July 29, 2022

Guangzhou Hua Kai Electronic Technology Co., Ltd.
% Cassie Lee
Official Correspondent
2231, Building 1, Rui Feng Center, Kaichuang Road,
Huangpu District
Guangzhou, Guangdong 510000
China

Re: K221251
Trade/Device Name: Ems Foot Stimulator (model: HK701, HK701A, HK701B, HK701C)
Regulation Number: 21 CFR 882.5890
Regulation Name: Transcutaneous Electrical Nerve Stimulator For Pain Relief
Regulatory Class: Class II
Product Code: NUH, NGX, IRT
Dated: April 21, 2022
Received: May 2, 2022

Dear Cassie Lee:

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,

Pamela Scott
Assistant 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: 06/30/2023
*See PRA Statement below.*

510(k) Number *(if known)*
K220251

Device Name
Ems Foot Stimulator (model: HK701, HK701A, HK701B, HK701C)

Indications for Use *(Describe)*
PMS (mode 1~3): It is intended to stimulate healthy muscles in order to improve and facilitate muscle performance.

TENS (mode 4~6): To be used for temporary relief of pain associated with sore and aching muscles in 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.

Heating: This function is designed to be used for temporary relief of minor aches and pains.

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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**Chapter 6. 510(k) Summary**

**510(k) Summary**

This summary of 510(K) safety and effectiveness information is being submitted in accordance with the requirement of 21 CFR 807.92.

**1. Submitter's Information**

Name: Guangzhou Hua Kai Electronic Technology Co., Ltd.

Address: 4th Floor, Building 8, No.39 Bi Gang Road, Dongqu Street, Huangpu District Guangzhou, Guangdong, 510730, CHINA

Contact name: Cao Ke

Title: Manager

Tel: +86-020-82061985

E-mail: 252288906@qq.com

Email: annaosto@163.com

**2. Application Correspondent:**

Contact Person: Ms. Cassie Lee

Guangzhou GLOMED Biological Technology Co., Ltd.

Address: 2231, Building 1, Rui Feng Center, Kaichuang Road, Huangpu District, Guangzhou, Guangdong, China

Tel: +86 20 8266 2446

Email: regulatory@glomed-info.com

**3. Subject Device Information**

Common Name: Transcutaneous electrical nerve stimulator for pain relief

Trade Name: Ems Foot Stimulator

Classification Name: Stimulator, Nerve, Transcutaneous, Over-the-Counter

Model: HK-701, HK-701A, HK-701B, HK-701C

Regulatory Class: II

Product Code: NUH, NGX, IRT

Regulation Number: 882.5890, 890.5850, 890.5740

**2. Predicate Device Information**

**Predicate Device 1:**

510(K) Number: K203574

Company Name: HIVOX BIOTEK INC.

Address: 5F., No. 123, Xingde Rd., Sanchong Dist., New Taipei City 24158, Taiwan, R.O.C.

Trade Name: Health Expert Electronic Stimulator

Model: EM59-1, EM59-2

Regulation Number: 882.5890, 890.5850, 890.5740

Regulatory Class: II

Product Code: NUH, NGX, IRT

**Predicate Device 2:**

510(K) Number: K190783

Company Name: Shenzhen OSTO Technology Company Limited

Address: No.43 Longfeng Road, Xinsheng Community, Longgang Street, Longgang District, Shenzhen City, Guangdong Province, China

Trade Name: Health Expert Electronic Stimulator

Model: AST-300L

Common Name: Electronic Stimulator

Regulation Number: 882.5890

Regulatory Class: II

Product Code: NUH, NGX

**3. Device Description**

Ems Foot Stimulator is a portable and adapter powered multifunctional device, offering both Transcutaneous Electronic Nerve Stimulator (TENS), Powered Muscle Stimulator (PMS) and heating qualities.

Ems Foot Stimulator has 6 modes (PMS mode 1~3, TENS mode 4~6), which can give certain electrical pulse through 6 pcs of electrode Pad placed on the body to help users to enjoy body stimulation. There are 2 big electrode pads in foot conductive area for feet placed on the main unit to help users to enjoy sole stimulation. And a heating belt can provide heating treatment on waist area.

The main unit has the operating elements of Power on/off switch, ON/OFF Switch, Display screen, 2 Mode Selection keys, 2 Intensity Selection keys and a time setting key.

The LCD display screen can show selected mode, output intensity of body and sole, heating level and time remaining of an application mode.

The remote controller has a ON/OFF Switch to control the EMS/ TENS treatment, a ON/OFF switch to control heating treatment, 2 mode selection keys, 2 intensity selection keys, 2 heating adjust keys and a time setting key.

The heating belt and foot conductive pad can only warm the waist and foot rang 30 to 41 ℃

The Heating adjust keys on remote controller can help user to adjust the temperature for warming the waist and foot simultaneously. The heating time is same as the treatment time you selected. The heating and stimulation can be applied simultaneously.

There are 4 models, model HK701, HK701A, HK701B, and HK701C, all the four models include a main unit and many accessories. The main unit of the four models are the same, the difference is only the accessories included in the package, so the function is a little different.

Model difference is as below:

| Item | HK701 | HK701A | HK701B | HK701C |
|---|---|---|---|---|
| Function | Stimulation on foot and body, heating on foot and waist. | Stimulation on foot, heating on foot. | Stimulation on foot, heating on waist. | Stimulation on foot and body, heating on foot. |
| Accessories. | 3 pairs of electrode pads, a heating belt, an adapter, 2 electrode wire, a remote controller. | An adapter, a remote controller. | A heating belt, an adapter, a remote controller. | 3 pairs of electrode pads, an adapter, 2 electrode wire, a remote controller. |

**4. Intended Use / Indications for Use**

PMS (mode 1~3): It is intended to stimulate healthy muscles in order to improve and facilitate muscle performance.

TENS (mode 4~6): To be used for temporary relief of pain associated with sore and aching muscles in 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.

Heating: This function is designed to be used for temporary relief of minor aches and pains.

**5. Performance data and test summary**

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

**Nonclinical test performed**

1) Biocompatibility testing

The biocompatibility evaluation for the Ems Foot Stimulator was conducted in accordance with "Use of International Standard ISO 10993-1, "Biological evaluation of medical devices -

Part 1: Evaluation and testing within a risk management process" as recognized by FDA. The biocompatibility testing included the following tests:

- Cytotoxicity
- Sensitization
- Irritation

According to the test results, the subject device is biocompatible for its intended use. And it is complied with biocompatibility standards ISO 10993-5 (Cytotoxicity) and ISO 10993-10 Irritation and Sensitization).

2) Electrical safety and electromagnetic compatibility (EMC)

Electrical safety and EMC testing were conducted on the Ems Foot Stimulator, the device complies with the IEC 60601-1, IEC 60601-1-11, and IEC 60601-2-10 standards for safety and the IEC 60601-1-2 standard for EMC.

3) Usability Testing

Usability testing were conducted on the Ems Foot Stimulator, the device complies with IEC 62366-1 and IEC 60601-1-6.

4) Software Verification and Validation Testing

Software verification and validation testing were conducted and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." The software for this device was considered as a "moderate" level of concern, since a malfunction of, or a latent design flaw in, the Software Device lead s to an erroneous diagnosis or a delay in delivery of appropriate medical care that would likely lead to Minor Injury.

**Clinical performance testing performed**

No clinical study was performed.

## 6. Comparison to predicate device and conclusion

The technological characteristics, features, specifications, materials, mode of operation, and intended use of Ems Foot Stimulator is substantially equivalent to the predicate devices quoted above.
The differences between the subject device and predicate devices do not raise new issues of safety or effectiveness.

**Comparison in Detail(s):**

| Elements of Comparison | Subject Device | Primary Predicate Device | Secondary Predicate Device | Remark |
|---|---|---|---|---|
| Device Name and Model | Ems Foot Stimulator<br>Model: 701, 701A, 701B, 701C | HIVOX OTC Electrical Stimulator<br>Model: EM59-1, EM59-2 | Health Expert Electronic Stimulator<br>Model: AST-300L | -- |
| 510(k) Number | Applying | K203574 | K190783 | -- |
| Product Code | NUH, NGX, IRT | NUH, NGX, IRT | NUH, NGX | Same |
| Intended Use | PMS (mode 1~3): It is intended to stimulate healthy muscles in order to improve and facilitate muscle performance.<br>TENS (mode 4~6): To be used for temporary relief of pain associated with sore and aching muscles in 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.<br>Heating: This function is designed to be used for temporary relief of minor aches and pains. | HIVOX OTC Electrical Stimulator, EM59-2<br>TENS: This function is designed to be used for temporary relief of pain associated with sore and aching muscles in the shoulder, waist, back, upper extremities (arm) and lower extremities (leg) due to strain from exercise or normal household work activities.<br>EMS: This function is designed to be used for stimulating healthy muscles in order to improve and facilitate muscle performance.<br>SH: This function is designed to be used for temporary relief of minor aches and pains. | PMS (Mode 1~8)<br>It is intended to stimulate healthy muscles in order to improve and facilitate muscle performance.<br>TENS (Mode 9~25)<br>To be used for temporary relief of pain associated with sore and aching muscles in 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. | Same |

| Elements of Comparison | | Subject Device | Primary Predicate Device | Secondary Predicate Device | Remark |
|---|---|---|---|---|---|
| Power Source(s) | | Adaptor Input: 100-240Vac, 50-60Hz, 0.1A<br>Output: DC12V-3A | Rechargeable battery | Adaptor Input: 100-240Vac, 50-60Hz, 0.1A<br>Output: 5Vdc, 2A<br>Unit Input: 5Vdc, 2A | Similar Note 1 |
| Function and Design | | Electrical stimulation and heat | Electrical stimulation and heat | Electrical stimulation and heat | Same |
| Heating Setting | | Adjustable | Low and high | Adjustable | Same |
| Output Patterns | | ● Electrical stimulation only<br>● Heat only<br>● Electrical stimulation + heat simultaneously | ● Electrical stimulation only<br>● Heat only<br>● Electrical stimulation + heat simultaneously | Not public available | Same |
| Method of Line Current Isolation | | Type BF Applied Part | N/A (internal power source) | Type BF Applied Part | Same |
| Patient Leakage Current | NC | AC: 54.5μA, DC: 0.5μA | 6.0 μA | AC: 54.5μA, DC: 0.5μA | Same |
| | SFC | AC:120.0μA, DC: 0.6μA | 5.6 μA | AC:120.0μA, DC: 0.6μA | |
| Average DC current through electrodes when device is on but no pulses are being applied | | < 0.01μA | Not public available | < 0.01μA | Same |
| Number of Output Channel | | 2 | 2 | 2 | Same |
| Number of Output Modes | | 6 | Model EM 59-2:<br>TENS: 15<br>EMS: 35 | 25 | Similar Note 2 |

| Elements of Comparison | | Subject Device | Primary Predicate Device | Secondary Predicate Device | Remark |
|---|---|---|---|---|---|
| | | | SH: 1 | | |
| Heating temperature | | 30-41°C | Maximum temperature setting 43°C | 30-40°C | Similar Note 2 |
| Output Intensity Level | | TENS: 99 steps<br>EMS: 99 steps<br>Heating: 6 levels | TENS: level 0 to 50<br>EMS: Level 0 to 50<br>SH: Level LOW to HI | 99 steps | Similar Note 2 |
| Synchronous or Alternating? | | Synchronous | Synchronous | Synchronous | Same |
| Method of Channel Isolation | | By electrical circuit and software | By electrical circuit and software | Voltage Transform Isolation<br>"Body+" and "Body-" buttons for body channel, "Sole+" and "Sole-" buttons for feet channel | Same |
| Regulated Current or Regulated Voltage? | | Voltage Control | Regulated current | Voltage Control | Same |
| Software/Firmware/Microprocessor Control? | | Yes | Yes | Yes | Same |
| Automatic Overload Trip | | No | Yes | No | Same |
| Automatic No-Load Trip | | No | Yes | No | Same |
| Automatic Shut Off | | Yes | Yes | Yes | Same |
| User Override Control | | Yes | Yes | Yes | Same |
| Indicator Display | On/Off Status | Yes | Yes | Yes | Same |
| | Low Battery | No | Yes | No | Same |

| Elements of Comparison | | Subject Device | Primary Predicate Device | Secondary Predicate Device | Remark |
|---|---|---|---|---|---|
| | Voltage/ Current Level | Yes | Yes | Yes | Same |
| Timer Range | | 15min, 20min, 25min, 30min | 5 to 100 minutes adjustable | 25 to 60 min | Similar Note 2 |
| Weight | | 2.28Kg (Without accessories) | Approx. 125 (including belt clip and battery) | 2.1Kg (Without accessories) | Different Note 3 |
| Dimensions | | 41 x 40 x 13cm | Approx. 139 x 66 x26 (including belt clip) | 429.2mm x 401mm x 152.8mm | Different Note 3 |
| Housing Materials and Construction | | Main unit: ABS plastic | Plastic (ABS) enclosure | Main unit: ABS plastic | Same |
| Waveform | | Pulsed, symmetric, biphasic | Biphasic | Pulsed, symmetric, biphasic | Same |
| Shape | | Rectangular, with interphase interval | Rectangular | Rectangular, with interphase interval | Same |
| Maximum Output Voltage | | 44V±10% @ 500Ω | 50V±20% @ 500Ω | 44V±10% @ 500Ω | Same |
| | | 80V±10% @ 2KΩ | 90V±20% @ 2KΩ | 80V±10% @ 2KΩ | |
| | | 112V±10% @ 10KΩ | 125V±20% @ 10KΩ | 112V±10% @ 10KΩ | |
| Maximum Output Current | | 88mA±10% @ 500Ω | 100mA±20% @ 500Ω | 88mA±10% @ 500Ω | Same |
| | | 40mA±10% @ 2KΩ | 45mA±20% @ 2KΩ | 40mA±10% @ 2KΩ | |
| | | 11.2mA±10% @ 10KΩ | 12.5mA±20% @ 10KΩ | 11.2mA±10% @ 10KΩ | |
| Pulse Duration | | 120μs | 50 to 450 | 120μs | Same |
| Pulse frequency | | 77.3Hz | 1 to 150 | 77.3Hz | Same |
| Net Charge (per pulse) | | 0μC @ 500Ω | 0μC @ 500Ω | 0μC @ 500Ω Method: Balanced waveform | Same |

| Elements of Comparison | Subject Device | Primary Predicate Device | Secondary Predicate Device | Remark |
|---|---|---|---|---|
| Maximum Phase Charge | 10.56μC @ 500Ω | 45μC @ 500Ω | 10.56μC @ 500Ω | Same |
| Maximum Average Current | 1.63mA @ 500Ω | 13.5 mA @ 500Ω | 1.63mA @ 500Ω | Same |
| Maximum Current Density (r.m.s) | 5.5 mA/cm² @ 500Ω | 0.667mA/cm2 @500Ω | 0.0326 mA/cm² @ 500Ω | Different Note 2 |
| Maximum Average Power Density | 0.0000831mW/cm² @ 500Ω | 0.0046 W/cm²@500Ω | 0.0000266mW/cm² @ 500Ω | Different Note 2 |
| Environment for operating | Temperature: 5 ~ 45° C<br>Humidity: 20 ~ 65% RH | Temperature: 5~40° C<br>Humidity: 15% RH to 90% RH | Temperature: 5 ~ 45° C<br>Humidity: 20 ~ 65% RH | Same |
| Environment for storage | Temperature: 0 ~ 45°C,<br>Humidity: 10 ~ 90% RH<br>Electrode Pad: 10~20°C | Temperature: 0~40° C<br>Humidity: 0% RH to 90% RH | Temperature: 0 ~ 45°C,<br>Humidity: 10 ~ 90% RH<br>Electrode Pad: 10~20°C | Same |
| Biocompatibility | All user directly contacting materials are compliance with ISO10993-5 and ISO10993-10 requirements. | ISO 10993-5<br>ISO 10993-10 | All user directly contacting materials are compliance with ISO10993-5 and ISO10993-10 requirements. | Same |
| Electrical Safety | IEC 60601-1<br>IEC 60601-2-10 | ES 60601-1<br>IEC 60601-2-10 | Comply with IEC 60601-1 and IEC 60601-2-10 | Same |
| EMC | 60601-1-2 | IEC 60601-1-2 | Comply with IEC 60601-1-2 | Same |

**Comparison in Detail(s):**

**Note 1:**

Although the "Power Source" is little different from the predicate devices, but it is complying with the IEC 60601-1 requirements. Therefore, the difference will not raise any safety or effectiveness issue.

**Note 2:**
Although the "number of output modes", "heating temperature", "output intensity level", "timer range", "maximum current density", and "maximum average power density" are a little different from the predicate devices, the subject devices have undergone and passed a series of safety tests complied with the specified FDA-recognized consensus standards to demonstrate these differences would not adversely impact the safety and effectiveness of the subject device. Therefore, the differences will not raise any safety or effectiveness issue.

**Note 3:**
Although the "weight" and "dimension" are a little different from the predicate devices, but the difference with not raise safety or effectiveness issue.

**Finial Conclusion:**
The subject device is as safe, as effective, and performs as well as the legally marketed predicated devices K203574 and K190378.

**8. Date of the summary prepared: April 20, 2022**