December 15, 2023

TensCare Ltd
Saskia Eldridge-Hinmers
Regulatory Affairs Associate
9 Blenheim Road
Epsom, Surrey KT19 9BE
United Kingdom

Re: K230926
Trade/Device Name: Ova+ (K-OVAP-USA)
Regulation Number: 21 CFR 882.5890
Regulation Name: Transcutaneous Electrical Nerve Stimulator For Pain Relief
Regulatory Class: Class II
Product Code: NUH
Dated: November 13, 2023
Received: November 13, 2023

Dear Saskia Eldridge-Hinmers:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Doe W. Kumsa -S

for Pamela Scott, MS
Assistant Director
DHT5B: Division of Neuromodulation
and Rehabilitation 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)*
K230926

Device Name
Ova+ (K-OVAP-USA)

Indications for Use *(Describe)*
For Mode 0, Ova+ is indicated for temporary relief of pain associated with dysmenorrhea (menstrual cramps) when used with over-the-counter pain medication.

For Modes 1, 2& 3 Ova+ is indicated 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.

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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TensCare LTD.
PainAway House
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United Kingdom

510(k) SUMMARY

1. Submitters Identification

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Date Prepared: 15th November 2022

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Address of American Representative:
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Contact Last Name: BEDNAR
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BEAVER , PENNSYLVANIA , 15009 , UNITED STATES
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2. Subject Device

Manufacturer	: Tenscare Limited
Trade/Device Name	: Ova+ (K-OVAP-USA)
510(k) Number	: K230926
Device Classification Name	: Stimulator, Nerve, Transcutaneous, Over-the-counter
Common Name:	: Transcutaneous Electrical Nerve Stimulator for Pain Relief
Classification Name	: Stimulator, Nerve, Transcutaneous, Over-The-Counter
CFR Regulation Number	: 21 CFR 882.5890
Product Code	: NUH
FDA Device Classification	: Class II Medical Device
Device Type ID	3755
Device Definition	: TEMPORARY RELIEF OF PAIN DUE TO SORE/ACHING MUSCLES

3. Predicate Devices

3.1. Primary Predicate Device

Manufacturer	:Life Care Limited.
Trade/Device Name	:Livia
510(k) Number	:K183110
Device Classification Name	:Stimulator, Nerve, Transcutaneous, Over-the-counter
Regulation Description	:Transcutaneous Electrical Nerve Stimulator for Pain Relief
CFR Regulation Number	:21 CFR 882.5890
Product Code	:NUH
FDA Device Classification	:Class II Medical Device
Device Type ID	3755
Device Definition	: TEMPORARY RELIEF OF PAIN DUE TO SORE/ACHING MUSCLES

3.2. Secondary Predicate Device

Manufacturer	:TensCare Ltd
Trade/Device Name	:Perfect EMS_OTC
510(k) Number	:K200694
Device Classification Name	:Stimulator, Nerve, Transcutaneous, Over-the-counter, Powered muscle stimulator
Regulation Description	:Transcutaneous Electrical Nerve Stimulator for Pain Relief
CFR Regulation Number	:21 CFR 882.5890
Product Code	:NUH (Stimulator, Nerve, Transcutaneous, Over-The-Counter) NGX (Stimulator, Muscle, Powered, For Muscle Conditioning)
Classification Panel:	Neurology; Physical Medicine
FDA Device Classification	:Class II Medical Device

4. Device Description

The Ova+ is a non-invasive small and convenient unit that can be worn under clothing to provide safe, continuous, drug-free period pain relief whilst maintaining a normal, active lifestyle.

The device is battery powered, single channel home using Transcutaneous Electrical Nerve Stimulation (TENS).
The device is supplied with self-adhesive electrodes which connect to the control unit by cable and plug and are placed on patients' intact skin by the end user. Electrical stimulation is delivered via these self-adhesive electrodes to superficial nerves.

The unit is intended for home use by the patient and is designed with simplicity and ease of use in mind. It has four preset treatment Modes. The level of electrical stimulation of Ova+ is easily controlled by the end user using manual, push-button controls.

The new device Ova+ uses the same technical principle and substantially equivalent stimulation parameters to the marketed device Livia (K183110) and/or reference predicate device Perfect EMS (K200694)

The Ova+ uses a rechargeable Li-Ion polymer battery and a custom TENS connecting lead with 2mm connecting pins.

The Ova+ is supplied with adhesive electrodes that are similar to those of the predicate devices.

5. Indication For Use/Intended Use

For Mode 0, Ova+ is indicated for temporary relief of pain associated with dysmenorrhea (menstrual cramps) when used with over-the-counter pain medication.

For Modes 1, 2& 3 Ova+ is indicated 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.

Intended Use
The Ova+ is intended for use in the home.
It should be used only by women aged 18 and above.

6. Indication for Use comparison

TABLE 1: Indication For Use Comparison Table

Characteristic	New Device Ova+	Primary Predicate Device Livia	Secondary Predicate Device Perfect EMS OTC
Manufacturer	Tenscare Limited	Life Care Ltd.	TensCare Ltd
510(k) No.	K230926	K183110	K200694
Indications for Use	For Mode 0, Ova+ is indicated for temporary relief of pain associated with dysmenorrhea (menstrual cramps) when used with over-the-counter pain medication. For Modes 1, 2& 3 Ova+ is indicated 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 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.	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), lower extremities (leg), abdomen and bottom due to strain from exercise or normal household work activities
Intended Users	The Ova+ is intended for use in the home. It should be used only by women aged 18 and above.	Livia should be used only by women aged 18 and above.	Keep away from children
Class	II	II	II
Product code	NUH	NUH	NUH
Regulation number	21 CFR 882.5890	21 CFR 882.5890	21 CFR 882.5890
OTC Use	Yes	Yes	Yes
Single Use or Reusable	Reusable For single patient use	Reusable For single patient use	Reusable For single patient use

The Indication for Use of the Ova+ is identical with that of the primary predicate device Livia

7. Technological comparison

Table 2: Basic Unit Characteristics Comparison Table

Characteristic	New Device	Primary Predicate Device	Secondary Predicate Device	Comparison
Device Name/Model	**Ova+**	**Livia**	**Perfect EMS**	
510(k)	K230926	K183110	K200694	
Manufacturer	TensCare Ltd	LifeCare Ltd.	TensCare Ltd	
Power Source(s)[1]	3.7V Lithium ion battery(rechargeable)	3.7V Lithium ion battery(rechargeable)	2 x AA alkaline battery	Internal power source Substantially Equivalent.
Method of Line current Isolation	Not possible to connect patient lead and charger at same time – use same socket	Output is electrically disabled when connect to charger, by means of microprocessor charging circuit	No connection to Line Current	Substantially Equivalent.
Patient Leakage Current - Normal Condition (µA)	Battery powered (< 10µA)	Battery powered (< 10µA)	Battery powered (< 10µA)	Identical
Patient Leakage Current - Single Fault Condition (µA)	Battery powered (< 50µA)	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	0 µA	Identical with primary predicate
Number of Output Modes	4 1 Dysmenorrhea & 3 Pain	1 Dysmenorrhea	1 Pain	Substantially equivalent
Number of Output Channels	1	1	2	Identical with primary predicate
Regulated Current or Voltage?	Voltage	Current	Voltage	Substantially Equivalent.
Software/Firmware/ Microprocessor Control?	Yes	Yes	Yes	Identical
Automatic No-Load Trip?	No	Yes	Yes	Substantially Equivalent.
Automatic Overload Trip?	No	Yes	Yes	Substantially Equivalent.
Automatic Shut Off?	No	No	Yes	Identical

Characteristic	New Device	Primary Predicate Device	Secondary Predicate Device	Comparison
Device Name/Model	**Ova+**	**Livia**	**Perfect EMS**	
User Override Control?	Yes	Yes	Yes	Substantially Equivalent.
Indicator Display: -On/Off status -Low battery -Voltage/Current level -Time to cut-off	 Yes Yes Yes	 Yes Yes Yes	 Yes Yes Yes	Identical
Timer Range (minutes)	No Timer	The Livia has no internal timer	20-40	Identical with primary predicate
Compliance with Voluntary Standards?	IEC 60601-1, IEC 60601-1-2 IEC 60601-2-10 IEC 60601-1-11 IEC 62304 ISO 14971 IEC 60601-1-6 IEC 62366-1	IEC 60601-1, IEC 60601-1-2, IEC 60601-2-10, ISO 10993-1, -5 and -10	IEC 60601-1:2005 IEC 60601-1-2 IEC 60601-2-10 IEC 60601-1-11 IEC 62304 ISO 14971	Substantially Equivalent.
Compliance with 21 CFR 898?	Yes	Yes	Yes	Identical
Weight g	19.5	37	146.5	Similar
Dimensions (mm)	65 x 38 x 10	55X 55 X 20	66×136×30.7	Similar
Housing Materials and Construction	Silicone, ABS plastics	ABS plastics	ABS plastics	Substantially Equivalent.
Sterilization	N/A	N/A	N/A	Identical

Table 3: Comparison of output specifications

Parameter	New Device	Primary Predicate Device	Secondary Predicate Device	Comparison
Device Name/Model	**Ova+**	**Livia**	**Perfect EMS OTC**	
510(k)	K230926	K183110	K200694	
Manufacturer	TensCare Ltd	LifeCare Ltd.	TensCare Ltd	
Waveform	Biphasic, Equal duration	Bi-phasic, Symmetrical	Biphasic Equal duration	
Shape	Rectangular	Rectangular	Rectangular	
Maximum Output Voltage (V) 500 ohm 2k ohm 10k ohm	 26V 28V 29V	 50V 64V	 50V 90V 125V	Substantially Equivalent
Maximum Output Current (mA) 500 ohm 2k ohm 10k ohm	 52mA 28mA 3mA	 50mA 31mA 6.4mA	 100mA 45mA 12.5mA	Substantially Equivalent
Dysmenorrhea Mode				
Pulse Width (μs)	100μs,	100μs		Substantially Equivalent
Frequency(Hz)	110Hz	100Hz		Substantially Equivalent
Pain Modes 1,2&3				
Pulse Width (μs)	50μs, 100μs, 150μs, 200μs		TENS 50-250μs, in steps of 50μs	Substantially Equivalent
Frequency(Hz)	10 Hz, 100Hz, 110Hz		TENS From 1Hz to 120Hz	Substantially Equivalent
Net Charge (μC per pulse) at 500Ω	2.24μC	0	1 μC	Similar.
Maximum Phase Charge, (μC)	9.6μC	6.4μC	20.5μC	Substantially Equivalent
Maximum Current Density[6], (mA/cm²)	0.175 Surface= 45cm²	0.38	0.01013mA/cm2	Substantially Equivalent
Maximum Power Density[6], (mW/cm²)	0.693 Surface= 45cm²	2.05	0.53mW/ cm2 Surface= 25cm²	Substantially Equivalent

8. Summary of Technological Characteristics Compared to the Predicate Devices

- **Basic Design Features and Technological Characteristics (7. Table 2)**
  Comparison Tables 1 above summarizes the shared and unique technological elements between the Ova+, Livia (K183110), and Perfect EMS OTC (K200694).

- Output Regulation (Regulated Current or Voltage?)
  The stimulation current required for TENS depends on electrode position and the individual patient's nervous system. To deliver appropriate substantially equivalent stimulation, TENS intensity must be controlled in accordance with the patient's sensation..

  With regard to safety, there is little difference between the two control methods. Constant current would give a slightly higher risk of burn due to current density changes with detaching electrode if the maximum voltage were not limited.

- **Safety Features - Automatic No-Load Trip and Automatic Overload Trip**

  The main risks caused by short circuit are
  a. Damage to device causing it not to function correctly.
     Ova+ is not damaged by short circuit. Additionally, the device does not perform any clinical functions whose loss or degradation would present an unacceptable clinical risk, and improper device function caused by a short circuit would not foreseeably result in any greater risk to the patient than the occurrence of a short circuit in the predicate device.

  b. Overheating causing fire or injury.
     The single fault test in the provided evidence of testing to IEC 60601-1 showed that even short-circuiting the battery does not generate hazardous temperatures.

  Although Ova+ does not incorporate automatic no-load and overload trips, the intrinsic safety of its design assures that the is no adverse effect on safety or effectiveness.

- **Accessories and biocompatibility**
  Ova+ uses single patient use, disposable skin electrodes (510(k) number K210448) that connect to a patient lead. Livia uses a reusable electrode with integral lead, and a disposable gel pad.
  The method of delivery of stimulation, type of conductive medium, and biocompatibility requirements are the same for both devices.

The skin electrodes are the only components intended for skin contact for more than one hour.

The skin-contacting material in the electrodes is a Hydro-gel whose main ingredients are Distilled water, Medical glycerin and Sodium Chloride.

Biocompatibility – and thus, substantial equivalence – of the electrodes was determined via the declaration of identical skin- contacting materials relative to the E-CM5090 electrodes 510(k)-cleared under K210448, for which biocompatibility testing was conducted according to ISO 10993-1, -5, and -10.

- **Power Supply.** All three devices are battery operated. Ova+ and Livia have internal rechargeable lithium ion batteries, but this difference has no effect on safety or efficacy.

- **Performance Characteristics (7. Table 3)**
  The stimulation parameters of the new device Ova+ are similar to those of primary predicate device Livia (K183110) and Secondary Predicate device Perfect EMS OTC (K200694).

- Ova+ has 4 modes, the first of these, Mode 0 for Dysmennorrhea, uses parameter settings that are very close to those of the primary predicate device Livia (K183110) and are substantially equivalent.

- The parameters of Ova+ Modes 1-3 for general pain are in the same range as Secondary Predicate device Perfect EMS OTC (K200694) when used for temporary relief of pain associated with sore and aching muscles.

The results of bench testing show that the performance characteristics of the subject device are substantially equivalent to those of the predicate devices Livia (K183110) and Perfect EMS (K200694), with any differences limited to minor differences in design and performance that do not raise any new questions of safety or effectiveness.

9. Human Factors

- **Electrode positioning**
  The electrode positioning of the Ova+ device Mode 0 is from side to side on the front of the pelvis or the lower back and is substantially equivalent with the electrode positioning of the primary predicate device Livia (K183110)

  The secondary predicate device Perfect EMS (K200694) used a general-purpose TENS electrode positioning guidance insert. The Ova+ device Modes 1,2 &3 use a reduced version of this, with all positions taken from the original guidance document. These positions are identical, and therefore substantially equivalent with, the electrode positioning of the secondary predicate device Perfect EMS (K200694)

- **Contraindications, Cautions and warnings** are identical and thus substantially equivalent

- **Usability Study.** Tenscare has conducted a Usability Study according to ISO 62366.

OTC users were able to adequately understand the instructions and to use the device as intended. There is no evidence that the small differences from the predicate device in technical operation raise additional concerns to operation of the Ova+.

10. Summary of Non-Clinical Performance Testing as Basis for Substantial Equivalence

The Ova+ was tested to provide data for Table 3: Comparison of output specifications for comparison with data provided in the Livia 510(k) Summary and Perfect EMS 510(k) Summary. A current production model of the Livia was also tested using the same test instruments for a direct comparison.

Results summary is shown in the comparison tables above.

Both Subject and Predicate devices are provided non-sterile, have comparable operations and technology. The design of Ova+ does not introduce any new risks

The new device Ova+ and the marketed devices Livia (K183110) and Perfect EMS (K200694) are certified to comply with same applicable recognized consensus standards for medical device electrical safety, EMC safety, nerve stimulators, and home use as shown in Compliance with Voluntary Standards row in Table 2 above.

Softrware verification testing on 10 OVA+ prototypes demonstrated that the software of Ova+ meets the requirements of the specifications.

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Tenscare has made a detailed comparison of Human Factors between the new device and the primary and secondary predicate devices and concluded that they are substantially equivalent.

They also conducted a Usability Study according to ISO 62366.
“Both the FORMATIVE EVALUATION and SUMMATIVE EVALUATION conclude that the LAY OPERATOR requires limited training to intervene and maintain BASIC SAFETY and ESSENTIAL PERFORMANCE with the Ova+ device.”

11. Summary of Clinical Testing as Basis for Substantial Equivalence

No clinical testing was considered necessary for the Ova+ subject device.

The primary predicate device Livia (K183110) obtained clearance as an over-the-counter TENS device that included the temporary relief of menstrual pain within its Indications for Use based on clinical performance data.

The predicate device’s manufacturer (LifeCare Ltd.) conducted a clinical trial designed to show the safety and effectiveness of the Livia device for the indication of temporary relief of pain

associated with dysmenorrhea (menstrual cramps) when used with over-the-counter pain medication.

11 Conclusion

No clinical tests were performed.

The nonclinical bench tests demonstrate that the device is as safe, as effective, and performs as well as or better than the legally marketed predicate devices listed above.

This conclusion is based upon the devices' similarity in principles of operation, technology, materials, and indications for use.