May 4, 2020

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

Re: K183110
Trade/Device Name: Livia
Regulation Number: 21 CFR 882.5890
Regulation Name: Transcutaneous electrical stimulator for pain relief
Regulatory Class: Class II
Product Code: NUH
Dated: June 11, 2019
Received: March 3, 2020

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. 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 J. Pinto -S

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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K183110

Device Name
Livia

Indications for Use *(Describe)*
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. The Livia is also indicated for temporary relief of pain associated with dysmenorrhea (menstrual cramps) when used with over-the-counter pain medication.

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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Section 5: 510(K) SUMMARY

The assigned 510(K) Number: K183110

1. Submitter's Identification:

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

Date Summary Prepared: May 1, 2020

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:

LIVIA K163153

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 patient 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. The Livia is also indicated for temporary relief of pain associated with dysmenorrhea (menstrual cramps) when used with over-the-counter pain medications.

7. Comparison to Predicate Devices:

The Livia proposed device technological characteristics are identical to Livia K163153. The indications for use are the same except that the Indications for Use of the proposed device includes dysmenorrhea (menstrual cramps) as a kind of pain which may be treated by the device. In the User Manual of the predicate device, menstrual cramps are included as an appropriate use of the device, along with illustrations of electrode placement for such use. The purpose of the instant 510K is to include menstrual pain in the types of pain included in the Indications for Use, for the education of the consumer who may be searching for a product which is appropriate for that use, before or at the point of sale. While the predicate device already contains menstrual pain as a use of the device, LifeCare has conducted a clinical trial designed to show efficacy and safety in that indication. The report of this trial is included in this application, 020_Performance Testing-Clinical.

TABLE 1: Indication For Use Comparison Table

Comparison Tables – Technological Characteristics

Parameter	Proposed Device	Predicate Device LIVIA
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	The Livia is designed for symptomatic relief and management of chronic pain, and for temporary relief of pain associated with sore and aching

	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 for temporary relief of pain associated with dysmenorrhea (menstrual cramps). 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.	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.
Class	II	II
Product Code	NUH	NUH
Regulation Number	21 CFR 882.5890	21 CFR 882.5890

Table 2: Basic Unit Characteristics Comparison Table

Parameter	**Proposed Device**	**Predicate - Livia**	**Significant Differences**
510(k) Number		K163153	N/A
Device Name and Model Number	LIVIA	LIVIA	N/A
Manufacturer	Life Care Ltd	Life Care Ltd	N/A
Power Source(s)	3.7V Lithium-ion battery (rechargeable)	3.7V Lithium-ion battery (rechargeable)	Identical
Method of Line Current Isolation	Output is electrically disabled when connect to charger, by	Output is electrically disabled when connect to charger, by	Identical

		means of microprocessor charging circuit	means of microprocessor charging circuit	
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
Average DC current through Electrodes when device is on but no pulses are being applied (µA)		0 µA	0 µA	Identical
Number of Output Modes		1	1	Identical
Number of Output Channels:	**Synchronous or Alternating**	1	1	Identical
	Method of Channel Isolation	N/A	N/A	Identical
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
Timer Range (minutes)		The Livia has no internal timer, a minor difference, as there is no treatment time limitation for using the Livia—see Instructions for Use.	The Livia has no internal timer, a minor difference, as there is no treatment time limitation for using the Livia—see Instructions for Use.	Identical
Compliance with Voluntary Standards?		IEC 60601-1, IEC 60601-1-2, IEC 60601-2-10, ISO	IEC 60601-1, IEC 60601-1-2 IEC 60601-1-11 IEC 60601-2-	Identical

	10993-5 and -10	10, ISO 10993-5 and -10	
Compliance with 21 CFR 898?	Yes	Yes	Identical
Weight (g)	36g	36 g	Identical
Dimensions (mm) (W x H x D)	55 x 55 x 18	55 x 55 x 18	Identical
Housing Materials and Construction	PC/ABS plastic	PC/ABS plastic	Identical

Table 3: Output Specification for TENS Mode Comparison Table

Parameter		**Proposed Device**	**Predicate - 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
		64V @ 2kΩ	64V @ 2kΩ	Identical
		64V @ 2kΩ	64V @ 2kΩ	Identical
Maximum Output Current (mA) (+/-10%)		50 mA @ 500Ω	50 mA @ 500Ω	Identical
		31mA @ 2kΩ	31mA @ 2kΩ	Identical
		6.4mA @ 10kΩ	6.4mA @ 10kΩ	Identical
Duration of primary (depolarizing) phase (usec)		100 µs	100 µs	Identical
Pulse Duration (both phases) (usec)		100 µs	100 µs	Identical
Frequency (Hz)		100 Hz	100 Hz	Identical
For multiphasic waveforms only:	**Symmetrical phases**	Yes	Yes	Identical
	Phase Duration (include units), (state range, if applicable), (both phases, if asymmetrical)	100µs	100 µs	Identical
Net Charge (microcoulombs (µC) per pulse) (If zero, state how this was achieved)		0uC @ 500Ω	0uC @ 500Ω	Identical
Maximum Phase Charge, (µC)		6.4 µC @ 500Ω	6.4 µC @ 500Ω	Identical
Maximum Current Density, (mA/cm2, r.m.s.)		0.38 mA/cm2 @500Ω	0.38 mA/cm2 @500Ω	Identical
Maximum Average Current (average absolute value), mA		1.19 mW/cm2 @500Ω	1.19 mW/cm2 @500Ω	Identical
Maximum Average Power Density, (W/cm2), (using smallest conductive		2.05 mW/cm2 @500Ω	2.05 mW/cm2 @500Ω	Identical

surface area)				
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 only difference between the candidate and predicate devices is the addition of dysmenorrhea to the list of the examples of pain relieved and managed by the device. Otherwise, the candidate device is the same as the predicate devices in its major claims. The 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:

Not Applicable.
The proposed device is the same as the predicate device. Accordingly, no additional Non-Clinical tests are needed for the proposed device.

9. Discussion of Clinical Tests Performed:

A clinical study was performed to assess the efficacy of the Livia device in treating dysmenorrhea. The study, entitled "A Randomized, Controlled, Multi-Center, Crossover, Prospective, Double-blind Clinical Study to Assess the Effectiveness and Safety of Livia® Transcutaneous Electrical Nerve Stimulation (TENS) in Women Suffering from Primary Dysmenorrhea," was a randomized, controlled, multi-center, crossover, double-blind clinical study assessing the Livia® device in women suffering from primary dysmenorrhea. The study, conducted at four study sites, compared results from the Livia to a sham device. The trial evaluated the safety and efficacy of Livia vs. Sham using 65 Participants at 4 different sites.

Subjects in the study experienced a decline in pain as assessed by the Visual Analogue Scale (VAS).
The use of Livia succeeded in reducing the VAS score by an average of 28.1 points. The use of the Sham device reduced the VAS score by 17.6 points.
A statistically significant difference between Livia and the Sham device was observed ($P<0.0001$).
Most subjects used pain relief pills in all treatments and treatment sequences. The QoL score was higher in both sequence treatment groups compared to Baseline. The improvement in QoL was higher in sequence A (first Livia, then sham) compared to sequence B (first sham, then Livia).
Usability of the device received good scores by users and no technical problems were detected.

10. Conclusions:

LifeCare considers Livia to be equivalent to the predicate devices listed above. This conclusion is based upon the devices' similarities in principles of operation, technology, materials and indications for use.