July 22, 2024

Shenzhen Yicai Health Technology Co., Ltd.
Xie Jie
General Manager
11th floor, Zhenqian Building, Yousong Community,
Longhua Street, Longhua District
Shenzhen, 518110
China

Re: K241119
Trade/Device Name: Transcutaneous Electrical Nerve Stimulator (K6106)
Regulation Number: 21 CFR 882.5890, 21 CFR 890.5850
Regulation Name: Transcutaneous Electrical Nerve Stimulator For Pain Relief
Regulatory Class: Class II
Product Code: NUH, NGX
Dated: April 22, 2024
Received: April 23, 2024

Dear Xie Jie:

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,

Robert Kang -S

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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K241119

Device Name

Transcutaneous Electrical Nerve Stimulator (K6106)

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 to 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.

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510(k) Summary

Prepared on: 2024-07-11

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Shenzhen Yicai Health Technology Co., Ltd.
Applicant Address	11th floor, Zhenqian Building, Yousong Community, Longhua Street, Longhua District Shenzhen 518110 China
Applicant Contact Telephone	+86 13682320556
Applicant Contact	Mr. Xie Jie
Applicant Contact Email	mdc-fs@foxmail.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	Transcutaneous Electrical Nerve Stimulator (K6106)
Common Name	Transcutaneous electrical nerve stimulator for pain relief
Classification Name	Stimulator, Nerve, Transcutaneous, Over-The-Counter
Regulation Number	882.5890
Product Code(s)	NUH, NGX

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K171803	HIVOX OTC Electrical Stimulator	NUH
K192264	HIVOX Spopad EMS	NGX
K201354	TENS & PMS	NUH
K191151	JKH Stimulator Plus	NUH

Device Description Summary

21 CFR 807.92(a)(4)

Transcutaneous Electrical Nerve Stimulator is a portable and DC 3.7V battery powered multifunction device that adopts modern electronic science and technology to delivers electric pulses generated to the user's skin through the electrodes. It has two functions: Transcutaneous electrical nerve stimulation(TENS) and Electrical muscle stimulation (EMS).
The device has 20 operation programs. It includes operating elements of Power ON/OFF button, intensity increase button, intensity decrease button, Menu selection button, and A/B channel selection button.
The display screen can show battery power, program, mode, keylock status, intensity level, treatment time and output channel.
The device is equipped with accessories of electrode pads, electrode cables, and one Type-C cable. The electrode cables are used to connect the pads to the device; the Type-C cable is used to connect the charger and the built-in lithium battery.
In additional, according to different simulation-needed bodies, users can choose the three types of electrode pad based on their own situation. The electrode pads are manufactured by ShenZhen Quality Medical Technology Co.,Ltd with 510(k) cleared Number K171381.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

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 to stimulate healthy muscles in order to improve and facilitate muscle performance.

Indications for Use Comparison

21 CFR 807.92(a)(5)

The subject device has the same indications for use as the predicate devices as below:
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 to stimulate healthy muscles in order to improve and facilitate muscle performance.

Technological Comparison

21 CFR 807.92(a)(6)

See Comparison Table on pg. 4 below.

Note 1
Dimension / Weight / Electrode area would be different for different device design in internal circuit and components choosing, which won't affect the safety and effectiveness, so it can deem as the substantially equivalence. The design of the timer range is based on the intended use. For the subject device, the user could adjust the time based on user's need, and the range is included in predicate device.
Note 2
The subject device has 20 output modes while the predicate devices have 50 or 15 output modes. All of the treatment programs of the subject device have passed the IEC 60601-2-10 and AAMI / ANSI ES60601-1 test. So this difference doesn't raise any safety or effectiveness issue.

Note 3
Although the "Waveform", "Maximum Output Voltage" and "Maximum Output Current" of the subject device are a little different from the predicate devices, the ranges are included in predicate device and 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.

Note 4
Frequency and pulse width is the time parameter of the waveform. There is only little difference between the Frequency and Pulse width of the subject device, which is in the range of predicate device. As the subject devices comply with IEC 60601-1, and IEC60601-2-10, which means we have proved its safety as well as the effectiveness comparing with the predicate device. Therefore, the subject device and predicate device are substantially equivalence on these parameters.

Note 5
Although the "Maximum Phase Charge", "Maximum Current Density", "Maximum Average Current", and "Maximum Power Density" of the subject device is a little different from the predicate device, the ranges are included in predicate device and they all comply with the requirements of IEC 60601-1 and IEC 60601-2-10 standard. Besides, the maximum power density meets with the maximum allowed value 0.25 (W/cm²) required in FDA guidance. Therefore, the subject device and predicate device are substantially equivalence on these parameters.

Non-Clinical and/or Clinical Tests Summary & Conclusions

21 CFR 807.92(b)

Non-Clinical Test Conclusion
The Transcutaneous Electrical Nerve Stimulator comply with the following Electrical, Mechanical & Thermal Safety, and Electromagnetic Compatibility standards:
1. IEC 60601-1:2005+A1:2012+A2:2020 Medical Electrical Equipment - Part 1: General Requirements for Safety
2. IEC 60601-2-10:2012+A1:2016, Medical electrical equipment - Part 2-10: Particular requirements for the safety of nerve and muscle stimulators
3.IEC 60601-1-2:2014+A1:2020 , Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests, 2007
4. 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.

FDA software validation guidance "General Principles of Software Validation; Final Guidance for Industry and FDA Staff, Document issued on: January 11, 2002".

Guidance Document for Powered Muscle Stimulator 510(k)s Document issued on: June 9, 1999

Clinical Test
Clinical testing was not performed on the device.

Conclusions
The electrical safety, EMC, biocompatibility, software verification and validation, and output specifications information provided is sufficient to demonstrate substantial equivalence to the predicate devices. As the Transcutaneous Electrical Nerve Stimulator, model: K6106 is nearly identical to the predicate devices, differences in their characteristics do not raise any raise new questions regarding safety and effectiveness with identical indications for use and essentially identical technological characteristics, the Transcutaneous Electrical Nerve Stimulator, model: K6106 is substantially equivalent to the predicate devices.

Substantial Equivalence Comparison

The technological characteristics, features, specifications, materials, and intended use of TRANSCUTANEOUS ELECTRICAL NERVE STIMULATOR is substantially equivalent to the predicate devices quoted below. The differences between the subject device and predicate devices do not raise new issues of safety or effectiveness.

Elements of Comparison	**Subject Device**	**Predicate Device (Primary)**	**Reference Device**	**Reference Device**	**Reference Device**	**Comparison**
Manufacturer	Shenzhen Yicai Health Technology Co., Ltd.	HIVOX BIOTEK INC.	Hivox Biotek Inc.	Hong Qiangxing (Shenzhen) Electronics Limited	JKH USA, LLC	--
510 (k) Number	-	K171803	K192264	K201354	K191151	--
Product Name	Transcutaneous Electrical Nerve Stimulator	HIVOX OTC Electrical Stimulator	HIVOX Spopad EMS	TENS & PMS	JKH Stimulator Plus	--
Models	K6106	SEM44, SEM44-1,	SP-911, SP-921	SM9196	PL-029K5BL	--
Product code	NUH, NGX	NUH, NGX	NGX	NUH, NGX	NUH, NGX, NYN, GZJ, IPF, IRT	Same
Regulation number	21 CFR 882.5890 21 CFR 890.5850	21 CFR 882.5890 21 CFR 890.5850	21 CFR 890.5850	21 CFR 882.5890 21 CFR 890.5850	21 CFR 882.5890	Same
Prescription/ OTC	OTC	OTC	OTC	OTC	OTC	Same

Intended 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 to stimulate healthy muscles in order to improve and facilitate muscle performance.	SEM44 – 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. SEM44-1 – 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.	Indicated for the improvement of muscle tone and firmness, for strengthening muscles in arms, abdomen, thighs, and buttocks areas. Not intended for use in any therapy or for the treatment of any medical conditions or diseases.	TENS(10~15): To be used 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. PMS(1~9): It is intended to be used to stimulate healthy muscles in order to improve and facilitate muscle performance.	TENS :PL-029K5BL , PL-029K15 , and PL-029I are used for temporary relief of pain associated with sore and aching muscles in the shoulder . waist . back . arm . and leg . due to strain from exercise or normal household and work activities PL-029K5BL , PL-029K15 , and PL-029T are also intended for symptomatic relief and management of chronic , intractable pain and relief of pain associated with arthritis The device of PL-029K5BL and PL-029K15 may be used during sleep . The device of PL-029K5BL and PL-029K15labeled for use only with its own compatible electrodes PMS PL-029K5BL , PL-029K 15 , and PL-029T are used to stimulate healthy muscles in order to improve and facilitate muscle performance . To	Same

					be used for the improvement of muscle tone and firmness , and for strengthening muscles in the arms abdomen , legs , and buttocks . Not intended for use in any therapy or for the treatment of any medical conditions for diseases PL-029K5BL , PL-029K15 and PL-029T are also intended to temporarily increase local blood circulation in the healthy muscles of lower extremities	

Power Supply	Internal battery: 3.7Vd.c. 300mAh	4.5V (batteries, 3x1.5V AAA)	3 V battery × 1	DC 3.7V lithium battery	Rechargeable or non-rechargeable battery	Same
Method of Line Current Isolation	Type BF	N/A	Battery supply	Type BF	Battery Supply	Same
Size (L × W × H)	118mm x 65mm x 20mm	132 x 63 x 29.5 mm (including belt clip)	8.15 × 4.06 ×0.51 inch	180mm x 58mm x 15.5mm	PL-029K5BL: 66x56x18mm	Similar Note 1
Weight(g)	110 g / 0.24 lb	89 g (including belt clip, without batteries), 123 g (including belt clip and batteries)	24.2 g	100g±5g	PL-029K5BL: 40g	Similar Note 1
Patient Leakage Current Normal Condition (μA)	<1 μA	N/A	2.0 μA	< 10μA	N/A	Same
Patient Leakage Current Single Fault Condition (μA)	<1 μA	N/A	2.1 μA	<50 μA	N/A	Same
Number of Output Modes	TENS mode: 10 EMS mode: 10	TENS mode: 15 EMS mode: 35 / TENS mode: 15	1	15	PL-029K5BL: 6-8	Similar Note 2
Number of output channels:	4	2	1	4	1-2	Same

Synchronous or Alternating		Synchronous	Synchronous	Single channel	Synchronous & Alternating	N/A	Same
Method of channel isolation		By electrical circuit and software	By electrical circuit and software	Single channel	Voltage transformer Isolation	N/A	Same
Regulated current or regulated voltage?		Regulated Voltage	Regulated Voltage	Regulated Voltage	Voltage control	Voltage	Same
Software/Firmware/ Microprocessor Control?		Software	Software	Software	Software	Software	Same
Automatic overload trip?		No	Yes	No	No	No	Same
Automatic no-load trip?		No	Yes	No	No	Yes	Same
Automatic shut-off?		Yes	Yes	Yes	Yes	Yes	Same
User overrides control?		Yes	Yes	Yes	Yes	Yes	Same
Indicator Display	On/Off Status	Yes	Yes	No	Yes	Yes	Same
	Low Battery	Yes	Yes	No	Yes	Yes	Same
	Voltage /Current Level	Yes	Yes	No	Yes	Yes	Same
Timer range (minutes)		10 - 60 minutes	5-100 minutes	20	60 minutes	PL-029K5BL: 10-540	Similar Note 1
Compliance with voluntary standards?		IEC 60601-1 IEC 60601-1-2 IEC 60601-1-11 IEC 60601-2-10	IEC 60601-1, IEC 60601-1-2 IEC 60601-2-10 ISO10993-5/10	IEC 60601-1 IEC 60601-1-2 IEC 60601-1-11 IEC 60601-2-10	AAMI/ANSI ES60601-1, IEC 60601-1-2, IEC 60601-2-10, IEC 62133, IEC 60601-1-11	AAMI/ANSI ES60601-1, IEC 60601-1-2, IEC 60601-2-10, ISO10993-5/10	Same

Compliance with 21 CFR 898-7	Yes	Yes	Yes	Yes	Yes	Same
Housing material and construction	ABS plastic	ABS plastic	Silicone	ABS	Silicone & ABS	Same
Waveform (e.g., pulsed monophasic, biphasic)	Biphasic	Biphasic	Symmetrical biphasic	Pulsed, symmetric, biphasic	Biphasic	Same
Shape	Square	Square	Rectangular	Rectangle	Rectangular	Same
Maximum output voltage (V, ±10%) at 500 Ω	68	50	52	54V±20% @500Ω	PL-029K5BL:65 ±20%	Note 3
Maximum output voltage (V, ±10%) at 2k Ω	136	90	102	101	PL-029K5BL: 132±20%	Note 3
Maximum output voltage (V, ±10%) at 10k Ω	208	125	150	133	PL-029K5BL: 180±20%	Note 3
Maximum output current (mA, ±10%) at 500 Ω	136	200	104	108mA±20% @500Ω	PL-029K5BL: 130±20%	Note 3
Maximum output current (mA, ±10%) at 2k Ω	68	90	51	50.5	PL-029K5BL: 66±20%	Note 3
Maximum output current (mA, ±10%) at 10k Ω	20.8	25	15	13.3	PL-029K5BL: 18±20%	Note 3
Duration of primary phase	120-400μS	50-450μS	0	Not publicly available	50~500μS	Note 4
Pulse duration (μs)	120-400μS	50-450μS	400μs	200-210μs	50~500μS	Note 4

Frequency (Hz)		2-80 Hz	1-150Hz	3/4/5 HZ	1.613-49.02Hz	PL-029K5BL: 1~500 Hz	Note 4
For interferential modes only – Beat Frequency		N/A	N/A	Not publicly available	Not publicly available	Not publicly available	Same
For multi-program waveforms only –	N/A	N/A	Not publicly available	Not publicly available	Not publicly available	Not publicly available	Same
	N/A	N/A	Not publicly available	Not publicly available	Not publicly available	Not publicly available	Same
Net charge per pulse at 500 Ω (μC)		0μC @500Ω	0.001μC@500Ω	0.416	0μC @500Ω	Not publicly available	Same
Maximum Phase charge at 500 Ω (μC)		65.82	45	41.6	17	PL-029K5BL: 78 μC	Note 5
Maximum current density at 500 Ω (mA/cm^2)		1.001	0.667	1.672	0.08mA/cm2 @500Ω	PL-029K5BL: 1.86	Note 5
Max. Average current (average absolute value), mA		24.33@500Ω	13.5@500Ω	Not publicly available	1.88	Not publicly available	Note 5
Maximum average power density W/cm^2 at 500 Ω(using smallest electrode conductive surface area)		0.0122	0.0046@500Ω	0.0869 W/cm^2	0.00365	0.028	Note 5
Burst mode	A. Pulse per burst	NA	3	N/A	Not publicly available	N/A	Same
	B. Burst per second	NA	2/60Hz	N/A			

	C. Burst duration (sec)	NA	36ms	N/A			
	D. Duty cycle	NA	36ms/390ms	N/A			
ON Time (seconds)		1s	2s	Not publicly available	3.1-20	1~20	Same
OFF Time (seconds)		1s	2s	Not publicly available	1-3	0~10	Same
Electrode area		S(24.3cm^2)，M(40.8 cm^2)，L(67.71 cm^2)	20.25sqcm x4 (81sqcm)	62.20 cm^2 (Two electrodes)	Not publicly available	Not publicly available	Note 1
Average DC current through electrodes when device is on but no pulses are being applied (μA)		0	0	Not publicly available	< 0.01μA	0	Same

Note 1

Dimension / Weight / Electrode area would be different for different device design in internal circuit and components choosing, which won't affect the safety and effectiveness, so it can deem as the substantially equivalence. The design of the timer range is based on the intended use. For the subject device, the user could adjust the time based on user's need, and the range is included in predicate device.

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Frequency and pulse width is the time parameter of the waveform. There is only little difference between the Frequency and Pulse width of the subject device, which is in the range of predicate device. As the subject devices comply with IEC 60601-1, and IEC60601-2-10, which means we have proved its safety as well as the effectiveness comparing with the predicate device. Therefore, the subject device and predicate device are substantially equivalence on these parameters.

Note 5

Although the "Maximum Phase Charge", "Maximum Current Density", "Maximum Average Current", and "Maximum Power Density" of the subject device is a little different from the predicate device, the ranges are included in predicate device and they all comply with the requirements of IEC 60601-1 and IEC 60601-2-10 standard. Besides, the maximum power density meets with the maximum allowed value 0.25 (W/cm^2) required in FDA guidance. Therefore, the subject device and predicate device are substantially equivalence on these parameters.

Conclusion

Based on the performance testing, comparison and analysis, the subject device Transcutaneous Electrical Nerve Stimulator (Model: K6106) is substantially equivalent to the predicate device.