March 22, 2024

Hong Kong Etech Groups Limited
% Riley Chen
RA Specialist
Feiying Drug & Medical Consulting Technical Service Group
Rm 2401 Zhenye International Business Center, No. 3101-90
Qianhai Road
Shenzhen, Guangdong 518052
China

Re: K240292
Trade/Device Name: Transcutaneous Electrical Nerve Stimulator (9029SCM)
Regulation Number: 21 CFR 882.5890
Regulation Name: Transcutaneous electrical nerve stimulator for pain relief
Regulatory Class: Class II
Product Code: NUH, NGX
Dated: January 31, 2024
Received: February 1, 2024

Dear Riley Chen:

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,

Tushar Bansal -S

for Heather Dean, PhD
Assistant Director, Acute Injury Devices Team
DHT5B: Division of Neuromodulation

and Rehabilitation 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)*

K240292

Device Name

Transcutaneous Electrical Nerve Stimulator (9029SCM)

Indications for Use *(Describe)*

TENS (Mode 1~6)
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.
EMS (Mode 1~6)
It is intended 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.

510(k) #: K240292

510(k) Summary

Prepared on: 2024-03-22

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	HONG KONG ETECH GROUPS LIMITED
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Correspondent Contact	Ms. Riley Chen
Correspondent Contact Email	c3714930@gmail.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	Transcutaneous Electrical Nerve Stimulator (9029SCM)
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
K191982	Low-frequency Multi-function physiotherapy instrument	NUH
K133929	Health Expert Electronic Stimulator, Model: AST-300C and AST-	NUH

Device Description Summary

21 CFR 807.92(a)(4)

1)Stylish appearance, compact size, humanized design for easy portability.
2)TENS and EMS modes with 6 different modes each, catering to various treatment needs and a wider range of users.
3)Dual-channel output, allowing control of intensity for each channel.
4)Unique combination of electric pulses for a different sensory experience.
5)LCD display for clear and easy use.
6)Powered by three AAA batteries (size 7), providing long-lasting usage and convenient for home and travel use.
7) The electrode patches used with the device are previously cleared under K221589 for safety use. The main unit delivers the electrical

stimulation through the patches pasted to the user.

Intended Use/Indications for Use 21 CFR 807.92(a)(5)

TENS (Mode 1~6)
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.
EMS (Mode 1~6)
It is intended 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 and predicate devices have the same indications for use.

Technological Comparison 21 CFR 807.92(a)(6)

The technical characteristics of Transcutaneous Electrical Nerve Stimulator (Model:9029SCM) are substantially equivalent to the predicate devices in the following aspects:
1. the same intended use: both use electrical stimulation to temporary relief of pain under TENS mode and improve and facilitate muscle performance by using EMS mode.
2. operate with the same mode of action: the device would generate electrical pulses and transmit it to the electrodes, which are attached to the patient's skin to the underlying peripheral nerves and muscle.
3. the same design: two output channel for voltage control, which can be adjusted separately, and also design with display screen for treatment parameters display.
4. similar output parameters, such as Maximum Output Voltage, Maximum Output Current, Pulse frequency, Maximum Phase Charge, Maximum Average Current, Maximum Current Density(r.m.s), and Maximum Average Power Density. The product waveform parameters were tested according to FDA guidance documents and the requirements of IEC 60601-2-10, the tests are all passed.
5. the same waveform and shape: biphasic symmetric square wave, rectangular
6. the same safety features: Type BF applied part.
7. the same housing materials: ABS plastic for main unit.
8. similar enrgy source as the primary predicate device: both use three AAA batteries (4.5V DC), and they all pass electrical safety test.

The difference between subject device and the predicate devices mainly includes the following:
1. The numbers of output modes (12 modes) and the output intensity level (18 gears) are different from those of the predicate devices (50 modes and 16 steps for K191982, 25 modes and 99 steps for K133929), but the output parameters of each mode were tested and found to be similar with the predicate devices, and the subject device has passed IEC 60601-1 and IEC 60601-2-10 test, so these differences do not lead to safety and effectiveness problems.
2. The weight (main unit: 111.5g) and dimensions (108.5×33.8×67.5mm) of the subject device are different from the predicate devices, but these differences are insignificant and will not affect the safety and effectiveness of the device.

Thus, the subject device is determined to be substantially equivalent to the predicate devices.

Non-Clinical and/or Clinical Tests Summary & Conclusions 21 CFR 807.92(b)

Non-clinical testings have been conducted to verify that the Transcutaneous Electrical Nerve Stimulator meets all design specifications which supports the conclusion that it's Substantially Equivalent (SE) to the predicate devices. The testing results demonstrate that the subject device complies with the following standards:
 IEC 60601-1, Medical electrical equipment -- Part 1: General requirements for basic safety and essential performance
 IEC 60601-1-2, Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic disturbances - Requirements and tests
 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

The body-contacting components of this device are electrode patches. We have directly purchased the electrode patches from qualified supplier which has obtained FDA clearance with a 510(k) number of K221589 and been marketed to US market. So we have reason to believe that the electrode patches are safe for the users. The electrode patches comply with the following standards.
ISO 10993-5, Biological Evaluation of Medical Devices -- Part 5: Tests for InVitroCytotoxicity
ISO 10993-10, Biological Evaluation of Medical Devices - Part 10: Tests for Irritation and Skin Sensitization.

We have also conducted:
 Software verification and validation test according to the requirements of the FDA “Guidance for Pre Market Submissions and for Software Contained in Medical Devices” .
The waveform test report has also been conducted to verify the output specifications of the device according to "Guidance Document for Powered Muscle Stimulator 510(k)s"

The clinical test is not applicable, there is no clinical data.

The subject device and predicate devices have the same indications for use, technological characteristics.
The subject device is as safe, as effective and performs as well as the predicate devices.