August 12, 2020

Tyece Limited
% Maria Griffin
Senior Consultant
mdi Consultants, Inc.
55 Northern Blvd, Ste 200
Great Neck, New York 11021

Re: K200838
Trade/Device Name: Tyece OTC TENS Device EM26, EM27, EM28, and EM29
Regulation Number: 21 CFR 882.5890
Regulation Name: Transcutaneous electrical nerve stimulator for pain relief
Regulatory Class: Class II
Product Code: NUH
Dated: May 27, 2020
Received: June 1, 2020

Dear Maria Griffin:

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,

Vivek Pinto, PhD
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K200838

Device Name
Tyece TENS Device Models: EM26, EM27, EM28, EM29

Indications for Use *(Describe)*
The Tyece OTC TENS Device EM26 is intended for use by healthy adults for temporary relief of pain associated with sore and aching muscles in the shoulder and neck due to strain from exercise or normal household and work activities.

The Tyece OTC TENS Device EM27 is intended for use by healthy adults for temporary relief of pain associated with sore and aching muscles in the lower extremities (leg) due to strain from exercise or normal household and work activities.

The Tyece OTC TENS Device EM28 is intended for use by healthy adults for temporary relief of pain associated with sore and aching muscles in the upper extremities (arm) due to strain from exercise or normal household and work activities.

The Tyece OTC TENS Device EM29 is intended for use by healthy adults for temporary relief of pain associated with sore and aching muscles in the upper extremities (arm) and lower extremities (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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510k Summary

The assigned 510(k) number is: **K200838**

1. Submitter's identifications:

Tyece Limited
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Contact: Parshid Falahati
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Email: parshid@tyece.com

Date of Summary Preparation: July 28, 2020

2. Device:

Trade Name: Tyece OTC TENS Device EM26, EM27, EM28 and EM29

Common Name: TENS Device
Classification Name: Transcutaneous Electrical Nerve Stimulator for Pain Relief
Product code: NUH
Regulation class: II
Regulation Number: 21 CFR 882.5890

3. Predicate Device

Trade/Device Name: LT3060
510(k) Number: K130802

4. Reference Device

Trade/Device Name: Savia OTC TENS Model EM-38
510(k) Number: K113321

5. Device Description:

The Tyece OTC TENS Device EM26 is intended for use by healthy adults for temporary relief of pain associated with sore and aching muscles in the shoulder and neck due to strain from exercise or normal household and work activities.
The Tyece OTC TENS Device EM27 is intended for use by healthy adults for temporary relief of

pain associated with sore and aching muscles in the lower extremities (leg) due to strain from exercise or normal household and work activities.
The Tyece OTC TENS Device EM28 is intended for use by healthy adults for temporary relief of pain associated with sore and aching muscles in the upper extremities (arm) due to strain from exercise or normal household and work activities.
The Tyece OTC TENS Device EM29 is intended for use by healthy adults for temporary relief of pain associated with sore and aching muscles in the upper extremities (arm) and lower extremities (leg) due to strain from exercise or normal household and work activities.

The Tyece OTC TENS Device EM26, EM27, EM28 and EM29 powered by 4.5V (3 x 1.5V AAA /Alkaline batteries), is similar to the predicate device, LT3060 (K130802), with the following features:

a. It is a portable single-channel, battery operated Transcutaneous Electrical Nerve Stimulator stimulation system. The predicate is a dual-channel TENS device.
b. It contains 4 programs, similar to the predicate device which has 12 programs
c. The output strength is adjustable from 0-110mA, similar to the predicate device at 0-96mA, via regulated voltage.
d. The LCD display is provided for the indication of operation status including operation mode, output program mode, output intensity, time to cut-off, and battery low indication.

6. Intended Use:

The Tyece OTC TENS Device EM26 is intended for use by healthy adults for temporary relief of pain associated with sore and aching muscles in the shoulder and neck due to strain from exercise or normal household and work activities.
The Tyece OTC TENS Device EM27 is intended for use by healthy adults for temporary relief of pain associated with sore and aching muscles in the lower extremities (leg) due to strain from exercise or normal household and work activities.
The Tyece OTC TENS Device EM28 is intended for use by healthy adults for temporary relief of pain associated with sore and aching muscles in the upper extremities (arm) due to strain from exercise or normal household and work activities.
The Tyece OTC TENS Device EM29 is intended for use by healthy adults for temporary relief of pain associated with sore and aching muscles in the upper extremities (arm) and lower extremities (leg) due to strain from exercise or normal household and work activities.

7. Technological Comparison to Predicate Devices:

Tyece OTC TENS Device EM26, EM27, EM28 and EM29 has similar technological characteristics to the predicate device in product design, material, energy source type, main program modes and the main output waveform etc. Through detailed calculation comparison

of stimulation output energy, we found that the output levels for the subject device and the predicate device are very similar and within acceptable ranges as specified in the FDA guidance. We believe that the differences between the two devices do not affect the determination of substantial equivalence.

8. Discussion of Non-clinical Tests Performed for Determination of Substantial Equivalence are as follows:

Non-clinical testing was performed in order to validate the design according to the company's specified design requirements, and to assure conformance with the following voluntary design standards. The device passes all testing performed below:

- IEC 60601-1: 2005 + AM1 (2012) Medical Devices Part 1: General Requirement for Safety Report
- IEC 60601-1-2:2014 Medical Devices Part 2: General Requirements for Safety – Harmonized Standards: Electromagnetic Compatibility –Test and Requirement Report
- IEC 60601-1-11 Medical Electrical Equipment – Part 1-11: General requirements for basic safety and essential performance – Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment Report
- IEC 60601-2-10 Medical electrical equipment Part 2-10: Particular requirements for the basic safety and essential performance of nerve and muscle stimulators Report
- Software Validation

The Tyece OTC TENS Device, Models EM26, EM27, EM28 and EM29, by applying the same stimulus parameters has the same intended use as the cleared predicate device, LT3060 (K130802).

A summary of the technological characteristics of Models EM26, EM27, EM28 and EM29 compared to the predicate device is given below:

Basic Unit Characteristics:

Item	Subject Device	Predicate Device	Discussion of differences
510(k) Number	K200838	K130802	Similar
Device Name, Model	Tyece OTC TENS Device EM26, EM27, EM28 and EM29	LT3060	Similar
Manufacturer	Savia Electronics (Shenzhen) Co. Ltd.	Shenzhen Dongdixin Technology Co., Ltd	Different but does not adversely impact safety and effectiveness of subject device

Intended Use	The Tyece OTC TENS Device EM26 is intended for use by healthy adults for temporary relief of pain associated with sore and aching muscles in the shoulder and neck due to strain from exercise or normal household and work activities. The Tyece OTC TENS Device EM27 is intended for use by healthy adults for temporary relief of pain associated with sore and aching muscles in the lower extremities (leg) due to strain from exercise or normal household and work activities. The Tyece OTC TENS Device EM28 is intended for use by healthy adults for temporary relief of pain associated with sore and aching muscles in the upper extremities (arm) due to strain from exercise or normal household and work activities. The Tyece OTC TENS Device EM29 is intended for use by healthy adults for	LT3060 OTC TENS Device: The device is designed to be used for temporary relief of pain associated with sore and aching muscles in the shoulder, waist, back, neck, upper extremities (arm), and lower extremities (leg) due to strain from exercise or normal household work activities.	Same
Prescription or OTC	OTC	OTC	Same
Power Source	4.5V (3 x 1.5V AAA, type LR03 Alkaline batteries)	Battery powered, d.c. 9.0V, one 6F22 battery	Different but does not adversely impact safety and effectiveness of subject device

-Method of Line Current Isolation	No line connection possible when connected to body	No line connection possible when connected to body	Same
-Patient Leakage Current - Normal condition - Single fault condition	Not applicable, no line connection, no AC charger connection or operation. Connection method does not allow AC charger connection to patient	0.61uA 0.68uA	Different but does not adversely impact safety and effectiveness of subject device
Average DC current through electrodes when device is on but no pulses are being applied	0µA	0µA	Same
Number of Output Models	TENS	TENS	Same
Number of Output Channels	1	2	Different but does not adversely impact safety and effectiveness of subject device
-Synchronous or Alternating?	Synchronous	Alternating	Different but does not adversely impact safety and effectiveness of subject device
-Method of Channel Isolation	Single Channel	Dual Channel	Different but does not adversely impact safety and effectiveness of subject device
Regulated Current or Regulated	Constant Voltage	Constant Voltage	Same
Software/Firmware/Microprocessor Control?	YES	YES	Same
Automatic Overload Trip?	YES	YES	Same
Automatic No-Load Trip?	YES	YES	Same
Automatic Shut Off?	YES	YES	Same
Patient Override Control?	YES	YES	Same
Indicator Display: - On/Off Status? - Low Battery? - Voltage/Current Level?	 YES YES YES (Voltage)	 YES YES YES (Voltage)	Same
Timer Range (minutes)	30 mins - Program A, 25 mins - Programs B, C, D	1 - 60 mins	Different but does not adversely impact safety and effectiveness of subject device
Compliance with Voluntary Standards?	60601-1 & 60601-1-2	60601-1 & 60601-1-2	Same
Compliance with 21 CFR 898?	YES	YES	Same

Weight (lbs., oz.)	EM26 - Approx. 0.6 lb (280g) with batteries EM27 - Approx. 0.34 lb (155g) with batteries EM28 - Approx. 0.39 lb (175g) with batteries EM29 - Approx. 0.46 lb (210g) with batteries	Approx. 0.28 lb with batteries	Different but does not adversely impact safety and effectiveness of subject device
Dimensions (in.) [W x H x D]	3.4 x 1.4 x 2.3 in	4.5 x 2.55 x 0.9 in	Different but does not adversely impact safety and effectiveness of subject device
Housing Materials and Construction	ABS	ABS	Same
Electrode Cable Length	1.2m	1.2m	Same

Output Specifications

Attribute		Subject Device: Tyece OTC TENS Device, Models EM26, EM27, EM28 and EM29	Predicate Device: LT3060 (K130802)	Discussion of Difference
Waveform		Symmetrical biphasic	Symmetrical biphasic	Same
Shape		Rectangular	Rectangular	Same
Channels		Single	Dual	Different but does not adversely impact safety and effectiveness of subject device
Maximum Output Voltage (Volts) (±20%)	@500Ω	54.4Vp-p	48Vp-p	Different but does not adversely impact safety and effectiveness of subject device
	@2kΩ	112Vp-p	114Vp-p	
	@10Ω	198Vp-p	115Vp-p	
Maximum Output Current (mA) (±20%)	@500Ω	108.8mAp-p	96mAp-p	Different but does not adversely impact safety and effectiveness of subject device
	@2kΩ	56mAp-p	57mAp-p	
	@10Ω	19.8mAp-p	11.5mAp-p	
Amplitude (mA)		0-110	0-96	Different but does not adversely impact safety and effectiveness of subject device
Frequency (Hz)		4-110	1-150	
Pulse Width (μS)		60-220μs per phase	50-300μs per phase	

For multiphasic waveforms only	Symmetrical phases?	No multiphasic waveforms	Yes	Different but does not adversely impact safety and effectiveness of subject device.
	Phase Duration		50-300uS	
Power ON indicator		LCD	LCD	Same
Net Charge (μC per pulse) (if zero state method of achieving zero net charge)		0.00246 μC@500Ω	0 μC@500Ω	Different but does not adversely impact safety and effectiveness of subject device
Maximum Phase Charge (μC) @500Ω		0.02398	0.0288	
Maximum Current Density (mA/cm^2) @500Ω		0.52	1.15	
Maximum Power Density (W/ cm^2) @500Ω (using smallest electrode conductive area)		0.033	0.373	
RMS Voltage (RMSV) (±20%)	@500Ω	5.5V	5.2V	Different but does not adversely impact safety and effectiveness of subject device
	@2kΩ	16.3V	14.2V	
	@10Ω	27.2V	20.2V	
RMS Current (RMSA) (±20%)	@500Ω	11mA	10mA	
	@2kΩ	7.35mA	8.85mA	
	@10Ω	2.02mA	1.88mA	
Burst Mode - Pulses per burst - Burst per second - Burst duration (seconds) - Duty cycle: Line (b) x Line (c)		 110 2 0.5s 1	N/A	Different but does not adversely impact safety and effectiveness of subject device
ON Time (seconds)		N/A	N/A	Same
OFF Time (seconds)		N/A	N/A	
Additional Features (specify, if applicable)		Not applicable	Not applicable	Same

Summary for the technology comparison

The Tyece OTC TENS Device EM26, EM27, EM28 and EM29 has similar technological characteristics to the predicate device in product design, material, energy source type, main program modes and the main output waveform etc. Through detailed calculation comparison of stimulation output energy, we found that the output levels for the subject device and the predicate device are very similar and within acceptable ranges as specified in the FDA guidance. We believe that the differences between the two devices do not affect the determination of substantial equivalence.

Conclusion

The Tyece OTC TENS Device EM26, EM27, EM28 and EM29 has the same intended use and similar technological characteristics as the cleared predicate device. Moreover, verification and validation tests demonstrate that the differences in the submitted models maintain the same safety and effectiveness as that of the cleared device. Therefore, we conclude that the subject device is substantially equivalent to the predicate device.