DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

April 29, 2017

Shenzhen Eapply Technology Co., Ltd
Lisa Huang
Business Manager
3rd Floor, 2nd Building, Hezhou New Industrial Area
Xixiang Town
Shenzhen City, 518000 CN

Re: K170145/S001
Trade/Device Name: Digital Tens Unit (Model: 1653195)
Regulation Number: 21 CFR 882.5890
Regulation Name: Transcutaneous Electrical Nerve Stimulator For Pain Relief
Regulatory Class: Class II
Product Code: NUH
Dated: March 31, 2017
Received: April 07, 2017

Dear Lisa Huang:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

William J. Heetderks -S

Digitally signed by William J. Heetderks -S
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, 0.9.2342.19200300.100.1.1=0010149848, cn=William J. Heetderks -S
Date: 2017.04.29 17:34:11 -04'00'

for Carlos L. Peña, PhD, MS
Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
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)*
/ K170145

Device Name
Digital TENS Unit (Model: 1653195)

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.

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510(k) Summary

"510(k) Summary" as required by section 807.92(c).

1. Submitter Information

- 510(k) Owner's Name: Shenzhen Eapply Technology Co., Ltd
- Establishment Registration Number: Applying
- Address: 3rd floor, 2nd building, Hezhou New Industrial Area, Xixiang Town, Shenzhen City, Guangdong Province, China
- Postal Code: 518000
- Tel: +86 755 3391 9819
- Fax: +86 755 6164 0964
- Contact Person: Lisa Huang
- Title: Business manager
- Tel: +86 755 3391 9819 ext.817
- Fax: +86 755 6164 0964
- Email: sales06@eapply.net

2. Subject Device Information

- Trade Name: Digital TENS Unit (Model: 1653195)
- Common Name: Transcutaneous electrical nerve stimulator
- Classification name: Transcutaneous electrical nerve stimulator for pain relief
- Review Panel: Neurology
- Product Code: NUH
- Regulation Class: II
- Regulation Number: 882.5890

3. Predicate Device Information

Sponsor	Shenzhen Jingkehui Electronic Co. LTD	Beijing Choice Electronic Technology Co., Ltd.	Tyece Ltd.	IQ Technologies Inc.
Device Name and Model	Electronic Pulse Stimulator	Electronic Pulse Stimulator, Model:MDTS100	Tyece OTC TENS Device, Model SEM44	IQ Technologies

510(k) Number	K141260	K160508	K150386	K131290
Product Code	NUH	NUH	NUH	NUH
Regulation Number	21 CFR 882.5890	21 CFR 882.5890	21 CFR 882.5890	21 CFR 882.5890
Regulation Class	II	II	II	II

2. Device Description

Digital TENS Unit is a Transcutaneous Electrical Nerve Stimulator (TENS), intended for the over-the-counter use to relieve pain in different body areas (neck, shoulders, back, waists, arms, and legs). At the same time, the proposed TENS device, which is compact, portable, and microprocessor-controlled, delivers a gentle electrical pulse through the Pad Lead Cords and Electrode Gel Pads to the uses' skin for pain relief. to the user's skin through the pad lead cords and electrode gel pads to the user's skin for pain relief. According to the need of users, the pulse intensity can be adjustable on the Controller's interface of the device.

5. Intended Use / 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. Test Summary

Digital TENS Unit has been evaluated the safety and performance as following:

- Biocompatibility test according to ISO 10993-5 and ISO 10993-10 standards
- Electromagnetic compatibility test according to IEC 60601-1-2 standard
- Electrical safety test according to IEC 60601-1, IEC 60601-2-10 and IEC 60601-1-11 standards
- Software verification and validation test according to the requirements of the FDA "Guidance for Pre Market Submissions and for Software Contained in Medical Devices"
- The waveform test report has also been conducted to verify the output specifications of the device according to Guidance for Transcutaneous Electrical Nerve Stimulator for Pain Relief Intended for Over the Counter Use

7. Comparison to predicate device and conclusion

The technological characteristics, features, specifications, materials, mode of operation, and intended use of the subject device is substantially equivalent to the predicate devices quoted above. The differences between the subject device and predicate devices do not raise new issues of safety or effectiveness.

Comparison Items	**Subject Device**	**Predicate Device**				**Remark**
Device Name and Model	Digital TENS Unit	Electronic Pulse Stimulator	Electronic Pulse Stimulator, Model:MDTS100	Tyece OTC TENS Device, Model SEM44	IQ Technologies	--
510(k) Number	Applying	K141260	K160508	K150386	K131290	--
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.	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 Electronic Pulse Stimulator MDTS100 is 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	The Tyece OTC TENS Device, Model SEM44 is to be used for temporary relief of pain associated with sore and aching muscles in the lower back, arms, or legs due to strain from exercise or normal household activities.	TENS: 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.	SE

Comparison Items	Subject Device	Predicate Device				Remark
			normal household and work activities.		PMS: It is intended to be used to stimulate healthy muscles in order to improve and facilitate muscle performance.	
Basic Unit Specifications						
Power Source(s)	DC 3.7V Lithium Battery(rechargeable)	/	DC 3V, 2 AAA batteries	4.5V(batteries, 3x1.5V AM)	DC 3.7V Lithium Battery(rechargeable)	SE
- Method of Line Current Isolation	Not applicable for DC current	/	Not applicable for DC current	Not applicable for DC current	Not applicable for DC current	SE
- Patient Leakage Current	--	--	--	--	--	--
-Normal Condition (μA)	0.7＜10μA	/	≤10μA	Not applicable	/	SE
- Single Fault Condition(μA)	0.7＜50μA	/	≤50μA	Not applicable	/	SE
Number of Output Modes	6		7	15	6	SE

Comparison Items	**Subject Device**	**Predicate Device**				**Remark**
Number of Output Channels	2	/	2	2	2	SE
-Synchronous or Alternating?	Synchronous	/	Alternating	Synchronous	/	SE
-Method of Channel Isolation	No	/	No	PCB Insulation Boost Isolation	No	SE
Regulated Current or Regulated Voltage?	Regulated Voltage	/	Regulated Voltage	Regulated Voltage	Regulated Voltage	SE
Software/Firmware/Microprocessor Control?	Yes	/	Yes	Yes	Yes	SE
Automatic Overload Trip?	No	No	No	No	No	SE
Automatic No-Load Trip?	Yes	No	Yes	Yes	No	SE
Automatic Shut Off?	Yes	/	Yes	Yes	Yes	SE
User Override Control	Yes	/	Yes	Yes	Yes	SE
Indicator - On/O	Yes	Yes	Yes	Yes	Yes	SE

Comparison Items		Subject Device	Predicate Device				Remark
Display:	ff Status?						
	- Low Battery?	Yes	Yes	Yes	Yes	Yes	SE
	-Volt age/ Curre nt Level?	Yes for Voltage	Yes	Yes	Yes for Voltage	Yes	SE
Timer Range (Min)		10, 20, 30, 40, 50 and 60	/	20	5-100	10 to 60	SE
Weight		35g (1.2 oz, Battery Included)	/	62.3 g(2.2 oz, Battery Excluded)	/	/	SE Note 1
Dimensions (W x H x D)		84.93mm x 43mm x 10.3 mm	/	661 mm x 1560 mm x 265 mm(2.17 in. x 5.12 in. x 0.87 in.)	135 mm x 65 mm x 20 mm	/	SE Note 1
Housing Materials and Construction		ABS	/	ABS	ABS	/	SE
Compliance with Voluntary Standards		IEC 60601-1, IEC 60601-1-2, IEC 60601-2-	IEC 60601-1, IEC 60601-1-2, IEC 60601-2-	IEC 60601-1, IEC 60601-1-2, IEC 60601-2-	IEC 60601-1, IEC 60601-1-2, IEC 60601-2-	IEC 60601-1, IEC 60601-1-2, IEC 60601-2-	SE

Comparison Items	**Subject Device**	**Predicate Device**				**Remark**
	10, IEC 60601-1-11, ISO 10993-5 and -10	10, IEC 60601-1-11, ISO 10993-5 and -10	10, IEC 60601-1-11, ISO 10993-5 and -10	10, IEC 60601-1-11, ISO 10993-5 and -10	10, IEC 60601-1-11, ISO 10993-5 and -10	
Compliance with 21 CFR 898	Yes	Yes	Yes	Yes	Yes	SE
Output Specifications						
Waveform	Pulsed symmetric, biphasic/ Pulsed monophasic	/	Pulsed monophasic	Biphasic	Pulsed	SE
Shape	Rectangular	/	Rectangular	Rectangular	Rectangular	SE
Maximum Output Voltage	58 V @ 500 Ω	75.2V@500Ω	150V@500Ω	70V@500 Ω	64V@500 Ω	SE
	86 V @ 2k Ω	121V @2kΩ	160V @2kΩ	110V @2kΩ	94,4V @2kΩ	
	142V @ 10k Ω	134V@10kΩ	165V@10kΩ	190V@10kΩ	129V@10kΩ	
Maximum Output Current	116 mA @ 500 Ω	121.6 mA @500Ω	300 mA @500Ω	86 mA@50Ω	128mA@50Ω	SE
	43 mA @ 2k Ω	60.5 mA @2kΩ	80 mA @2kΩ	23.3 mA@2KΩ	47.2 mA@2KΩ	
	14.2 mA @ 10k Ω	13.4 mA @10kΩ	16.5 mA @10kΩ	3.75 mA@10KΩ	12.9 mA@10KΩ	
Pulse Width	94 μs	100 μs	50~140 μs	50 ~360 μs	100 μs	SE
Pulse frequency	1.2~100Hz	1.2Hz~164.4 Hz	0.9Hz~82Hz	1-150Hz	1.2~100Hz	SE
Net Charge (per pulse)	0 μC @ 500Ω/	/	42μC@ 500Ω	0.001 μC @ 500Ω	0 μC @ 500Ω	SE

Comparison Items	Subject Device	Predicate Device				Remark
	13.28 μC @ 500Ω					
Maximum Phase Charge	13.28 μC @ 500Ω	31.3 μC @ 500Ω	42 μC @ 500Ω	45.4 μC @ 500Ω	16.8 μC @ 500Ω	SE
Maximum Average Current	8.79 mA @ 500Ω	/	2.8mA @500Ω	16.0 mA @500Ω	/	SE
Maximum Current Density (r.m.s)	0.235 mA/cm^2 @ 500 Ω	6.02mA/cm^2 @500Ω	3.3mA/cm2@1.57″×1.57″Electrode Pad	0.790mA/cm2 @500Ω	5.12 mA @500Ω	SE
Maximum Power Density	0.029 W/cm2 @ 500 Ω	0.002 W/cm^2@500 Ω	0.02 W/cm^2@1.57″×1.57″Electrode Pad	0.00632 W/cm^2 @500Ω	0.00211 W/cm2 @500Ω	SE
ON Time	1s	/	≤1s	2s	/	SE
OFF Time	1s	/	≤1 s	2s	/	SE

Comparison in Detail(s):

Note 1:

Although there are differences of weight, dimensions observed between the predicate devices and Digital TENS Unit, the differences are insignificant in the terms of safety or effectiveness.

Finial Conclusion:

The subject device “Digital TENS Unit” is Substantial Equivalent to the predicate devices.

8. Date of the summary prepared: March 22, 2017