and effectiveness questions.

Maximum output current and maximum output voltage at 10k Ω are not defined in the subject device because 10k Ω is the upper limit of the range of charge at which the subject device stops delivering currents. For the comfort and safety of the patient a limited range of charge has been defined in the subject device, to forbid electric current generation in case of short circuit or if an electrode is peeling off of the patient skin.

The difference of frequencies and pulse width between the subject device and predicate device does not raise new types of safety or effectiveness questions because the user chooses the frequency and the pulse width through different kind of programs using the mobile application and programs are using standard TENS stimulation frequencies and pulse width.
The maximum current density and maximum average power density are directly linked to the pads surfaces used with the device. The only recommended pads with the subject device are 4.5cmX4.5cm then the density is calculating using the voltage and current generator capacities. The subject device presents maximum current density and maximum average power density higher than the predicate but the maximum power density is less than 250 mW/cm² as required by the guidance for Powered Muscle Stimulator the maximum power density is also less than 250 mW/cm². These technological differences between the subject and predicate device do not raise new safety and effectiveness questions.

VII. PERFORMANCE DATA

The following performance data were provided in support of the substantial equivalence determination.

Sterilization
N/A - Device is non-sterile.

Shelf-life Testing
The electrodes are already cleared under K070807, and shelf-life testing for the electrodes is provided in that submission.

The battery is the only component that is likely to be impacted by time-dependent product degradation for the controller. The balance of the hardware is not expected to be negatively impacted by time-dependent product degradation.

Information regarding the battery shelf-life was provided by the battery manufacturer and the battery shelf-life is 12 months.

Biocompatibility Testing
Biocompatibility of the electrodes was provided in a previous 510(k) submission (K070807).

Electrical safety and electromagnetic compatibility (EMC)
The following electrical safety and EMC testing reports were provided:

- Electrical Safety Testing IEC 60601-1, plus national deviations to address the differences between IEC 60601-1:2005 and ANSI AAMI ES 60601-1:2005/(R)2012 and A1:2012
- EMC Testing IEC 60601-1-2
- Usability IEC 60601-1-6
- Home Use Environment IEC 60601-1-11
- Nerve and Muscle Stimulators IEC 60601-2-10

Software Verification and Validation Testing
Software verification and validation testing was provided in accordance with IEC 62304 and FDA guidance documents.

Benchtop Performance Testing
The following benchtop performance testing was provided:

- Transportation Testing ASTM D4169-16
- Lithium Battery UL 1642
- Usability IEC 62366-1
- Lithium Battery IEC 62133-2

Animal Performance Testing
Animal performance testing was not required to demonstrate safety and effectiveness of the

device.

Human Clinical Performance Testing

Clinical testing was not required to demonstrate the safety and effectiveness of the device.

VIII. CONCLUSIONS

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.