June 4, 2021

TensCare Ltd.
Andrew Brown
Quality Manager
9 Blenheim Road, Longmead Business Park
Epsom, Surrey KT19 9BE
United Kingdom

Re: K200694
Trade/Device Name: Perfect EMS
Regulation Number: 21 CFR 882.5890
Regulation Name: Transcutaneous Electrical Nerve Stimulator for Pain Relief
Regulatory Class: Class II
Product Code: NUH, NGX
Dated: May 1, 2021
Received: May 17, 2021

Dear Andrew Brown:

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, Sub part 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,

Heather Dean, PhD
Assistant Director, Acute Injury Devices Team
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K200694

Device Name
Perfect EMS

Indications for Use *(Describe)*
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.

EMS: The device is designed 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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510(k) Summary

K200694

Date of Subimission prepared: March 5, 2020

I Submitter

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II Submitted Device:

Trade name:	Perfect EMS
Common name:	Transcutaneous Electrical Nerve Stimulator (TENS) / Electrical Muscle Stimulator (EMS)
Classification Number:	21 CFR 882.5890; 21 CFR 890.5850
Classification name:	Transcutaneous electrical nerve stimulator for pain relief; Powered muscle stimulator
Product Code:	NUH (Stimulator, Nerve, Transcutaneous, Over-The-Counter); NGX (Stimulator, Muscle, Powered, For Muscle Conditioning)
Classification Panel:	Neurology; Physical Medicine
Regulatory Class:	Class II

III Predicate Device:

Predicate Device:
Trade/Device Name: HIVOX OTC Electrical Stimulator
Model Number: EM49-2
Manufacturer: HIVOX BIOTEK INC.
510(k) Number: K190347
Product Code: NUH, NGX
Type of Use: Over-The-Counter Use (OTC Use)
Regulatory Class: Class II

IV Device Description:

Perfect EMS is a hand-held, home-use device designed to relief of pain and improve and facilitate muscle performance. Perfect EMS is intended for over-the-counter use.

The device is battery powered, two channels home use neuromuscular stimulation. 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 self-adhesive electrodes to nerves and muscles.

The level of electrical stimulation is easily controlled by the end user using manual, push-button controls.

The unit is intended for home use by the patient, and is designed with simplicity and ease of use in mind. It has six preset treatment programs and four manually adjustable programmes are available.

Accessories:
2 x 1.25m PVC Lead Wires (L-CPT)
50x50mm hydrogel electrode pads (E-CM5050)

Optional accessories:
50x100mm Large hydrogel electrode pads Pack of 4 (E-CM50100)

ENVIRONMENT OF USE: Clinics, hospital and home environments

V Indications for Use of the device:

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.

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

The Perfect EMS is intended for OTC use.

The indications for use of the Perfect EMS are the same as those of the predicate device HIVOX OTC Electrical Stimulator Model: EM49-2 (K190347).

VI Equivalence Comparison to the Predicate Devices:

Electrical nerve and muscle stimulation is the technological principle for both the Perfect EMS and the predicate device EM49-2 (K190347).

The technical characteristics of Perfect EMS are similar to those of the predicate device in design, intended use and function. The predicate device EM49-2 (K190347) and the Perfect EMS are devices apply an electrical current via electrodes to a patient's nerves and muscles.

The stimulation parameters of Perfect EMS are similar to those of predicate device EM49-2 (K190347). Perfect EMS totally has 10 programs, the parameter of Perfect EMS are all in the same range of those of predicate device EM49-2 (K190347).

Table 1 below summarizes the shared and unique technological elements between the Perfect EMS and EM49-2 (K190347). The technology, engineering, and performance for Perfect EMS are substantially equivalent to the predicate device.

From the view of safety and effectiveness, the output characteristics of Perfect EMS are similar to those of predicate device EM49-2 (K190347), see Table 1. The Perfect EMS is designed to comply with relevant safety applicable recognized consensus standards; the output energy is controlled well within the safety and effectiveness ranges specified by relevant FDA guidance. Detailed and strictly controlled testing has been carried out. The maximum power density of Perfect EMS is less than 0.25 watts per square centimeter of electrode conductive surface area to reduce the risk of thermal burns. Furthermore, Test results, Risk Analysis, and FMEA analysis show that the Perfect EMS is safe with no hazard.

As such:
1. the Perfect EMS has similar technological characteristics and intended uses as the predicate EM49-2 (K190347); and
2. the information submitted to the FDA for the Perfect EMS does not raise new questions about safety or effectiveness and demonstrates with reasonable assurance based on established controls that the device is at least as safe and effective as a legally marketed device.

Table 1 Substantial Equivalence Comparison Table

Attribute	Subject Device	Predicate Device	Comparison
Product Name	Perfect EMS	EM49-2	
510(K) number	K200694	K190347	
Product Code	NUH, NGX	NUH, NGX	Identical codes; Substantially equivalent
Regulation No.	21 CFR 882.5890; 21 CFR 890.5850	21 CFR 882.5890; 21 CFR 890.5850	Identical; Substantially equivalent
Manufacturer	TensCare Ltd	HIVOX BIOTEK INC.	
Indications for Use	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. EMS: The device is designed to be used for stimulate healthy muscles in order to improve and facilitate muscle performance.	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. EMS: The device is designed to be used for stimulate healthy muscles in order to improve and facilitate muscle performance.	Same indications for use; Substantially equivalent
Prescriptive or OTC	OTC	OTC	Identical; Substantially equivalent
Number of output modes	10	70*	Substantially equivalent
Number of output channels	2	2*	Substantially equivalent
Timer Range (minutes)	Default 20 minutes. Adjustable to 10, 20, 30, 45, 60, 90 minutes	Default 30 minutes. Adjustable from 5 to 100 minutes*	Both are adjustable; Substantially Equivalent
Regulated Current or Regulated Voltage?	None	None*	Substantially Equivalent.

Attribute	Subject Device	Predicate Device	Comparison
Software/Firmware/ Microprocessor Control?	Yes	Yes *	Identical control method
Automatic No-Load Trip?	Yes	Yes*	Identical
Automatic Overload Trip?	Yes	Yes*	Identical
Automatic Shut Off?	Yes	Yes*	Identical
User Override Control?	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*	Identical
Frequency (Hz)	1-120Hz	1-150Hz*	Substantially equivalent
Pulse Width (μs)	50-350μs	50-450μs*	Substantially equivalent
Waveform	Bi-phasic	Bi-phasic*	Identical
Shape	Rectangular	Rectangular*	Identical
Maximum Output Voltage (V)	50V@ 500Ω	50V@ 500Ω*	Substantially equivalent
Maximum Output Current (mA)	100mA@ 500Ω	100mA@ 500Ω*	Substantially equivalent
Maximum Phase Charge (μC)	20.5μC@ 500Ω	37.6μC@ 500Ω*	Substantially equivalent
Maximum Current Density, (mA/cm²)	0.01013mA/cm²@ 500Ω (Area=25cm^2)□	0.07426mA/cm²@ 500Ω* (Area=20.25cm^2)□	Substantially equivalent
Maximum Power Density, (W/cm²)	0.00053W/cm²@ 500Ω (Area=25cm^2)□	0.0066W/cm²@ 500Ω* (Area=20.25cm^2)□	Substantially equivalent
Power Source	2 Alkaline AA 1.5V Batteries	3 Alkaline AAA 1.5V Batteries	Both are internal power supply source; Substantially equivalent
Weight	120 x 60 x 31mm	132 x 63 x 29.5 mm*	Substantially Equivalent.
Dimensions (mm) [W x H x D]	75 g without batteries	83 g without batteries*	Substantially Equivalent.
Housing Materials and Construction	Silicone, ABS plastics	ABS plastics *	Substantially Equivalent.
Electrode lead wires and patient cable	Yes (PVC and nylon yarn)	Yes* PVC	Substantially equivalent

Attribute	Subject Device	Predicate Device	Comparison
compliance with 21 CFR 898			
Compliance with Voluntary Standards	Yes See section 1.3	Yes* See section 1.3	Substantially equivalent

Remark: The information marks with * means the information is not publicly available

VII Performance Tests:

A series of safety and performance tests were conducted on the subject device Perfect EMS See below:

FDA recognition No.	Standard Title
19-4	ANSI AAMI ES60601-1:2005/(R)2012 and A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012 (Consolidated Text) Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005, MOD)
19-8	IEC 60601-1-2 Edition 4.0 2014-02 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
19-14	IEC 60601-1-11 Edition 2.0 2015-01 Medical electrical equipment - Part 1-11: General requirements for basic safety and essential performance - Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment.
17-16	IEC 60601-2-10 Edition 2.1 2016-04 Medical electrical equipment - Part 2-10: Particular requirements for the basic safety and essential performance of nerve and muscle stimulators
13-79	IEC 62304 Edition 1.1 2015-06 CONSOLIDATED VERSION Medical device software - Software life cycle processes
2-220	ANSI AAMI ISO 10993-1:2009/(R)2013 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process Three biocompatibility tests conducted: - Cytotoxicity (per ISO 10993-5) - Sensitization (per ISO 10993-10) - Irritation (per ISO 10993-10)

All the test results demonstrate Perfect EMS meets the requirements of its pre-defined acceptance criteria and intended use, and is substantially equivalent to the predicate device.

VII Conclusion:

- The Perfect EMS has the same technological characteristics and intended uses as the predicateEM49-2 (K190347); and
- The labelling of the Perfect EMS is concordant with the predicate device and FDA requirements; and
- The information submitted to the FDA for the Perfect EMS does not raise new questions about safety or effectiveness and demonstrates with reasonable assurance based on established controls that the device is at least as safe and effective as a legally marketed device.

Therefore, the Perfect EMS is substantially equivalent to the predicate device.