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

June 28, 2017

Lifecare Ltd.
% Irving Wiesen
Official Correspondent
Cohen, Tauber, Spievack & Wagner
420 Lexington Avenue-suite 2400
New York, New York 10170

Re: K163153
Trade/Device Name: Livia
Regulation Number: 21 CFR 882.5890
Regulation Name: Transcutaneous Electrical Nerve Stimulator For Pain Relief
Regulatory Class: Class II
Product Code: NUH
Dated: May 25, 2017
Received: May 30, 2017

Dear Irving Wiesen:

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
2017.06.28 15:57:47 -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)*
K163153

Device Name
Livia

Indications for Use *(Describe)*
The Livia is designed for symptomatic relief and management of chronic intractable pain, and 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

Section 5: 510(K) SUMMARY

The assigned 510(K) Number: K163153

1. Submitter's Identification:

LifeCare Ltd.
Zipori St.2 1424602,
Tiberias, Israel

Date Summary Prepared: May 25, 2017

Contact Person:
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2. Name of the Device:

Livia

3. Common Name and Classification:

Stimulator, Nerve, Transcutaneous, Over-The-Counter
Regulation: 21 CFR Part 882.5890
Product Code: NUH

4. Predicate Device Information:

- Primary Predicate: Philips Consumer Lifestyle PulseRelief (K151035)
- Reference Predicate: NeuroMetrix ASCEND (K10433)

5. Device Description:

The LIVIA is a TENS device. TENS is an acronym for Transcutaneous Electrical Nerve Stimulator, and it works as a pain treatment system through electrotherapy. The unit sends light electrical pulses into the body through the skin by the use of electrodes, which are placed over peripheral nerves. The TENS unit works by sending high frequency electrical signals that are both continuous and mild to block out those pain signals that are being delivered to the brain. The Livia device was designed with specific pulse frequency and pulse length that are suitable for its intended use. When these pain signals are halted, pain isn't felt by the reactive area and the patiernt get relief. Low frequency bursts of mild electrotherapy also help the natural pain control response to activate, and these beta endorphins ease the pain that are being felt by the patient.

6. Indication For Use:

The Livia is designed for symptomatic relief and management of chronic pain, and 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.

7. Comparison to Predicate Devices:

The Livia device indications for use and technological characteristics are substantially equivalent to the Philips Consumer Lifestyle PulseRelief device application (K151035).

The primary predicate device is the Philips Consumer Lifestyle PulseRelief device and the reference predicate is NeuroMetrix ASCEND device application (K104333).

TABLE 1: Indication For Use Comparison Table

Comparison Tables – Technological Characteristics

Parameter	**Primary Predicate Philips Consumer Lifestyle PulseRelief (K151035)**	**Subject Device LIVIA**
Indication For Use	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	The Livia is designed for symptomatic relief and management of chronic pain, and 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.

	to improve and facilitate muscle performance.	
Class	II	II
Product Code	NUH; NGX	NUH; NGX
Regulation Number	21 CFR 882.5890(b); 21 CFR 890.5850	21 CFR 882.5890(b); 21 CFR 890.5850

Table 2: Basic Unit Characteristics Comparison Table

Parameter		**Primary Predicate Philips Consumer Lifestyle PulseRelief (K151035)**	**Livia**	**Significant Differences**
510(k) Number		K151035	K163153	N/A
Device Name and Model Number		PulseRelief	LIVIA	N/A
Manufacturer		Philips Consumer Lifestyle	Life Care Ltd	N/A
Power Source(s)		3.7V Lithium-ion	3.7V Lithium-ion battery (rechargeable)	Identical
Method of Line Current Isolation		N/A	Output is electrically disabled when connect to charger, by means of microprocessor charging circuit	Similar to the reference predicate Neurometrix device cannot be used while battery is charging
Patient Leakage Current - Normal Condition (µA)		Battery powered (< 10µA)	Battery powered (< 10µA)	Identical
Patient Leakage Current - Single Fault Condition (µA)		Battery powered (< 50µA)	Battery powered (< 50µA)	Identical to Philips
Average DC current through Electrodes when device is on but no pulses are being applied (µA)		0 µA	0 µA	Identical to Philips
Number of Output Modes		15 TENS, 5 EMS	1	Similar to the reference predicate Neurometrix
Number of Output Channels:	**Synchronous or Alternating**	1	1	Identical
	Method of Channel	N/A	N/A	Identical

	Isolation			
Regulated Current or Regulated Voltage		Current	Current	Identical
Software/Firmware/Microprocessor Control?		Yes	Yes	Identical
Automatic Overload Trip		Yes	Yes	Identical
Automatic No-Load Trip		Yes	Yes	Identical
Automatic Shut Off		Yes	No	
User Override Control		Yes	Yes	Identical
Indicator Display:	**On/Off Status**	Yes	Yes	Identical
	Low Battery	Yes	Yes	Identical
	Voltage/Current Level	Yes	Yes	Identical to Philip
Timer Range (minutes)		1-59 minutes		The Livia has no interal timer, a minor difference, as there is no treatment time limitation for using the Livia—see Instructions for Use.
Compliance with Voluntary Standards?		IEC 60601-1, IEC 60601-1-2, IEC 60601-2-10, ISO 10993-5 and -10	IEC 60601-1, IEC 60601-1-2 IEC 60601-1-11 IEC 60601-2-10, ISO 10993-5 and -10	Identical
Compliance with 21 CFR 898?		Yes	Yes	Identical
Weight (g)		62 g	36 g	None, all devices are of hand-held weight
Dimensions (mm) (W x H x D)		2 units, each 54 x 54 x14	55 x 55 x 18	None, all devices are of hand-held size
Housing Materials and Construction		PC/ABS plastic	PC/ABS plastic	Identical

Table 3: Output Specification for TENS Mode Comparison Table

Parameter	**Primary Predicate Philips Consumer Lifestyle PulseRelief (K151035)**	**Livia**	**Significant Differences**
Waveform (e.g., pulsed monophasic, biphasic)	Biphasic, Symmetrical	Biphasic, Symmetrical	Identical
Shape (e.g., rectangular, spike)	Rectangular	Rectangular	Identical
Maximum Output Voltage (volts) (+/-10%)	50V @ 500Ω	50V @ 500Ω	Identical to the reference predicate NeuroMetrix
	100V @ 2kΩ	64V @ 2kΩ	Similar to both devices and within

				their range
		100V @ 10kΩ	64V @ 2kΩ	Similar; the maximum output voltage of the Livia, although slightly lower than the predicates, provides the required intensity for an effective treatment with lower risk of discomfort to the user due to high voltage
Maximum Output Current (mA) (+/-10%)		100mA @ 500Ω	50 mA @ 500Ω	Similar to both devices and within their range The Livia was designed to supply the minimum required output for providing an effective treatment. This in fact lowers the risk to the patient
		50mA @ 2kΩ	31mA @ 2kΩ	The Livia was designed to supply the minimum required output for providing an effective treatment. This in fact lowers the risk to the patient
		10mA @ 10kΩ	6.4mA @ 10kΩ	The Livia was designed to supply the minimum required output for providing an effective treatment. This in fact lowers the risk to the patient
Duration of primary (depolarizing) phase (usec)		100 µs	100 µs	Same as the reference predicate NeuroMetrix
Pulse Duration (both phases) (usec)		200µs, additional 30µs inter-phase delay	100 µs	Similar, within the range of the predicate devices
Frequency (Hz)		Random, mean 80Hz, uniform distribution 60-100Hz	100 Hz	Identical to **PulseRelief**
For multiphasic waveforms only:	**Symmetrical phases**	Yes	Yes	Identical
	Phase Duration (include units), (state range, if applicable), (both phases, if asymmetrical)	100µs (each phase)	100 µs	Identical to the reference predicate NeuroMetrix
Net Charge (microcoulombs (µC)		Nominally 0uC @ 500Ω,	0uC @ 500Ω	Identical to **PulseRelief**

per pulse) (If zero, state how this was achieved)		zero net current		
Maximum Phase Charge, (µC)		10 µC @ 500Ω	6.4 µC @ 500Ω	Similar and within the range of **PulseRelief**
Maximum Current Density, (mA/cm2, r.m.s.)		0.51 mA/cm2 @ 500Ω	0.38 mA/cm2 @500Ω	The minor differences are resulting from the minor spec difference as well as the difference in electrode area.
Maximum Average Current (average absolute value), mA		1.6 mA @ 500Ω	1.19 mW/cm2 @500Ω	Similar **PulseRelief**
Maximum Average Power Density, (W/cm2), (using smallest conductive surface area)		3.6 mW/cm2 @ 500Ω	2.05 mW/cm2 @500Ω	Similar **PulseRelief**
NBurst Mode; (i.e., pulse trains)	**(a) Pulses per N/A**	N/A	N/A	N/A
	(b) Bursts per second	N/A	N/A	N/A
	(c) Burst duration (seconds)	N/A	N/A	N/A
	(d) Duty Cycle: Line (b) x Line (c)	N/A	N/A	N/A

The candidate device is similar or very close to the predicate devices in its all major claims. The minor differences between predicate and candidate device do not affect the safety and effectiveness.

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

Non-clinical verification testing of the LIVIA device included electrical, mechanical, and software tests to show the device meets its design specifications. Validation and performance testing validates that the device meets its user needs. Verification and validation test results established that the device meets its intended use, that it is as safe, as effective, and performs as well as the predicate devices, and that no new issues of safety and effectiveness were raised. The LIVIA device was designed, verified, and validated according to the company's Design Control process and has been

subjected to extensive safety and performance testing as shown in the test results provided in this submission. Verification and Validation testing data demonstrate that the device meets all of its specifications including compliance with the following standards:

Safety :

- IEC 60601-1:2005/A1:202, EN 60601-1:2006/A1:2013
- EN 60601-2-10:2012/A1:2012
- IEC 60601-1-11:2015

EMC:

- IEC 60601-1-2:2007

Software:

- IEC 62304:2006

Biocompatibility:

- ISO 10993-5:2009
- ISO 10993-10:2010

Usability Study:

- IEC 62366-1: 2015

  The Livia device and its accompanying documentation, i.e., the IFU have met all usability specifications that were defined. No user errors or near errors were observed.

9. Discussion of Clinical Tests Performed:

Livia Inc. determined that bench and non clinical testing were sufficient to demonstrate that the LIVIA device is as safe and effective as the predicate devices.

10. Conclusions:

Livia is substantially equivalent in its intended use, performance, safety, effectiveness and underlying scientific and operating principal used, to the predicate devices.