December 13, 2021

Famidoc Technology Co., Ltd.
Amos Zou
Management Representative
No.212 Yilong Road, Hexi Industrial Zone, Jinxia,
Changan Town
Dongguan, Guangdong 523853
China

Re: K212918
Trade/Device Name: Heat StimPlus
Regulation Number: 21 CFR 882.5890
Regulation Name: Transcutaneous electrical nerve stimulator for pain relief
Regulatory Class: Class II
Product Code: NUH, NGX
Dated: September 8, 2021
Received: September 14, 2021

Dear Amos Zou:

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 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)*
K212918

Device Name
Heat StimPlus（Model FDES115）

Indications for Use *(Describe)*
The Heat StimPlus, Model FDES115 is intended
TENS: This function is designated 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.
EMS: This function is designed to be used for stimulating 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.

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510(K) SUMMARY

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

1. Submitter of 510(K):

Date of Prepared:	12/07/2021
Submitter's Name:	Famidoc Technology Co., Ltd.
Address:	No.212 Yilong Road, Hexi Industrial Zone,Jinxia ,Changan Town, Dongguan City, Guangdong Province,523853,P.R.China
Contact person:	Mr. Amos Zou
TEL:	+86-769-89272488
FAX:	+86-769-89272498
Email:	qa@famidoc.com

2. Proposed Device and code:

Device name:	Heat StimPlus
Model:	FDES115
Classification product code:	NUH
Subsequent product code:	NGX
Regulation number:	1) 882.5890 2) 890.5850
Regulation description:	1) Transcutaneous electrical nerve stimulator for pain relief 2) Powered muscle stimulator
Review panel:	1) Neurology 2) Physical Medicine
Device class:	II
Sterilization facility	Not applicable
Type:	Traditional

3. Predicate Device:

510(K)	Trade or Proprietary or Model Name	Manufacturer
K203574	HIVOX OTC Electrical Stimulator EM59-2	HIVOX BIOTEK INC.

4. Description of Proposed Device:

The Heat StimPlus(Model:FDES115) is a small battery operated OTC device that provides a combination of TENS/EMS and heat for a warming sensation.
It delivers TENS/EMS only or alternating combinations of TENS/EMS and heat. TENS/EMS and heat are never applied at the same time. The device can connect to a specified external IEC 60601-1 compliant power supply for charging of the internal lithium ion battery. The device complies with AAMI/ ANSI/ES60601-1, IEC 60601-1-2 and IEC 60601-2-10.

FDES115 feature two independent output channels and four self-adhesive electrode gel pads. They offer a wide range of functions for increasing general well- being, pain relief, maintaining physical fitness, relaxation, muscle revitalization and combating tiredness. For these purpose, the user can either choose from pre-set programs or specify their own to suit the user's individual needs.
Stimulation from FDES115 is intended for application to the following areas: lower back, arms, legs, shoulder or foot. Software controls all controls and indicators. Software controls waveform characteristics.

The Heat StimPlus(Model:FDES115) is intended for:

TENS: This function is designated 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.

EMS: This function is designed to be used for stimulating healthy muscles in order to improve and facilitate muscle performance.

The accessories include:Type-C cable，an electrode cord / cable attached to electrodes pads and a Pad holder for storage.

The electrode pads allow for stimulation and have resistive elements to provide heat which is powered by the FDES115The electrodes cleared include the electrode patches/pads and electrode garments, which could be packaged together with the 510(k)-cleared devices or packaged separately as the replacement electrodes for 510(k)-cleared devices. The exact percentage of ingredients used in the electrode patch/pad may be withheld as the trade secret.

The device is battery powered and can be connected to an external power supply for charging the internal battery. The battery is lithium ion and is not user serviceable or accessible. The only external connections on the device are the power input and the electrode connector there is no connection to any other device.

The FDES115 is considered – OTC devices.

Patient Population:Adults

5. Intended for Use

TENS: This function is designated 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.

EMS: This function is designed to be used for stimulating healthy muscles in order to improve and facilitate muscle performance.

6. Technical and Performance

The following table compares the device to the predicate device with basic technological characteristics.

Heat StimPlus(Model:FDES115) has been compared to the HIVOX OTC Electrical Stimulator, Model:EM59-2(K203574) as a predicate device for substantial equivalence. A table comparing the two devices is provided as follows:

Feature	Predicate Device	Proposed Device
510(k) No.	K203574	K212918
Device Name	HIVOX OTC Electrical Stimulator	Heat StimPlus
Model	EM59-2	FDES115
Manufacturer	HIVOX BIOTEK INC.	Famidoc Technology Co., Ltd.
Intended Use	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. EMS: This function is designed to be used for stimulating healthy muscles in order to improve and facilitate muscle performance. SH: This function is designed to be used for temporary relief of minor aches and pains.	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. EMS: This function is designed to be used for stimulating healthy muscles in order to improve and facilitate muscle performance.
Prescription or OTC	OTC	OTC
FDA Product Code	NUH, NGX, IRT	NUH, NGX,
Power Source(s)	Rechargeable battery	Rechargeable battery
Function and Design	Electrical stimulation and heat	Electrical stimulation and heat
Heating Setting	Low and high	Low and high

Maximum Temperature Setting		43℃	43℃
Maximum Output Voltage (Vp, ±20%)	@ 500 Ω	50.0	35
	@ 2 kΩ	90.0	75
	@ 10 kΩ	125	88
Maximum Output Current (mAp, ±20%)	@ 500 Ω	100	70
	@ 2 kΩ	45.0	37.5
	@ 10 kΩ	12.5	8.8
Pulse Period (μs)		50 to 450	200 to 250
Frequency (Hz)		1 to 150	1 to 150
Maximum Phase Charge (μC @ 500Ω)		45	12.6
Maximum Current Density (mA/cm2 @ 500Ω)		0.667	0.63
Maximum Power Density (W/cm2 @ 500Ω)		0.0046	0.00294
Output Patterns		Electrical stimulation only Heat only Electrical stimulation+ Heat simultaneously	Electrical stimulation only Electrical stimulation+ Heat simultaneously

Comparison item	Predicate device	Subject device
510(k) Number	K203574	K212918
Device Name	HIVOX OTC Electrical Stimulator	Heat StimPlus
Model	EM59-2	FDES115
Manufacturer	HIVOX BIOTEK INC.	Famidoc Technology Co., Ltd.

Intended use		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. EMS: This function is designed to be used for stimulating healthy muscles in order to improve and facilitate muscle performance. SH: This function is designed to be used for temporary relief of minor aches and pains.	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. EMS: This function is designed to be used for stimulating healthy muscles in order to improve and facilitate muscle performance.
Prescription or OTC		OTC	OTC
FDA product code		NUH, NGX, IRT	NUH, NGX,
Power Source(s)		Battery powered, d.c. 3.7 V, 1 × built-in rechargeable lithium-ion battery	Battery powered, d.c. 3.7 V, 1 × built-in rechargeable lithium-ion battery
Method of Line Current Isolation		N/A (internal power source)	N/A (internal power source)
Patient Leakage Current	Normal condition (μA)	6.0	50
	Single fault condition (μA)	5.6	70
Number of Output Modes		TENS: 15 EMS: 35 SH: 1	TENS:12 EMS:12
Number of output Channels	Synchronous or Alternating?	2 Synchronous	2 Synchronous
	Method of Channel Isolation	By electrical circuit and software	By electrical circuit and software
Regulated Current or Regulated Voltage?		Regulated current	Regulated current
Software/Firmware/Microprocessor Control?		Yes	Yes
Automatic Overload Trip?		Yes	Yes
Automatic No-Load Trip?		Yes	Yes

Automatic Shut Off?		Yes	Yes
Patient Override Control?		Yes	Yes
Indicator Display	On/Off Status?	Yes	Yes
	Low Battery?	Yes	Yes
	Voltage/Current Level?	Yes	Yes
Timer Range (minute)		5 to 100 minutes adjustable	10 to 60 minutes adjustable
Compliant with Voluntary Standards?		ES60601-1 IEC 60601-1-2 IEC 60601-1-11 IEC 60601-2-10	ES60601-1 IEC 60601-1-2 IEC 60601-1-11 IEC 60601-2-10
Compliant with 21 CFR 898?		Yes	Yes
Weight (g)		Approx. 125 (including belt clip and battery)	Approx.65
Dimensions (mm) [W × H × D]		Approx. 139 × 66 × 26 (including belt clip)	Approx. 147.7*55.9*18.8
Housing Materials and Construction		Plastic (ABS) enclosure	Plastic (ABS) enclosure
Waveform		Biphasic	Biphasic
Shape		Rectangular	Rectangular
Maximum Output Voltage (Vp-p, ±10%)	@ 500Ω	100	70
	@ 2 kΩ	180	150
	@ 10 kΩ	250	176
Maximum Output Current (mAp-p, ±10%)	@ 500Ω	200	170
	@ 2 kΩ	90	75
	@ 10 kΩ	25	17.6
Pulse Width (μs)		50 to 450	80 to 300
Frequency (Hz)		1 to 150	1 to 150
For interferential modes only: - Beat Frequency (Hz)		N/A	N/A
For multiphasic waveforms only:	Symmetrical phases?	N/A	NA
	Phase Duration	N/A	NA
Net Charge (μC per pulse @ 500Ω)		0	0
Maximum Phase Charge			12.6

(μC @ 500Ω)	45	
Maximum Average Current (mA @ 500Ω)	13.5	9.39
Electrode Conductive Surface Area (cm2)	20.25	25
Maximum Current Density (mA/cm2 @ 500Ω)	0.667	0.063
Maximum Power Density (W/cm2 @ 500Ω)	0.0046	0.00294
Output Intensity	TENS: Level 0 to 50 EMS: Level 0 to 50 SH: Level LOW and HI	TENS: Level 0 to 40 EMS: Level 0 to 40
Heating Level (℃)	Level LOW: up to 41 Level HI: up to 43	Level E1:up to 37 Level E2:up to 41 Level E3:up to 43
Operating Condition	Temperature: 5℃ to 40℃ Humidity: 15% RH to 90% RH	Temperature: 5℃ ~40℃ Humidity: 30 % RH~85 % RH
Storage Condition	Temperature: 0℃ to 40℃ Humidity: 0% RH to 90% RH	Temperature: -10℃ ~50℃ Humidity: 15% RH~90% RH
Use Altitude Limit (m)	3000	3000
Use Atmospheric Pressure (hPa)	700 to 1060	70 kpa~106 kpa

Similarity and Difference
Based on the comparison information in our submission, we can determine that the subject device is almost identical to the predicate device in all aspect, except for removal of the SH function. On the other hand, the subject device has the same intended use and provides the same functions by the same operating principle as the predicate device #1. Although there are still several specifications different between the subject device and predicate device, the subject device has undergone and passed a series of safety tests complied with the specific FDA-recognized consensus standards to demonstrate these differences would not adversely impact the safety and effectiveness of the subject device. Therefore, the differences between the subject device and the predicate device are not expected to adversely impact the safety and effectiveness of the subject device.

7. Performance Testing:

Performance data includes "Non-Clinical Data" and "Clinical Data", brief description of which are shown as below.

7.1 Non-Clinical Data:

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

7.2 Biocompatibility testing

The biocompatibility evaluation for the Heat StimPlus(Model:FDES115) conducted in accordance with the 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 worst case of the whole system is considered tissue contacting for duration of less than 24 hours. And the testing included the following tests:

- Cytotoxicity
- Skin Sensitization
- Skin Irritation

7.3 Electrical safety and electromagnetic compatibility (EMC)

Electrical safety and EMC testing were conducted on the Heat StimPlus(Model:FDES115), consisting of all the modules and accessories in the system. The system complies with the IEC 60601-1: 2012 Medical electrical equipment Part 1: General requirements for basic safety and essential performance for safety and the IEC 60601-1-2: 2014 Medical electrical equipment –Part 1-2: General requirements for basic safety and essential performance – Collateral Standard:Electromagnetic disturbances – Requirements and tests standard for EMC.

7.4 Bench Testing

Bench testing was conducted on the Heat StimPlus(Model:FDES115) ,consisting of all the accessories in the system. The system complies with the IEC 60601-1-11: 2015 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,And IEC 60601-2-10 Medical electrical equipment - Part 2-10: Particular requirements for the basic safety and essential performance of nerve and muscle stimulators (Edition 2.1 2016-04)

7.5 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.

7.6 Usability Testing

Usability testing according to following FDA Guidance 1757, Applying Human Factors and Usability Engineering to Optimize Medical Device Design, was conducted.

7.7 Clinical data:

No clinical testing was performed

7.7 Summary

Based on the non-clinical and clinical performance as documented in the device development, the subject devices were found to have a safety and effectiveness profile that is similar to the predicate device.

8. Conclusions:

The proposed device has the same intended use and similar characteristics as the predicate device, Meanwhile, performance testing, bench testing, and safety report documentation supplied in this submission demonstrates that any differences in their technological characteristics do not raise any new questions of safety or effectiveness.

Famidoc maintains that the FDES115 is substantially equivalent to the predicate devices in indications for use, patient population, and environment for use, technology characteristics, specifications / performance and compliance with international standards.