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

July 21, 2015

Philips Consumer Lifestyle
Marta Walker
Senior Safety, Compliance & Regulatory Manager
1600 Summer Street
Stamford, Connecticut 06905

Re: K151035
Trade/Device Name: Pulserelief
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 1, 2015
Received: June 25, 2015

Dear Marta Walker:

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 yours,

Michael J. Hoffmann -S

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)*
K151035

Device Name
PulseRelief

Indications for Use *(Describe)*
The OTC TENS/EMS stimulator PulseRelief 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.
It should be applied to normal, healthy, dry and clean skin of adult patients, and is to be used for stimulate healthy muscles in order to improve and facilitate muscle performance.

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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Department of Health and Human Services
Centre of Device and Radiological Health
Office of Device Evaluation
Traditional 510(k) section

510(K) SUMMARY OF SAFETY AND EFFECTIVENESS INFORMATION

as required by section 21 CFR 807.92

1. SUBMITTER OF 510(K):

Company name:	Philips Consumer Lifestyle
Registration number:	3009181561
Address:	1600 Summer Street Stamford, CT 06905 USA
Phone:	+31 6 319 78 546
email	marta.walker@philips.com
Correspondent:	Marta Walker, Sr. Manager Safety, Compliance & Regulatory

Date of Preparation:	July 16th, 2015

2. DEVICE:

Trade/Proprietary Name:	PulseRelief
Common/Usual Name:	TENS
Regulation Name	Transcutaneous Electrical Nerve Stimulator for Pain Relief
Classification Name:	Neurological Therapeutic Devices
Classification:	21CFR 882.5890 and 890.5850 Class II
Product Code:	NUH and NGX

The PulseRelief device is to be used with the Philips Self-Adhesive Electrode (K151033).

3. PREDICATE DEVICE

Our new device is based on the legally marketed device cited in the table below:

Table 1: Predicate device

Manufacturer	Device	510(k) #	Product Code:
Shenzhen Dongdixin Technology Co., Ltd.	OTC Electrical stimulator Models MT900I, LT3060	K 130802	NUH, NGX

4. DEVICE DESCRIPTION

PulseRelief 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 and can be used to stimulate healthy muscles in order to improve and facilitate muscle performance. Pulse Relief is designed to be used at home, by adults of all genders

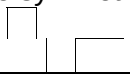
For Transcutaneous Electrical Nerve Stimulation (TENS) Self-adhesive electrodes are placed on the skin close to the area of pain. The device delivers pulses across the skin through these electrodes. This activates the underlying sensory nerves. The user can choose 15 pre-set TENS programs with different pulse settings. In each program, the intensity of the pulse can be adjusted.

For Electrical Muscle Stimulation (EMS), the electrodes are placed near the muscle to be stimulated. The device generates electrical pulses and passes these pulses across the surface of the skin to activate the underlying motor nerves. This makes the muscle contract. Contraction helps to condition the muscle in in order to facilitate performance

The PulseRelief system consists of the following elements:

- Control unit with cable: generates the TENS/EMS pulses; connects to the 1st electrode; communicates with the mobile device; connects to the battery unit. The control unit has an on-off button.
- Battery unit: contains a battery and charging circuit; connects the 2nd electrode to the control unit.
- Electrodes: Self-adhesive re-usable hydrogel electrodes with metal target plate for magnetic clamping to the control unit and battery unit.
- App on mobile device. The app controls the functions of the PulseRelief device via a Bluetooth Low Energy connection between the mobile device and the PulseRelief device.
- Adapter: for charging the battery unit via a micro-USB socket. To connect the USB-cable to the battery unit, the control unit needs to be disconnected.

Table 2: Main device parameters

	Parameter	PulseRelief Specification
Treatment modes	TENS	15 programs
	EMS	5 programs
Pulse Output parameters	Number of output channels	1
	Current pulse shape	Biphase symmetrical 
	Frequency range	1-100 Hz
	Pulse duration	60-350 µs
	Treatment duration	1-59min or continuous
General specifications	Power supply	DC 3.7V Li-ion
	System IP Classification	IP22
	Size	53.5mm x 53.5mm x 11.5mm
	Weight	62 grams

	Parameter	PulseRelief Specification
Operating conditions	Temperature	5°C to 40°C (41°F to 104°F)
	Relative humidity	15%-93% (non-condensing)
	Atmospheric pressure	700 to 1060 hPa
Storage conditions (device)	Temperature	-10ºC to 50ºC (14°F to 122°F)
	Relative humidity	less than 93% (non-condensing)
	Atmospheric pressure	700 to 1060 hPa
Storage conditions (electrodes)	Temperature	0ºC to 40ºC (32°F to 104°F)
	Relative humidity	less than 93% (non-condensing)
	Atmospheric pressure	700 to 1060 hPa
Adapter	Rated input	100-240V / 150mA
	Rated frequency	50-60 Hz
	Rated output	5V DC / 300mA
Electrode	Dimensions	50mm x 50mm (2.16in x 2.16in) (2pcs)

The PulseRelief device is controlled by means of an app on a mobile device (phone or tablet). The communication is done via Bluetooth Low Energy. The app operates on IOS and Android platforms (IOS 7 and 8, Android 4.4 KitKat and higher).

Interface with the user

With the app, the user can do the following:

- Select a body part (optional); by selecting a body part, a list of suggested treatments is provided
- Enter a pain score (optional)
- Select a treatment
- Select the treatment duration (optional)
- Start, pause and stop a treatment
- Increment and decrement the intensity
- Enter a post-treatment sensation score
- Display the Treatment Diary
- Display the Instructions for Use
- Display the battery status of the PulseRelief device
- Clear the Treatment Diary on a PulsRelief device
- Decouple with a PulseRelief device (“forget my device”)

Diary function

The app contains a Diary function that shows the details of over 200 past treatments. For each treatment, the information consists of treatment type, treatment data and time, treatment duration, treatment intensity, body part (if selected by user), pain score and satisfaction score (if scored by the user). The Diary data is stored on the PulseRelief device. The mobile device retrieves the actual Diary data from the connected PulseRelief.

Interface with the PulseRelief device

The following functions are provided for communication between the app and the PulseRelief device:

- Pair with a PulseRelief device
- Set or read the treatment program
- Read the connection status of the electrodes
- Read the stimulation intensity
- Set the treatment time
- Read the remaining treatment time
- Increment the stimulation intensity
- Decrement the stimulation intensity
- Set the stimulation intensity to zero
- Read the battery level of the PulseRelief device
- Set or read the body part
- Set or read the pain score
- Set or read the Post-treatment sensation
- Read the Treatment Diary data, system data and event log data
- Set the system time of the PulseRelief device
- Read the system ID and unique device ID of the PulseRelief device
- Read the firmware revision of the PulseRelief device
- Factory reset of the PulseRelief device

The controls and indicators of the PulseRelief device are listed in the Table below.

Table 3: PulseRelief device controls and indicators

Unit	Control/Indicator	User interface	Function
Control Unit	On-off button	Press button (when device is off)	Device on, such that mobile device can connect
		Press button (when device is on)	Device off (at any time, before, during or after treatment)
	LED indicator	Off	Device is off
		Green continuous	Device is on, no signal output is active
		Yellow blinking (1Hz)	Device is on, signal output is active
		Green rapid blinking (2Hz)	Device is on and in connection mode, no signal output is active
Battery Unit	LED indicator	Off	Device is not connected to charger
		Red continuous	Device is connected to a charger, battery is charging
		Green continuous	Device is connected to a charger, battery is fully charged

5. INDICATION FOR USE:

5.1 PulseRelief

The OTC TENS/EMS stimulator PulseRelief 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.
It should be applied to normal, healthy, dry and clean skin of adult patients, and is to be used for stimulate healthy muscles in order to improve and facilitate muscle performance.

5.2 Predicate MT9001 OTC TENS/EMS stimulator

TENS: 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.
EMS: The device is designed to be used for stimulate healthy muscles in order to improve and facilitate muscle performance.

As demonstrated above, there are no differences in the intended use of the PulseRelief and the selected predicate, MT9001 OTC.

6. SUMMARY OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

6.1 Basic Unit Characteristics

Both the PulseRelief and Predicate Device utilise the application of electrical current through electrodes placed on the skin for pain control, or electrical muscle stimulation (EMS) the elicitation of muscle contraction using electric impulses. The impulses are generated by the device and delivered through electrodes on the skin in direct proximity to the (painful) muscles to be stimulated.

A comparison of the basic characteristics of the PulseRelief and that of the Predicate is shown in the Table below.

Table 4: Substantial Equivalence Comparison Table

Parameter	PulseRelief	Predicate Device
510(k) Number	(to be assigned)	K130802
Device Name and Model	PulseRelief	MT9001 OTC TENS/EMS stimulator
Manufacturer	Philips Consumer Lifestyle	Shenzhen Dongdixin Technology Co., Ltd.
Regulation Number	882.5890 890.5850	882.5890 890.5850
Product Code	NUH NGX	NUH NGX
Power Source(s)†	Li-ion 3.7V 500mAh	9V battery

- Method of Line Current Isolation	N/A	N/A
- Patient Leakage Current†† - Normal Condition (µA)	<10 µA	0.61µA

Parameter		PulseRelief	Predicate Device
- Single Fault Condition (µA)		<50 µA	0.68µA
Average DC current through electrodes when device is on but no pulses are being applied (µA)		0	0
Number of Output Modes †††		15 TENS 5 EMS	2 (TENS/EMS)
Number of Output Channels††††:	Synchronous or Alternating?	N/A (1 output channel)	Alternating
	Method of Channel Isolation	N/A (1 output channel)	By electrical circuit and software
Regulated Current or Regulated Voltage?		Current control	Current control
Software/Firmware/Microprocessor Control?		Yes	Yes
Automatic Overload Trip?		Yes	Yes
Automatic No-Load Trip?		Yes	Yes
Automatic Shut Off?		Yes	Yes
User Override Control?		Yes power on/off button on the device, and power on/off in the App software	Yes Power on/off button on the device
Indicator Display:	On/Off Status?	Yes	Yes
	Low Battery?	Yes (on app)	Yes
	Voltage/Current Level?	Yes (on app)	Yes
Timer Range (minutes)		1~59 minutes and continuous	1~60 minutes
Compliance with Voluntary Standards?		IEC 60601-1, IEC 60601-1-2, IEC 60601-2-10, ISO10993-5/10	IEC 60601-1, IEC 60601-1-2, IEC 60601-2-10, ISO10993-5/10
Compliance with 21 CFR 898[7]?		Yes	Yes
Weight (grams)		62g (excl. electrodes)	128g
Dimensions (mm) [W x H x D]		2 units, each 54x54x14 (excl electrodes)	117x60x34
Housing Materials and Construction		PC ABS	Plastic ABS

Note! Table template from: Draft Guidance for Industry and FDA Staff: Class II Special Controls Guidance Document: Transcutaneous Electrical Nerve Stimulator for Pain Relief Intended for Over the Counter Use

6.2 Output Specifications TENS mode

Table 5: Output Specifications TENS mode

Parameter		PulseRelief	Predicate Device K130802
Mode or Program Name		TENS mode	TENS mode
Waveform (e.g., pulsed monophasic, biphasic)		Biphasic	Biphasic
Shape (e.g., rectangular, spike, rectified sinusoidal)		Rectangular	Rectangular
Maximum Output Voltage (volts) (+/- 20%)		31 @500Ω	48 @500Ω
		69 @ 2 kΩ	100 @ 2 kΩ
		70 @10 kΩ	105 @10 kΩ
Maximum Output Current (specify units) (+/- 20%)		62 @500Ω	96 @500Ω
		34 @ 2 kΩ	50 @ 2 kΩ
		7 @10 kΩ	10.5 @10 kΩ
Duration of primary (depolarizing) phase† (msec)		25 ~175 µs	50µs ~ 300 µs
Pulse Duration† (µsec)		60 ~ 350 µs	50µs ~ 300 µs
Frequency† (Hz) [or Rate† (pps)]		1 ~ 100 Hz	1Hz ~ 150Hz
For multiphasic waveforms only:	Symmetrical phases?	Yes	Yes
	Phase Duration† (include units),(state range, if applicable), (both phases, if asymmetrical)	25 ~ 175 µs	50µs ~ 300 µs
Net Charge (microcoulombs (mC) per pulse) (If zero, state method of achieving zero net charge.)		0 µC @500Ω	0 µC per pulse@500 ohm symmetric, biphasic and leading polarity alternates for each successive, Pulse + and pulse – pulse channel.
Maximum Phase Charge, (µC)		1.6 ~ 6.8 @500Ω	28.8 @500Ω
Maximum Current Density,††(mA/cm², r.m.s.)		0.002 ~ 0.045 @500Ω	1.15 @500Ω
Maximum Average Current (average absolute value), mA		0.06 ~1.36 @500Ω	4.32 @500Ω
Maximum Average Power Density,†† (mW/cm²), (using smallest electrode conductive surface area)		0.24 ~ 1.69 @500Ω *(* see comment 1)*	0.373 @500Ω
Burst Mode (i.e., pulse trains):	(a) Pulses per burst	5, 7	7
	(b) Bursts per second	1,2,3	0.5,1,2,3,4,5
	(c) Burst duration (ms)	62.5 ~ 87.5	70
	(d) Duty Cycle: Line (b) x Line (c)	6.3% ~ 19%	3.5 ~ 35%
ON Time (seconds)		N/A	N/A
OFF Time (seconds)		N/A	N/A
Additional Features (specify, if applicable)		N/A	N/A

Additional comments relating to the differences between the PulseRelief and selected predicate:

- Comment 1 – Maximum Average Power Density: The predicate device has a lower

value, but the maximum average power density is well below 250mW/cm2 as required by the FDA-guidance for TENS OTC. The safety and effectiveness of the device is not affected.

6.3 Output specifications EMS mode

Table 6: Output specifications EMS mode

Parameter		**PulseRelief**	**Predicate Device K130802**
Mode or Program Name		EMS mode	EMS mode
Waveform (e.g., pulsed monophasic, biphasic)		Biphasic	Biphasic
Shape (e.g., rectangular, spike, rectified sinusoidal)		Rectangular	Rectangular
Maximum Output Voltage (volts) (+/- 20%)		31 @500Ω	48 @500Ω
		69 @ 2 kΩ	114 @ 2 kΩ
		70 @10 kΩ	115 @10 kΩ
Maximum Output Current (specify units) (+/- 20%)		62 @500Ω	96 @500Ω
		34 @ 2 kΩ	57 @ 2 kΩ
		7 @10 kΩ	11.5 @10 kΩ
Duration of primary (depolarizing) phase† (msec)		75 ~175 µs	50µs ~ 300 µs
Pulse Duration† (µsec)		150 ~ 350 µs	50µs ~ 300 µs
Frequency† (Hz) [or Rate† (pps)]		40 ~ 65 Hz	1Hz ~ 150Hz
For multiphasic waveforms only:	Symmetrical phases?	Yes	Yes
	Phase Duration† (include units), (state range, if applicable), (both phases, if asymmetrical)	75 ~ 175 µs	50µs ~ 300 µs
Net Charge (microcoulombs (mC) per pulse) (If zero, state method of achieving zero net charge.)		0 µC @500Ω	0 µC per pulse@500 ohm symmetric, biphasic and leading polarity alternates for each successive, Pulse + and pulse – pulse channel.
Maximum Phase Charge, (µC)		4.7 ~ 10.9 @500Ω	28.8 @500Ω
Maximum Current Density,††(mA/cm², r.m.s.)		0.019 ~ 0.037 @500Ω	1.15 @500Ω
Maximum Average Current (average absolute value), mA		0.47 ~ 0.93 @500Ω	4.32 @500Ω
Maximum Average Power Density,†† (W/cm²), (using smallest electrode conductive surface area)		0.62~1.15 @500Ω *(* see comment 1 in paragraph 6.2)*	0.373 @500Ω
Burst Mode (i.e., pulse trains):	(a) Pulses per burst	N/A	N/A
	(b) Bursts per second	N/A	N/A
	(c) Burst duration (seconds)	N/A	N/A
	(d) Duty Cycle: Line (b) x Line (c)	N/A	N/A

Parameter	PulseRelief	Predicate Device K130802
ON Time (seconds) - Intensity ramp-up - Constant intensity - Intensity ramp-down	 2 ~ 4 sec 5 ~ 6 sec 1 ~ 2 sec	1 ~ 30
OFF Time (seconds)	15 sec	1 ~ 60
Additional Features (specify, if applicable)	N/A	N/A

7. PERFORMANCE DATA

The following performance data are provided in support of the substantial equivalence determination:

7.1 Biocompatibility testing

The biocompatibility evaluation for the Brand X device was conducted in accordance with the FDA Blue Book Memorandum #G95-1 "Use of International Standard ISO-10993, 'Biological Evaluation of Medical Devices Part 1: Evaluation and Testing,'" May 1, 1995, and International Standard ISO 10993-1 "Biological Evaluation of Medical Devices − Part 1: Evaluation and Testing Within a Risk Management Process," as recognized by FDA. As dictated by the application and duration of contact with the intact skin, the battery of testing included the following tests:

- Cytotoxicity
- Sensitization
- Irritation

7.2 Electrical safety and electromagnetic compatibility (EMC)

Electrical safety and EMC testing were conducted on the PulseRelief. The system complies with the IEC 60601-1, IEC 60601-1-6, IEC 60601-1-11 and IEC 60601-2-10 standards for safety and the IEC 60601-1-2 standard for EMC, and IEC 62133 for battery safety.

For FCC part 15 RADIO FREQUENCY DEVICES, Subpart B—Unintentional Radiators, Subpart C—Intentional Radiators.

7.3 Software Verification and Validation Testing

Software verification and validation testing were conducted and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." The software for this device was considered as a "Moderate" level of concern. IEC 62304 was followed.

7.4 Usability Testing

Usability testing according to IEC 62366 and following FDA Guidance 1757, Applying Human Factors and Usability Engineering to Optimize Medical Device Design, was conducted.

7.5 Risk management

The risks to people, property and the environment associated with the use of the PulseRelief was managed according to ISO 14971:2007 Medical Devices- Application of risk management to medical devices (Second Edition)

7.6 Symbols

The symbols used on the PulseRelief itself, on its packaging or in the associated documentation is conform ISO 15223-1:2012 Medical Devices - Symbols To Be Used With Medical Device Labels, Labelling, And Information To Be Supplied - Part 1: General Requirements (Second Edition)

8. CONCLUSION

The intended use and basic technological characteristics of the PulseRelief device are equivalent with those of the referenced Predicate device K130802. Any technological differences do not raise new questions regarding safety and effectiveness.