Shenzhen Leading Perfection Technology Co., Ltd
℅ Rain Yip
Registered Engineer
Feiying Drug & Medical Consulting Technical Service Group
Rm. 3005, Area B, Bldg.1, Southward Ruifeng Business Center,
Guimiao Road
Shenzhen, Guangdong 518000 CN

Re: K183674
Trade/Device Name: Electronic Pulse Stimulator, Model S3
Regulation Number: 21 CFR 882.5890
Regulation Name: Transcutaneous Electrical Nerve Stimulator For Pain Relief
Regulatory Class: Class II
Product Code: NUH. NGX
Dated: March 30, 2019
Received: September 9, 2019

Dear Rain Yip:

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,

For Vivek Pinto, PhD
Director (Acting)
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)*
K183674

Device Name
Electronic Pulse Stimulator (Model: S3)

Indications for Use *(Describe)*

Mode 1 (PMS):
To be used for stimulating healthy muscles in order to improve and facilitate muscle performance.

Mode 2 (TENS):
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

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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# 510(k) Summary

**"510(K) Summary" as required by 21CFR 807.92.**

**Date: 2019-01-25**

## I. Submitter

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## II. Device

Type of 510(k): Traditional
Common Name: Powered muscle stimulator
Trade Name: Electronic Pulse Stimulator
Model: S3
Classification Name: Transcutaneous electrical nerve stimulator for pain relief
Review Panel: Neurology
Regulatory Class: II
Product Code: NUH, NGX
Regulation Number: 21 CFR 882.5890

## III. Predicate Device

| Applicant | Predicate Device | 510(k) Number | Approval Date |
|---|---|---|---|
| Philips Consumer Lifstyle | (Primary): PulseRelief | K151035 | July 21,2015 |
| HIVOX BIOTEK INC. | HIVOX OTC Electrical Stimulator /SEM44 | K171803 | November 29, 2017 |
| Shenzhen OSTO Technology Company Limited | Health Expert Electronic Stimulator, Model AST-300C and AST-300D | K133929 | November 12, 2014 |

## IV. Device Description

Electronic Pulse Stimulator is a product that adopts modern electronic science and technology to delivers electric pulses generated to the user's skin through the electrodes. It has two modes of different pulse frequencies, mode 1 uses Electrical Muscle Stimulation (EMS) technology for muscle training and mode 2 uses Transcutaneous Electrical Nerve Stimulation (TENS) technology to temporary relieve pain. The device includes operating elements of Power ON/OFF button, intensity increase"+" button, and intensity decrease"-" button and Mode selection button, and could be attached and detached to the electrode pad through the snap-on connector.

In additional, according to different simulation-needed bodies, users can choose the four types of electrode pad based on their own situation. Electronic Pulse Stimulator is suitable for the simulation-needed bodies including hips, arms and legs, abdomen, and feet.

## V. Indications for Use

Mode 1 (PMS): To be used for stimulating healthy muscles in order to improve and facilitate muscle performance.
Mode 2 (TENS): To be used for temporary relief of pain associate 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.

## VI. Comparison of Technological Characteristics With the Predicate Devices

The Electronic Pulse Stimulator is substantially equivalent to the predicate devices based on intended use, design, specifications and performance.
The Electronic Pulse Stimulator raises no safety or efficacy concerns when compared to the following predicate devices.
Information for predicate device was obtained from publicly available sources, including the 510(k) Summary and device instruction manual. A technical comparison to the predicate is provided below:

| **Comparison Elements** | **Subject Device** | **(Primary) Predicate Device** K151035 | **Predicate Device K171803** | **Predicate Device K133929** | **Comparison** |
|---|---|---|---|---|---|
| Trade Name/Model | Electronic Pulse Stimulator/S3 | PulseRelief | HIVOX OTC Electrical Stimulator/SEM44 | Health Expert Electronic Stimulator, Model AST-300C and AST-300D | / |
| 510(k) Number | To be assigned | K151035 | K171803 | K133929 | / |
| Manufacturer | Shenzhen Leading Perfection Technology Co., Ltd | Philips Consumer Lifsty | HIVOX BIOTEK INC. | Shenzhen OSTO Technology Company Limited | / |
| Regulation Number | 21CFR 882.5890 | 21CFR 882.5890 and 890.5850 | 21CFR 882.5890 | 21 CFR 882.5890 | SE |
| Device Class | II | II | II | II | SE |
| Product Code | NUH, NGX | NUH, NGX | NUH, NGX | NUH, NGX | SE<br>NOTE 1 |
| Indication for Use/Intended Use | Mode 1(PMS): To be used for stimulating healthy muscles in order to improve and facilitate muscle performance.<br><br>Mode 2(TENS): To be used for temporary relief of pain associate with sore and aching muscles in the shoulder, waist, back, neck, upper extremities (arm), lower | 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 | SEM44 (EMS): The device is designed to be used for stimulate healthy muscles in order to improve and facilitate muscle performance.<br><br>SEM44 (TENS): The device is designed to be used for temporary relief | PMS (Mode 1~8)<br>It is intended to stimulate healthy muscles in order to improve and facilitate muscle performance.<br><br>TENS (Mode 9~25)<br>To be used for temporary relief of pain associated with sore and aching muscles in | SE<br>NOTE 1 |

| | | | | | |
|---|---|---|---|---|---|
| | extremities (leg), abdomen and bottom due to strain from exercise or normal household work activities | | | | |

| **Comparison Elements** | **Subject Device** | **(Primary) Predicate Device** K151035 | **Predicate Device K171803** | **Predicate Device K133929** | **Comparison** |
|---|---|---|---|---|---|
| | | lower extremities (leg) due to strain from exercise or normal household work activities.<br><br>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. | 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. | the shoulder, waist, back, back of the neck, arm, leg, and foot due to strain from exercise or normal household work activities by applying current to stimulate nerve. | |
| Shape of electrodes | Rectangle | Square | Unknown | Rectangle | SE |
| Anatomical application | Arm, leg, abdomen, hip, feet | Shoulder, waist, back, upper extremities (arm), and lower extremities (leg) | Shoulder, waist, back, neck, upper extremities (arm), lower extremities (leg), abdomen and bottom | Shoulder, waist, back, back of the neck, arm, leg, and foot | SE |
| Applicable People | Adults | Adults | Adults | Adults | SE |
| Location for Use | OTC | OTC | OTC | OTC | SE |
| **Basic Unit Characteristics** | | | | | |

| **Comparison Elements** | | **Subject Device** | **(Primary) Predicate Device** K151035 | **Predicate Device K171803** | **Predicate Device K133929** | **Comparison** |
|---|---|---|---|---|---|---|
| Power Supply | | USB rechargeable battery, 3.7V | Li-ion 3.7V 500mAH | 4.5V (batteries, 3×1.5V AAA) | Adaptor Input: 100-240Vac, 50-60Hz, 0.1A<br>Output: 5Vdc, 1A<br>Unit Input: 5Vdc, 1A | SE<br>NOTE 2 |
| Method of Line Current Isolation | | N/A | N/A | N/A | Type BF Applied Part | SE |
| Patient Leakage Current | Normal Condition | < 0.1 | <10μA | N/A | AC: 54.5μA, DC: 0.5μA | SE |
| | Signal Fault Condition | N/A | <50μA | N/A | AC:120.0μA,<br>DC: 0.6μA | SE |
| Number of Output Modes | | 2 (1 TENS and 1 EMS) | EMS: 5<br>TENS:15 | EMS: 35<br>TENS:15 | EMS: 8<br>TENS:17 | SE<br>NOTE 2 |
| Number of Output Channels | | 1 | 1 | 2 | 2 | SE<br>NOTE 2 |
| Synchronous or Alternating? | | N/A | N/A | Synchronous | Synchronous | SE |
| Method of Channel Isolation | | N/A | N/A | By electrical circuit and software | Voltage Transform Isolation<br>“BODY▼” and<br>“ BODY▼” buttons for body channel,<br>“ SOLE▲” and<br>“SOLE▼” buttons for feet channel | SE |

| **Comparison Elements** | | **Subject Device** | **(Primary) Predicate Device** K151035 | **Predicate Device K171803** | **Predicate Device K133929** | **Comparison** |
|---|---|---|---|---|---|---|
| Software /Firmware /Microprocessor Control? | | Yes | Yes | Yes | Yes | SE |
| Automatic Overload Trip? | | Yes | Yes | Yes | No | SE |
| Automatic No-Load Trip? | | Yes | Yes | Yes | No | SE |
| Automatic Shut OFF? | | Yes | Yes | Yes | Yes | SE |
| Patient Override Control? | | Yes | Yes | Yes | Yes | SE |
| Indicator Display | On/Off Status? | Yes | Yes | Yes | Yes | SE |
| | Low Battery? | Yes | Yes | Yes | No | SE |
| | Voltage/ Current Level? | No | Yes | Yes | Yes | SE |
| Timer Range | | 25 minutes | 1~59minutes and continuous | 5~100minutes | 25 minutes | SE<br>NOTE 2 |
| Compliance with Voluntary Standards? | | IEC60601-1-2<br>IEC60601-1<br>IEC60601-11 | IEC60601-1-2<br>IEC60601-1<br>IEC60601-2-10 | IEC60601-1-2<br>IEC60601-1<br>IEC60601-2-10 | IEC60601-1-2<br>IEC60601-1<br>IEC60601-2-10 | SE |

| **Comparison Elements** | | **Subject Device** | **(Primary) Predicate Device** K151035 | **Predicate Device K171803** | **Predicate Device K133929** | **Comparison** |
|---|---|---|---|---|---|---|
| | | IEC60601-2-10<br>ISO10993-5/10 | ISO10993-5/10 | ISO10993-5/10 | ISO10993-5/10 | |
| Compliance with 21CFR898 | | Yes | Yes | Yes | Yes | SE |
| Weight | | 14.5g(with battery) | 62g (excl. electrodes) | 89g (including belt clip, without batteries)<br>123g (including belt clip, and batteries) | 2Kg (Without accessories) | SE<br>NOTE 3 |
| Dimensions | | Φ4.2cm×1.38cm | 54×54×14mm (unit) | 132 x 63 x 29.5mm(including belt clip) | 428mm x 428.8mm x 185mm | SE<br>NOTE 3 |
| Housing Materials and Construction (Main unit) | | ABS | ABS, PC | ABS | ABS | SE |
| **Output Specifications** | | | | | | |
| Waveform | | Symmetrical rectangular | Biphasic, rectangular | Biphasic, square | Pulsed, symmetric, Biphasic, Rectangular, | SE<br>NOTE 4 |
| Maximum Output Voltage (Volts, | @500Ω | 40±20% | 31±20% | 100±10 % (50±10 %(Vp)) | 44±10% | SE<br>NOTE 4 |
| | @2kΩ | 64±20% | 69±20% | 180±10 % (90±10 %(Vp)) | 80±10% | SE<br>NOTE 4 |

| **Comparison Elements** | | **Subject Device** | **(Primary) Predicate Device** K151035 | **Predicate Device K171803** | **Predicate Device K133929** | **Comparison** |
|---|---|---|---|---|---|---|
| Vp) | @10kΩ | 76±20% | 70±20% | 250±10 % (125±10 %(Vp)) | 112±10% | SE NOTE 4 |
| Maximum Output Current (mA) | @500Ω | 80±20% | 62±20% | 200±10 % (100±10 %(Ip)) | 88±10% | SE NOTE 4 |
| | @2kΩ | 32±20% | 34±20% | 90±10 % (45±10 %(Ip)) | 40±10% | SE NOTE 4 |
| | @10kΩ | 7.6±20% | 7±20% | 25±10 % (12.5±10 %(Ip)) | 11.2±10% | SE NOTE 4 |
| Pulse Width | | 200μs | TENS: 60~350μs<br>EMS: 150~350μs | 50-450μs | 120μs | SE NOTE 4 |
| Frequency (Hz) | | Mode 1: 4-35Hz<br>Mode 2: 4-41Hz | TENS: 1~100Hz<br>EMS: 45~65Hz | 1-150Hz | 77.3Hz | SE NOTE 4 |
| Maximum Phase Charge (μC) @500Ω | | 22.31 | TENS: 1.6~6.8<br>EMS: 4.7~10.9 | 0.045 | 12.78μC @ 500Ω | SE NOTE 4 |
| Maximum Current Density ($mA/cm^2$) @500Ω | | Hips pad: 0.079<br>Arms and legs pad: 0.104<br>Abdomen pad: 0.111<br>Feet pad: 0.016 | TENS: 0.002~0.045<br>EMS: 0.019~0.037 | 0.667 | 0.235mA/cm² @ 500Ω | SE NOTE 4 |
| Maximum Power Density ($W/cm^2$) @500Ω | | Hips pad: 0.0001<br>Arms and legs pad: 0.0002<br>Abdomen pad: 0.0002 | (average)<br>TENS: 0.24~1.69<br>EMS: 0.62~1.15 | 0.0046 | 1.38mW/cm² @ 500Ω | SE NOTE 4 |

| **Comparison Elements** | | **Subject Device** | **(Primary) Predicate Device** K151035 | **Predicate Device K171803** | **Predicate Device K133929** | **Comparison** |
|---|---|---|---|---|---|---|
| | | Feet pad: 0.00003 | | | | |
| Burst Mode | Pulses per burst | N/A | TENS: 5, 7<br>EMS: N/A | 3 | -- | SE |
| | Bursts per second | N/A | TENS: 1, 2, 3<br>EMS: N/A | 2/60Hz | -- | SE |
| | Burst duration (seconds) | N/A | TENS: 62.5~87.5<br>EMS: N/A | 36ms | -- | SE |
| | Duty Cycle [Line(b) x Line (c)] | N/A | TENS: 6.3%~19%<br>EMS: N/A | 36ms/390ms | -- | SE |
| ON Time (seconds) | | 1s | TENS: N/A<br>EMS:<br>--intensity ramp-up: 2~4sec<br>--constant intensity: 5~6sec<br>--intensity ramp-down: 1~2sec | 2s | 0.6s | SE |
| OFF Time (seconds) | | 4s | TENS: N/A<br>EMS: N/A | 2s | 0.6s | SE |

**Comparison in details:**

NOTE 1: The "Intended Use" of the subject device is the substantially equivalent to the predicate devices selected, all have adopted TENS (Transcutaneous Electrical Nerve Stimulation) and EMS (Electrical Muscle Stimulation) technologies to the treatment of temporary relief of pain associate with sore and aching muscles and/or the muscle performance improvement of healthy muscles respectively. Meanwhile, the

"Product Code" of the subject device is the same as the predicate devices. This define does not affect the intended use or normal use of the subject device.

NOTE 2: Although the "Power Supply", "Number of Output Modes", "Number of Output Channels", and "Timer Range" of the subject device are a little different from the predicate devices, they are all complaint with the requirements of IEC 60601-1-2 and IEC 60601-1 standard. So these differences will not raise any safety or effectiveness issue.

NOTE 3: Although the "Weight" and "Dimensions" of the subject device are different from the predicate devices, these differences are insignificant in the terms of safety or effectiveness.

NOTE 4: Although the "Waveform", "Maximum Output Voltage", "Maximum Output Current", "Pulse Duration", "Frequency", "Maximum Phase Charge", "Maximum Current Density", and "Maximum Power Density" of the subject device are a little different from the predicate devices, they all comply with the requirements of IEC 60601-1 and IEC 60601-2-10 standard, as well as the Guidance for Powered Muscle Stimulator for Muscle Conditioning. So these differences will not raise any safety or effectiveness issue.

CONCLUSION: The subject device Electronic Pulse Stimulator is substantially equivalent to the predicate devices.

## VII. Performance Data

The following performance data were provided in support of the substantial equivalence determination.

**1) Biocompatibility Testing**

The direct components of applied parts contacting with the users in the Electronic Pulse Stimulator is as the following item:

| Component Name | Material of Component | Body Contact Category | Contact Duration |
|---|---|---|---|
| Electrode pads used for hips, arms and legs, and abdomen (hips pad, arms and legs pad, and abdomen pad) | Conductive hydrogel | Surface-contacting skin | Max. 25 minutes, less than 24 hours |
| Electrode pads used for feet (feet pad) | PU fabric (contained sliver paste and conductive oil) | Surface-contacting skin | Max. 25 minutes, less than 24 hours |

The electrode pads are directly purchased from qualified supplier which has been tested and passed the In Vitro Cytotoxicity, Skin Sensitization, and Skin Irritation test in accordance with the ISO10993-1 standards. So we have reason to believe that the electrode pads are safe for the users. For details, please refer to "Biocompatibility Discussion" in this application.

**2) Electrical and EMC Safety**

Electrical safety and EMC safety testing was performed to, and passed, the following standards:

- IEC 60601-1 Medical electrical equipment –Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-11 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
- IEC 60601-2-10 Medical electrical equipment -- Part 2-10: Particular requirements for the basic safety and essential performance of nerve and muscle stimulators
- IEC 60601-1-2 Medical electrical equipment –Part 1-2: General requirements for basic safety and essential performance –Collateral standard: electromagnetic compatibility – Requirements and tests

In addition to the compliance of voluntary standards:

- The software verification has been carries out according to the FDA Guidance for the Content of Premarket Submission for Software Contained in Medical Devices.
- The waveform test report has also been conducted to verify the output specifications of the subject device according to the FDA Guidance for Powered Muscle Stimulator 510(k)s
- The adhesion test report has been conducted to verify the maximum duration of use for the electrodes used by the subject device according to the requirements of AAMI EC 12_2000(R) 2010-Section 5.4.

- The dispersion and shelf life test report has been conducted to verify the current dispersion and shelf-life of the electrodes used by the subject device in the expiration date according to the requirements of the FDA guidance –Shelf Life of Medical Device and ASTM F 1980-07 standard.

**Summary**

Based on the above performance as documented in this application, Electronic Pulse Stimulator was found to have a safety and effectiveness profile that is similar to the predicate devices.

## VIII. Conclusions

The subject device Electronic Pulse Stimulator is to be concluded substantial equivalent to its predicate devices.