June 6, 2018

Everyway Medical Instruments CO., LDT.
% Aaron Hage
Associate Attorney
DuVal & Associates
825 Nicollet Mall, Suite 1820
Minneapolis, Minnesota 55402

Re: K181207
Trade/Device Name: Balego TENS Digital Edition with Accessories for Pain Relief (OTC)
Regulation Number: 21 CFR 882.5890
Regulation Name: Transcutaneous electrical nerve stimulator for pain relief
Regulatory Class: Class II
Product Code: NUH
Dated: May 4, 2018
Received: May 7, 2018

Dear Aaron Hage:

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.

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 comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

William J. Heetderks -S
2018.06.06 16:37:48 -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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K181207

Device Name
Balego™ TENS Digital Edition with Accessories for Pain Relief (OTC)

Indications for Use *(Describe)*
The Balego™ TENS Digital Edition with Accessories for Pain Relief (OTC) is intended for temporary relief of pain associated with sore and aching muscles in the low back as well as upper and lower extremities (arm and/or 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 summary of 510(k) safety and effectiveness information is being prepared in accordance with the requirements of 21 CFR 807.92.

The assigned 510(k) number is: K181207.

1. Submitter's Identifications:

Establishment:	Everyway Medical Instrument CO., LTD.
Address:	3 FL., NO. 5, Lane 155, Section 3, Beishen Rd. Shenkeng Dist., New Taipei City, 22203, Taiwan
Registration Number:	9616877
Operations Manufacturer Owner/Operator:	Everyway Medical Instrument CO., LTD.
Contact Person:	Robert Tu
Phone:	886-2-2662-0038
Fax No:	886-2-2664-5566
e-mail:	robert@everyway-medical.com

2. Date 510(k) Summary Prepared: April 25, 2018

3. Name of the Subject Device and Classification Information:

Tradename/Device Name	Balego™ TENS Digital Edition with Accessories for Pain Relief (OTC)
Regulation Number	21 CFR 882.5890
Classification Name	Transcutaneous electrical nerve stimulator for pain relief.
Regulatory Class	Class II
Product Code	NUH

4. Information of the 510(k) Cleared Device (Predicate Device):

Tradename/Device Name	EV-804 OTC Pain Relief TENS
510(k) Number	K172919
Regulation Number	21 CFR 882.5890
Classification Name	Transcutaneous electrical nerve stimulator for pain relief.
Regulatory Class	Class II
Product Code	NUH

5. Device Description:

   The Balego™ TENS Digital Edition with Accessories for Pain Relief (OTC) is a dual channel transcutaneous electrical nerve stimulator used for pain relief by applying an electrical current to electrodes, which are attached on the user's skin. The output and waveform characteristic are fixed for every operation mode, only the intensity is adjustable within specified limit.

   The Balego™ TENS Digital Edition consists mainly of two parts: the stimulus generator, electrode. The stimulus generator generates the output current specified as the input of controller. The output port transmits the output current to the electrode, which is attached to the user's skin so as to transmit this stimulus current for pain relief.

   The stimulation modes for Balego™ TENS Digital Edition are pre-program modes with fixed pulse width, pulse rate, frequency. The amplitude for each program are adjustable. The subject and predicate devices both use Everyway Electrode, Wire Series/ model no. KF5050, size 50x50mm, wire type as a standard accessory. The Electrode was cleared under K083302.

   With the combination of the main device parts, the device can be placed on the treatment locations as recommended in the user manual for temporary relief of pain associated with sore and aching muscles in the low back as well as upper and lower extremities (arm and/or leg) due to strain from exercise or normal household and work activities.

6. Indications for Use:

   The Balego™ TENS Digital Edition with Accessories for Pain Relief (OTC) is intended for temporary relief of pain associated with sore and aching muscles in the low back as well as upper and lower extremities (arm and/or leg) due to strain from exercise or normal household and work activities.

7. Comparison to the 510(k) Cleared Device (Predicate Device):

Table S-1. Overview of the predicate and proposed device model.

Features	**Predicate Model**	**Proposed Model**
Model	EV-804	BAL-820
510(K) No.	K172919	K18XXXX
Prescription or OTC	OTC	OTC
Indication for use	The OTC Pain Relief TENS, model EV-804, is intended for temporary relief of pain associated with sore and aching muscles in the low back as well as upper and lower extremities (arm and/or leg) due to strain from exercise or normal household and work activities.	The Balego™ TENS Digital Edition, model BAL-820, is intended for temporary relief of pain associated with sore and aching muscles in the low back as well as upper and lower extremities (arm and/or leg) due to strain from exercise or normal household and work activities.
FDA product code	NUH	NUH
Accessory	Self Adhesive Electrode (5x5 cm)/K083302	Self Adhesive Electrode (5x5 cm)/K083302

Table S-2. Comparison of significant output characteristics.

Comparison feature		Predicate Model	New Model
		EV-804	Balego TENS
Net charge		0	0
Max. phase charge		20.8 uc	20.8 uc
Max. current Density		0.0998 mA/cm2	0.0998 mA/cm2
Max. Average current (RMSA)	500Ω	80 mA	80 mA
	2KΩ	40 mA	40 mA
	10KΩ	10 mA	10 mA
Max. Power Density		0.00399 Watts/ cm2	0.00399 Watts/ cm2
Burst Mode		Yes	Yes

Table S-3. Comparison of output specifications.

		Predicate Device	New Device
Mode or Program Name		EV-804	Balego TENS
510(K) Number		K172919	K18XXXX
Waveform (e.g., pulsed monophasic, biphasic)		Biphasic asymmetric	Biphasic asymmetric
Shape (e.g., rectangular, spike, rectified sinusoidal)		Rectangular	Rectangular
Maximum Output Voltage (volts) (+/-_20 %)		40V @500Ω 80V @2KΩ 100V @10KΩ	40V @500Ω 80V @2KΩ 100V @10KΩ
Maximum Output Current (mA) (+/-_20 %)		80mA @500Ω 40mA @2KΩ 10mA @10KΩ	80mA @500Ω 40mA @2KΩ 10mA @10KΩ
Duration of primary phase (*u*sec)		260 max	260 max
Pulse Duration (*u*sec)		8333 max	8333 max
Frequency (Hz) [or Rate (pps)]		120 max	120 max
For multiphasic waveforms only:	Yes	Yes	Yes
	Not applicable	Not applicable	Not applicable

		Predicate Device	New Device
Power Source(s)		9V x 1 (6F22 Size)	9V x 1 (6F22 Size)
- Method of Line current Isolation		Type BF	Type BF
- Patient Leakage Current		---	---
- Normal condition (*u*A)		Under 0.1	Under 0.1
- single Fault condition (*u*A)		Under 0.5	Under 0.5
Average DC current through electrodes when device is on but no pulses are being applied (*u*A)		Not applicable	Not applicable
Number of Output Modes		8	8
Number of Output Channels:	Synchronous	Synchronous	Synchronous
	Output Coil	Transformer	Transformer
Regulated Current or Regulated Voltage?		Current	Current
Software/Firmware/Microprocessor control?		Yes	Yes
Automatic Overload Trip?		No	No
Automatic No-Load Trip?		Yes	Yes
Automatic Shut Off?		Yes	Yes
User Override control?		No	No
Indicator Display:	Yes	Yes	Yes
	Yes	Yes	Yes
	Yes	Yes	Yes
Timer Range (Minutes)		15, 30,60 and Continuous	15, 30,60 and Continuous
Compliance with Voluntary Standards?		IEC 60601-2-10	IEC 60601-2-10
Compliance with 21 CFR 898?		Yes	Yes
Weight (g) including battery		155	155
Dimensions (mm.) [W x H x D]		101×68×21.5	101×68×21.5
Housing Materials and construction		ABS	ABS
Pulse per burst		6	6
Burst per second		2	2
Bust duration		260us	260us
Duty Cycle		Same for each program	Same for each program
Method of achieving zero net charge for net charge/pulse		Biphasic asymmetric wave for each pulse	Biphasic asymmetric wave for each pulse

8. Non-Clinical Tests Performed to Determine the Safety and Performance of the Device:

Non-clinical performance data is not required to determine the safety and performance of the device. The subject device is identical to the predicate device with regards to intended use, technological characteristics, manufacturing, and labeling (apart from the different tradename). Therefore, descriptive information alone is sufficient to address the substantial equivalence determination.

9. Clinical Test Validation Activities Performed to Determine the Effectiveness of Device:

   Clinical tests were not conducted for the Balego TENS device because there were no changes to the indications for use or technological characteristics as compared to the predicate device that would warrant clinical testing.

10. Summary for the technology comparison.

    As evidence by The Balego™ TENS device has the same technological characteristics as the predicate device regarding product design, material, and energy source type, and all other technological features.

11. Conclusions

    The Balego TENS device is the identical device to the predicate device, apart from its tradename. The Balego TENS device has the same intended use and the same technological characteristics as the legally marketed predicate device. Therefore, the Balego TENS device is substantially equivalent to the predicate device.