March 4, 2026

Globalcare Medical Technology Co., Ltd.
Nathifa Bradshaw
Senior Manager Quality and Regulatory Affairs
7th Bldg., 39 Middle Industrial Main Rd.,
European Industrial Zone Xiaolan Town
Zhongshan City, Guangdong 528415
China

Re: K253896
Trade/Device Name: TENS/EMS device (GUSE01)
Regulation Number: 21 CFR 882.5890
Regulation Name: Transcutaneous Electrical Nerve Stimulator For Pain Relief
Regulatory Class: Class II
Product Code: NUH, NGX
Dated: December 3, 2025
Received: December 5, 2025

Dear Nathifa Bradshaw:

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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K253896

Please provide the device trade name(s).

TENS/EMS device (GUSE01)

Please provide your Indications for Use below.

TENS: The device is designed to be used for temporary relief of pain associated with sore and aching muscles due to strain from exercise or normal household and work activities
EMS: The device is designed to be used for stimulating healthy muscles in order to improve and facilitate muscle performance.

Please select the types of uses (select one or both, as applicable).

- ☐ Prescription Use (21 CFR 801 Subpart D)
- ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

510(k) Summary for K253896

as required by section 21 CFR 807.92

Applicant Name:	Globalcare Medical Technology Co., Ltd
Applicant Address:	7th Building, 39 Middle Industrial Main Road, European Industrial Zone Xiaolan Town Zhongshan City Guangdong 528415 China
Applicant Phone:	086-760-22589901
Applicant Contact:	Valentina Sassi
Applicant Contact Email:	valentina.sassi@globalcare.com.hk
Date of Summary:	2026-03-04

Subject Device

Device Name:	TENS/EMS device GUSE01
Product code:	NUH
Subsequent Product Code:	NGX
Regulation Description:	Transcutaneous electrical nerve stimulator for pain relief
FDA Regulation Numbers:	882.5890
FDA Panel:	Neurology
FDA Classification:	Class II

Predicate Device

Legally Marketed Predicate Device Name and Model:	HIVOX OTC Electrical Stimulators Model SEM44 and Model SEM44-1
Predicate 510(k) number:	K171803
Manufacturer:	HIVOX BIOTEK INC.
Product Code:	NUH
Subsequent Product Code:	NGX
Regulation Description:	Transcutaneous electrical nerve stimulator for pain relief
FDA Regulation Numbers:	882.5890
FDA Panel:	Neurology
FDA Classification:	Class II

Reference Device

Legally Marketed Reference Device Name and Model:	Smart Pain Reliever Model LT5019

Reference 510(k) number:	K162479
Manufacturer:	Shenzhen Dongdixin Technology Co., Ltd.
Product Code:	NUH
Subsequent Product Codes:	NGX, NYN
Regulation Description:	Transcutaneous Electrical Nerve Stimulator For Pain Relief
FDA Regulation Numbers:	882.5890
FDA Panel:	Neurology
FDA Classification:	Class II

1. Device Description Summary

The GUSE01 TENS/EMS is a battery-powered device that delivers pulsed electrical currents through cables and self-adhesive electrodes applied to the skin.
TENS (Transcutaneous Electrical Nerve Stimulation) is a well-established technology that stimulates nerves through the skin. Electrodes are placed near the area of pain, where high-frequency impulses help block pain signals in the nerve fibers, reducing the perception of pain.
EMS (Electrical Muscle Stimulation) is also a widely recognized technology.
Different pre-programmed programs can be chosen for easy treatment of desired body treatment areas according to electrode positioning guide in User Manual. Each program allows for adjustable pulse intensity to suit individual needs. The integrated relax function delivers electrical stimulation that produces a massage-like sensation (MLS) to promote deep relaxation and recovery.

2. Intended Use/Indications for Use

TENS: The device is designed to be used for temporary relief of pain associated with sore and aching muscles due to strain from exercise or normal household and work activities.

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

3. Technological Characteristics and Substantial Equivalence

Table 1 – comparison between subject and predicate device

	Subject Device	**Predicate Device**	**SE Determination Notes**
510(k) Number	K253896	K171803	N/A
Device Name, Model	TENS/EMS device GUSE01	Model SEM44 and Model SEM44-1	N/A
Manufacturer	Globalcare Medical Technology Co., Ltd	HivoxBiotek Inc.	N/A
Product code	NUH, NGX	NUH, NGX	Same
FDA Regulation Numbers	882.5890	882.5890	Same
FDA Panel	Neurology	Neurology	Same
FDA Classification	Class II	Class II	Same

		Subject Device	Predicate Device	SE Determination Notes
Indication for use		TENS: The device is designed to be used for temporary relief of pain associated with sore and aching muscles due to strain from exercise or normal household and work activities. EMS: The device is designed to be used for stimulating healthy muscles in order to improve and facilitate muscle performance.	HIVOX OTC Electrical Stimulator, 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. HIVOX OTC Electrical Stimulator, 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.	Similar. Both devices utilize TENS to relieve pain associated with sore and aching muscles, and EMS to improve and facilitate muscle performance.
Type of use		OTC	OTC	Same
Basic Unit Characteristics				
Power Source(s)		3 x 1,5V AAA batteries (LR03)	4.5V (batteries, 3×1.5V AAA)	Same
Method of Line Current Isolation		N/A (battery operated device) Type BF Applied Part	N/A	Same
Patient Leakage Current	Normal condition [µA]	<10µA	N/A	Different but does not adversely impact safety and effectiveness of subject device
	Single fault condition [µA]	<50µA	N/A	
Number of Output Modes		1. TENS - ACUTE: 4 2. TENS - CHRONIC: 5 3. EMS - TRAINING: 8 4. EMS – RELAX/MLS: 5	EMS: 35 TENS:15	Different but does not adversely impact safety and effectiveness of subject device

		Subject Device	Predicate Device	SE Determination Notes
Number of Output Channels		2	2	Same
Synchronous or Alternating		Alternating	Synchronous	Different but does not adversely impact safety and effectiveness of subject device
Method of Channel Isolation		The channels are activated in alternating mode by software	By electrical circuit and software	Same
Regulated Current or Regulated Voltage		Regulated Current	Regulated voltage	Different but does not adversely impact safety and effectiveness of subject device
Software/Firmware/Microprocessor Control		yes	yes	Same
Automatic Overload Trip		yes	yes	Same
Automatic No-Load Trip		yes	yes	Same
Automatic Shut Off		yes	yes	Same
Patient Override Control		yes	yes	Same
Indicator Display	On/Off Status	yes	yes	Same
	Low Battery	yes	yes	Same
	Voltage/Current Level	yes	yes	Same
Timer Range (minutes)		15–40 minutes	5~100minutes	Different but does not adversely impact safety and effectiveness of subject device
Compliance with Voluntary Standards		IEC 60601-1, IEC 60601-1-11, IEC 60601-1-2, IEC 60601-2-10, ISO 10993	IEC 60601-1, IEC 60601-1-2, IEC 60601-2-10, ISO10993-5/10	Similar. In addition subject device also tested according to IEC IEC 60601-1-11
Compliance with 21 CFR 898		yes	yes	Same
Weight		104g	89g (including belt clip, without batteries) 123g (including belt clip, and batteries)	Similar. The slight difference does not impact safety and effectiveness of subject device.
Dimensions (in.) [W x H x D]		132 x 66 x 26 mm	132 x 63 x 29.5mm (including belt clip)	Similar. The slight difference does not impact safety and effectiveness of subject device.

		Subject Device	Predicate Device	SE Determination Notes
Housing Materials and Construction		ABS	ABS	Same
Output Specifications				
Waveform (e.g., pulsed monophasic, biphasic)		Biphasic	Biphasic	Same
Shape (e.g., rectangular, spike, rectified sinusoidal)		rectangular and spike	square	Different but does not adversely impact safety and effectiveness of subject device
Maximum Output Voltage (specify units) (+/- 10%)	@ 500 Ω	100 Vpp	100 Vpp	Same
	@ 2 kΩ	200 Vpp	180 Vpp	Similar. Slight difference does not adversely impact safety and effectiveness of subject device which also has lower output
	@ 10 kΩ	200 Vpp	250 Vpp	Similar. Slight difference does not adversely impact safety and effectiveness of subject device which also has lower output
Maximum Output Current (specify units) (+/- 10%)	@ 500 Ω	200 mA	200 mA	Same
	@ 2 kΩ	100 mA	90 mA	Similar. Slight difference does not adversely impact safety and effectiveness of subject device which also has lower output
	@ 10 kΩ	20 mA	25 mA	Similar. Slight difference does not adversely impact safety and effectiveness of subject device which also has lower output
Pulse Width (specify units)		50-400 µs	50-450µs	Similar. Slight difference does not adversely impact safety and effectiveness of subject device
Frequency (Hz)		2–120 Hz	1-150Hz	Similar. Slight difference does not adversely impact safety and effectiveness of subject device
For interferential modes only: - Beat Frequency (Hz)		N/A	not specified	N/A

		Subject Device	Predicate Device	SE Determination Notes
For multiphasic waveforms only:	Symmetrical phases	yes	N/A	Different but does not adversely impact safety and effectiveness of subject device
	Phase Duration	70us - 400us	N/A	Different but does not adversely impact safety and effectiveness of subject device
Net Charge (mC per pulse) (If zero, state method of achieving zero net charge.)		nominally 0. Method: symmetrical phases	0.001µC @500Ω	Similar. Slight difference does not adversely impact safety and effectiveness of subject device
Maximum Phase Charge, (mC) @ 500 Ω		0.04 mC	0.045 mC	Same
Maximum Current Density, (mA/cm²)		1.1 mA/cm²	0.667 mA/cm²	Different but does not adversely impact safety and effectiveness of subject device
Maximum Power Density, (W/cm²) (using smallest electrode conductive surface area)		0.0012 W/cm²	0.0046 W/cm²	Different but does not adversely impact safety and effectiveness of subject device.
Burst Mode (i.e., pulse trains)	a. Pulses per burst	6	3	Different but does not adversely impact safety and effectiveness of subject device
	b. Bursts per second	4	2	
	c. Burst duration (seconds)	50ms	36ms	
	d. Duty Cycle [Line (b) x Line (c)]	50/250ms	36ms/390ms	
ON Time (seconds)		N/A	2	N/A to subject device
OFF Time (seconds)		NA	2	N/A to subject device
Electrode conductive surface area		4 electrodes each 20.25 cm²	4 electrodes each 20.25 cm²	Same

Table 2 – comparison between subject device RELAX/MLS mode and reference device MASSAGE mode

		Subject Device	Reference Device	Remark
510(k) Number		K253896	K162479	N/A
Device Name, Model		TENS/EMS device GUSE01	Smart Pain Reliever Mode: LT5019	N/A
Manufacturer		Globalcare Medical Technology Co., Ltd	Shenzhen Dongdixin Technology Co., Ltd.	N/A
Product code		NUH, NGX	NUH, NGX, NYN	Similar
FDA Regulation Numbers		882.5890	882.5890	Same
FDA Panel		Neurology	Neurology	Same
FDA Classification		Class II	Class II	Same
Indication for use		TENS: The device is designed to be used for temporary relief of pain associated with sore and aching muscles due to strain from exercise or normal household and work activities. EMS: The device is designed to be used for stimulating healthy muscles in order to improve and facilitate muscle performance.	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) and lower extremities (leg) due to strain from exercise or normal household work activities. And to be used for the symptomatic relief and management of chronic, intractable pain and relief of pain associated with arthritis. EMS: The device is designed to be used for stimulate healthy muscles in order to improve and facilitate muscle performance.	Similar
Basic Unit Characteristics				
Number of Output Modes		1. TENS - ACUTE: 4 2. TENS - CHRONIC: 5 3. EMS - TRAINING: 8 4. EMS – RELAX/MLS: 5	2 (TENS/EMS(including MASSAGE program))	Similar, reference include MASSAGE program
Output Specifications				
Waveform (e.g., pulsed monophasic, biphasic)		Biphasic	Biphasic	Same
Shape (e.g., rectangular, spike, rectified sinusoidal)		rectangular	rectangular	Same
Maximum Output Voltage (specify units)	@ 500 Ω	50 V (+/- 10%)	31.2 V (+/- 20%)	Similar
	@ 2 kΩ	100 V (+/- 10%)	69.6 V (+/- 20%)	Similar
	@ 10 kΩ	100 V (+/- 10%)	69.6 V (+/- 20%)	Similar
Pulse Width (specify units)		100-300 µs	250 µs	Similar

	Subject Device	Reference Device	Remark
Frequency (Hz)	2–50 Hz	10-80 Hz	Similar
Maximum Phase Charge, (mC) @ 500 Ω	0.04 mC	0.03 mC	Similar
Maximum Current Density, (mA/cm²)	1.1 mA/cm²	0.32 mA/cm²	Similar
Maximum Power Density, (W/cm²)	0.0012 W/cm²	0.0019 W/cm²	Similar

The technical characteristics of TENS/EMS device GUSE01 are equivalent to the predicate device in the following aspects:

- mode of action: both devices generate electrical pulses and transmit them to the electrodes, which are attached to the patient's skin to stimulate the underlying peripheral nerves and muscle.
- design: two separately adjustable output channels and display screen.

The differences between subject device and predicate device mainly include the following:

- output parameters: Maximum Output Voltage, Maximum Output Current, Pulse Width, Frequency, Net Charge, Maximum Phase Charge. Although the parameters differ from the predicate device, they are only slightly different from those of the predicate and will not ultimately affect the device's ability to equivalently stimulate the user.
- Waveform shape: subject device was successfully tested according to IEC 60601-2-10 standard, moreover both subject device and predicate devices use biphasic waveform. This difference does not introduce any concerns on subject device's safety and performance.
- Number/Type of programs: this difference does not introduce any concerns on subject device's safety and performance. Moreover, the reference device was included because it employs a similar RELAX/MLS mode that is not present in the predicate device. However, the parameters of this mode are still within the range of the predicate device, and the reference device is being leveraged for the specific claim of producing a massage-like sensation.
- Patient leakage current: subject device was tested and found in compliance with IEC 60601-1. This difference does not introduce any concerns on subject device's safety and performance.
- Timer range: the fact that predicate device is used for longer time does not introduce any concerns on subject device's safety and performance.
- Maximum Current Density and Maximum Power Density: subject device was successfully tested according to IEC 60601-2-10 standard; this difference does not introduce any concerns on subject device's safety and performance. Moreover, according to guidelines the maximum power density should be less than 0.25 W/cm^2.
- Burst Mode characteristics: subject device was successfully tested according to IEC 60601-2-10 standard; this difference does not introduce any concerns on subject device's safety and performance.

4. Non-Clinical Test Summary

Non-clinical testing has been performed to confirm that the subject device adheres to all design specifications, thereby supporting the determination of Substantial Equivalence (SE) to the predicate device. The results of these evaluations 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 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

5. Clinical Testing Summary

No clinical test data was used to support the decision of substantial equivalence.

6. Conclusions

The intended use and basic technological characteristics of the subject device are equivalent with those of the referenced predicate device in K171803. Although there are some differences in terms of the subject device's stimulation parameters and technological characteristics, the subject device complies with the requirements of the IEC60601-1, IEC 60601-2-10, IEC60601-1-2 and IEC60601-1-11 test standards. The bench testing and safety report documentation supplied in this submission demonstrates that any differences in their technological characteristics do not raise any different questions of safety or effectiveness, and the reference device supports the statement that the device can produce a massage-like sensation (MLS) with certain output parameters. Moreover, the bench testing includes the testing performed to characterize the waveform and stimulus parameters, and the performance testing demonstrated that the subject device can deliver a stimulus that meets design specifications. Overall, the subject device can be considered substantially equivalent to the predicate device in terms of safety and effectiveness.