September 4, 2020

Self Doctor Care, LLC
Wei Wei
Manager
8811 Teel Pkwy Ste 100, Unit 6141
Frisco, Texas 75036

Re: K193655
Trade/Device Name: MSLS6QF TENS/PMS Device
Regulation Number: 21 CFR 882.5890
Regulation Name: Transcutaneous Electrical Nerve Stimulator For Pain Relief
Regulatory Class: Class II
Product Code: NUH, NGX
Dated: April 24, 2020
Received: June 9, 2020

Dear Wei Wei:

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
Acting 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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K193655

Device Name
MSLS6QF TENS/PMS Device

Indications for Use *(Describe)*
TENS (Transcutaneous Electric Nerve Stimulation):
To be used for temporary relief of pain associated with sore and aching muscles in the shoulder, waist, back, upper extremities (arm), and lower extremities (leg) due to strain from exercise or normal household work activities.
Mode 1,3,4,5,6

PMS (Powered Muscle Stimulation):
It is intended to be used to stimulate healthy muscles in order to improve and facilitate muscle performance.
Mode 2,6

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: Self Doctor Care, LLC
Address: 8811 Teel Pkwy Ste 100,Unit 6141, Frisco, TX 75036
Contact Person: Wei Wei
Tel: 516-289-8425
Email: massagelossage@gmail.com
Date of Preparation: 12/26/2019

2. Correspondent's Information

Correspondent: Self Doctor Care, LLC
Address: 8811 Teel Pkwy Ste 100, Unit 6141, Frisco, TX 75036
Contact Person: Wei Wei
Tel: 516-289-8425
Email: massagelossage@gmail.com

3. Subject Device

Device Name: MSLS6QF TENS/PMS Device
Common Name: Transcutaneous electrical nerve stimulator (TENS) and Powered MuscleStimulator(PMS)
Model: MSLS6QF
Classification Name: Stimulator, Nerve, Transcutaneous, Over-The-Counter (OTC)
Regulation Description: Transcutaneous electrical nerve stimulator for pain relief
Regulation Medical Specialty: Neurology
Review Panel: Neurology
Product Code: NUH, NGX
Regulation Number: 21 CFR 882.5890
Device Class: II
Use: Over-The-Counter

4. Predicate device

Predicate Device: TENS&PMS, IQ Technologies

510(k) Number: K131290
Use: Over-The-Counter
Submitter: IQ Technologies Inc.

5. Description of Subject Device

The subject device *MSLS6QF* is a Transcutaneous Electrical Nerve Stimulator (TENS) and Powered Muscle Stimulator (PMS), intended for the over-the-counter use to temporarily relieve pain and stimulate muscle in different body areas.
This double-channel subject device, which is compact, portable, effectively transfer programmed electrical pulses directly through the self-adhesive electrodes to the suggested area of the body where the electrodes are placed. It delivers a gentle electrical pulse through the connecting wires and electrode pads to the user's skin for pain relief and muscle stimulation.
The subject device has 6 operation modes,which can give certain electrical pulse through the 4 pcs of electrodes placed on the skin to help users to enjoy body stimulation. The subject device has the operating elements of ON/OFF Switch, Display screen, Mode Selection key and Intensity Modification keys. The LCD display screen can show selected mode, output intensity of the pulse, and time remaining of an application mode. The subject device could be easily operated through its toggle switch or buttons to manually realize its functions according to the need of users.
The subject device is equipped with accessories of the electrodes, lead wires, AC adapter and USB cable. The lead wire is used to connect the electrodes to the main unit; the USB cable is used to connect the AC adapter to the main unit when charging the built-in Li battery; the pads holders are used to storage the electrodes after therapy treatment for the convenience.
The self-adhesive electrodes are important accessories of the subject device, and are contact with the skin surface. It is consists of gel, carbon film, cloth backing ,and electrode connector. The electrode is complying with the biocompatibility standards ISO 10993-5 (Cytotoxicity) and ISO 10993-10 (Irritation and Sensitization).

6. Intended Use of Subject Device

TENS (Transcutaneous Electric Nerve Stimulation):
To be used for temporary relief of pain associated with sore and aching muscles in the shoulder, waist,back, upper extremities (arm), and lower extremities (leg) due to strain from exercise or normal household work activities.
Mode 1,3,4,5,6

PMS(Powered Muscle Stimulation):
It is intended to be used to stimulate healthy muscles in order to improve and facilitate

muscle performance.
Mode 2,6

7. Summary of Substantial Equivalence

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

	Subject Device	**Predicate Device**	Judgment
510(k) Number	K193655	K131290	/
Company Name	Self Doctor Care, LLC	IQ Technologies Inc.	/
Device Name	MSLS6QF	IQ Technologies	/
Operational Principle	Generate small pulses of electrical current and delivers the pulses to the user's skin through adhesive electrode pads such that the underlying nerves and/or muscles are activated	Generate small pulses of electrical current and delivers the pulses to the user's skin through adhesive electrode pads such that the underlying nerves and/or muscles are activated	SE
Intended Use	TENS (Transcutaneous Electric Nerve Stimulation): To be used for temporary relief of pain associated with sore and aching muscles in the shoulder, waist, back, upper extremities (arm), and lower extremities (leg) due to strain from exercise or normal household work activities. Mode 1,3,4,5,6 PMS (Powered Muscle Stimulation): It is intended to be used to stimulate healthy muscles in order to improve and facilitate muscle performance.	To be used for temporary relief of pain associated with sore and aching muscles in the shoulder, waist, back, upper extremities (arm), and lower extremities (leg) due to strain from exercise or normal household work activities. It is intended to be used to stimulate healthy muscles in order to improve and facilitate muscle performance.	SE

		Mode 2,6		
Prescription/over-the-counter use		OTC	OTC	SE
Power Source		DC 3.7V Lithium Battery	DC 3.7V Lithium Battery	SE
Method of Line Current Isolation		Type BF Applied Part	Type BF Applied Part	SE
Patient Leakage Current - Normal Condition (μA) - Single Fault Condition (μA)		 < 1 μA 6 μA	 Not publicly available	 Note 1
Number of output modes		6	6	SE
Regulated Current or Regulated Voltage		Voltage Control	Voltage Control	SE
Number of Output Channels		2	2	SE
Automatic Overload Trip		No	No	SE
Automatic No-Load Trip		No	No	SE
Automatic Shut Off		Yes	Yes	SE
User Override Control		Yes	Yes	SE
Indicator Display	On/Off Status?	Yes	Yes	SE
	Low Battery?	Yes	Yes	SE
	Voltage/Current Level?	No	No	SE
Timer Range (minutes)		10 ~ 60 minutes, 10 min/step	10 ~ 60 minutes, 10 min/step	SE
Weight(g)		40g	37g	Similar, Note 2
Size(mm)		80×41×16	80×42×13	
Housing Materials and Construction		ABS	ABS and Aluminum alloy	
Burst Mode a) Pulses per burst b) Bursts per second c) Burst duration (seconds) d) Duty Cycle [Line(b) x Line (c)]		N/A (no pulse train or burst)	N/A	
ON Time (seconds)		N/A	N/A	
OFF Time (seconds)		N/A	N/A	
Accessories intended for use with device		Self-adhesive Electrodes, Lead wires, Battery charger, USB cable	Self-adhesive Electrodes, Lead wires, Battery charger, USB	SE

		cable	
Waveform	Pulsed	Pulsed	SE
Shape	Rectangular	Rectangular	SE
Maximum output voltage (Volts +/- 20%) at 500Ω	Mode 1: 45.9 Mode 2: 61.6 Mode 3: 46.7 Mode 4: 39.0 Mode 5: 36.1 Mode 6: This mode cycles the above five modes	Mode 1: 42 Mode 2: 63.2 Mode 3: 64 Mode 4: 34.4 Mode 5: 32 Mode 6: This mode cycles the above five modes	Similar, Note 3
Maximum output voltage (Volts +/- 20%) at 2KΩ	Mode 1: 74.2 Mode 2: 87.4 Mode 3: 60.5 Mode 4: 65.1 Mode 5: 60.5 Mode 6: This mode cycles the above five modes	Mode 1: 80.8 Mode 2: 94.4 Mode 3: 87.2 Mode 4: 68 Mode 5: 64 Mode 6: This mode cycles the above five modes	
Maximum output voltage (Volts +/- 20%) at 10kΩ	Mode 1: 126.0 Mode 2: 128.0 Mode 3: 88.0 Mode 4: 124.7 Mode 5: 120.7 Mode 6: This mode cycles the above five modes	Mode 1: 129 Mode 2: 129 Mode 3: 96.8 Mode 4: 128 Mode 5: 119 Mode 6: This mode cycles the above five modes	
Maximum output current (mA +/- 20%) at 500Ω	Mode 1: 91.8 Mode 2: 123.2 Mode 3: 93.4 Mode 4: 78.0 Mode 5: 72.2 Mode 6: This mode cycles the above five modes	Mode 1: 84 Mode 2: 126.4 Mode 3: 128 Mode 4: 68.8 Mode 5: 64 Mode 6: This mode cycles the above five modes	

Maximum output current (mA +/- 20%) at 2KΩ	Mode 1: 37.1 Mode 2: 43.7 Mode 3: 30.3 Mode 4: 32.6 Mode 5: 30.3 Mode 6: This mode cycles the above five modes	Mode 1: 40.4 Mode 2: 47.2 Mode 3: 43.6 Mode 4: 34 Mode 5: 32 Mode 6: This mode cycles the above five modes	
Maximum output current (mA +/- 20%) at 10KΩ	Mode 1: 12.6 Mode 2: 12.8 Mode 3: 8.8 Mode 4: 12.5 Mode 5: 12.1 Mode 6: This mode cycles the above five modes	Mode 1: 12.9 Mode 2: 12.9 Mode 3: 9.7 Mode 4: 12.8 Mode 5: 11.9 Mode 6: This mode cycles the above five modes	
Frequency (Hz)	Mode 1: 68.7 Mode 2: 12.2~53.4 Mode 3: 1.2 Mode 4: 96.1 Mode 5: 96.1 Mode 6: This mode cycles the above five modes	Mode 1: 69.4 Mode 2: 12.3~54.3 Mode 3: 1.2 Mode 4: 100 Mode 5: 100 Mode 6: This mode cycles the above five modes	
Pulse period (mSec)	Mode 1: 14.6 Mode 2: 18.7~82.0 Mode 3: 840.0 Mode 4: 10.4 Mode 5: 10.4 Mode 6: This mode cycles the above five modes	10~840	SE
Pulse Width (µSec)	100	100	SE
Maximum Phase charge (µC) at 500Ω	17.42	16.8	Similar,

Maximum current density (mA/cm^2) at 500Ω	Mode 1: 3.67 Mode 2: 4.93 Mode 3: 3.74 Mode 4: 3.12 Mode 5: 2.89 Mode 6: This mode cycles the above five modes	Mode 1: 3.36 Mode 2: 5.06 Mode 3: 5.12 Mode 4: 2.75 Mode 5: 2.56 Mode 6: This mode cycles the above five modes	Note 4
Maximum average current density @500Ω(mA/cm^2)	Mode 1: 0.03556 Mode 2: 0.0085~0.03726 Mode 3: 0.00063 Mode 4: 0.04242 Mode 5: 0.03927 Mode 6: This mode cycles the above five modes	Not publicly available	Similar, Note 5
Maximum average power density (mW/cm^2) at 500Ω	Mode 1: 1.63 Mode 2: 0.52~2.30 Mode 3: 0.03 Mode 4: 1.65 Mode 5: 1.42 Mode 6: This mode cycles the above five modes	Mode 1: 2.11 Mode 2: 0.85~3.75 Mode 3: 0.08 Mode 4: 2.05 Mode 5: 1.64 Mode 6: This mode cycles the above five modes	
Maximum average current density @2KΩ(mA/cm^2)	Mode 1: 0.01437 Mode 2: 0.0030~0.0132 Mode 3: 0.00020 Mode 4: 0.01770 Mode 5: 0.01645 Mode 6: This mode cycles the above five modes	Not publicly available	
Maximum average power density (mW/cm^2) @2KΩ	Mode 1: 1.06643 Mode 2: 0.2634~1.1552 Mode 3: 0.01232 Mode 4: 1.15241 Mode 5: 0.99531 Mode 6: This mode cycles the above five modes	Not publicly available	

Maximum average current density @10KΩ(mA/cm^2)	Mode 1: 0.00488 Mode 2: 0.0009~0.0039 Mode 3: 0.00006 Mode 4: 0.00678 Mode 5: 0.00656 Mode 6: This mode cycles the above five modes	Not publicly available	
Maximum average power density (mW/cm^2) @10KΩ	Mode 1: 0.61503 Mode 2: 0.1130~0.4956 Mode 3: 0.00521 Mode 4: 0.84569 Mode 5: 0.79230 Mode 6: This mode cycles the above five modes	Not publicly available	
Compliance with Voluntary Standards	IEC 60601-1, IEC 60601-1-2, IEC 60601-2-10	IEC 60601-1, IEC 60601-1-2, IEC 60601-2-10	SE
Compliance with 21 CFR 898	Yes	Yes	SE

Comparison in details:

Note 1: The Predicate Device K131290 this information is Not publicly available. The subject device MSLS6QF which conformance to the IEC 60601-1:2012 passed the Leakage Current tests already. So the Subject Device will not raise new problem of safety and effectiveness in this issue.

Note 2: The weight, dimensions differences between the subject device and the predicate device are very small. These differences won't raise any safety or effectiveness issue. And the housing material, appearance of subject device MSLS6QF are a little different from predicate device K131290. Consider the same intended use, components, working principle, test standards, these differences are insignificant in the terms of safety or effectiveness.

Note 3: There are some differences on the maximum output voltage, maximum output current, pulse width, frequency between the subject device and predicate device. But the differences are very insignificant. So these differences don't raise any new safety and effectiveness issues.

Note 4: Maximum current density(mA/cm^2) @ 500Ω, differences between the subject device and predicate device are very insignificant. And this parameter max value does not exceed the safety limit. So it does not raise any new safety and effectiveness issues.

Note 5:Based on the calculation ,maximum average current density and maximum average power density, these parameters of the subject device MSLS6QF don't exceed the safety limit. And these parameters have passed IEC 60601-2-10 test codes. Although the predicate device K131290

only public Maximum average power density (mW/cm^2) at 500Ω, this is simulating worst case conditions and considering the load range the device is expected to encounter with normal use. The differences of Maximum average power density (mW/cm^2) @500Ω for the subject device and predicate device are very insignificant. Both of the maximum average power density data for the subject device and predicate device are much lower than the 250mW/cm^2. So these differences don't raise any new safety and effectiveness issues.

Comparison Conclusion
Although the technological characteristics are a little different between the subject device and the predicate device, they all comply with IEC 60601-1, IEC 60601-1-2, IEC 60601-2-10 requirement, FDA guidance requirement for Transcutaneous Electrical Nerve Stimulator for Pain Relief and FDA guidance requirement for Powered Muscle Stimulator for Muscle Conditioning.
So the differences of function specification will not raise any safety or effectiveness issue.

8.Substantial Equivalence

The operational principle of the predicate device *IQ Technologies* is to generate small pulses of electrical current and delivers the pulses to the user's skin through adhesive electrode pads such that the underlying nerves and/or muscles are activated. The subject device *MSLS6QF* indicates the same principle.
The comparison of the performance data and other aspects between the subject device and predicate device demonstrates the technical characteristics, specifications, and intended use of the subject device are substantially equivalent to those of the predicate device.
The electrical stimulation provided by the MSLS6QF device is substantially equivalent to that commonly employed by muscle stimulator and TENS devices that have been cleared for marketing without prescription labeling:i.e. for OTC sale. The pulses in the wave form combinations are restricted in amplitude and duration to values consistent
with the other device quote above.
The differences that exist between the devices are insignificant in the terms of safety or effectiveness.
The MSLS6QF device offers substantially equivalent technical specifications, features and effective results as the predicate device listed.
The technological characteristics, features, specifications, materials and intended uses of the MSLS6QF device are substantially equivalent to the quoted predicate device.

9.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 standards in connection with medical device electrical safety, and electromagnetic compatibility.
(a) IEC 60601-1:2012 Medical Electrical Equipment - Part 1: General requirements for basic safety and essential performance
(b) IEC 60601-1-2:2014 Medical Electrical Equipment - Part 1-2: General Requirements for Safety - Collateral standard: Electromagnetic Compatibility - Requirements and Tests
(c) IEC 60601-2-10:2016 Medical electrical equipment - Part 2-10: Particular requirements for the basic safety and essential performance of nerve and muscle stimulators
(d) ISO 10993-5:2009 Biological evaluation of medical devices — Part 5: Tests for in vitro cytotoxicity
(e) ISO 10993-10:2010 Biological evaluation of medical devices — Part 10: Tests for irritation and skin sensitization
(f) IEC 62133:2012 Secondary cells and batteries containing alkaline or other non-acid electrolytes – Safety requirements for portable sealed secondary cells, and for batteries made from them, for use in portable applications
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.

10. Conclusion

The tests performed and the comparison of technical characteristics, specifications, and intended use demonstrate the subject device MSLS6QF is substantially equivalent to the predicate device *IQ Technologies*. Therefore, the subject device is as safe and effective as the foregoing identified OTC predicate devices that have been legally marketed in the United States.