October 21, 2022

Beijing Choice Electronic Technology Co., Ltd.
c/o Haiying Zhao
Quality Director
North Building 3F, No.9 Shuangyuan Road
Badachu Hi-tech Zone, Shijingshan District
Beijing, China 100041

Re: K221992
Trade/Device Name: Electronic Pulse Stimulator
Regulation Number: 21 CFR 882.5890
Regulation Name: Transcutaneous electrical nerve stimulator for pain relief
Regulatory Class: Class II
Product Code: NUH
Dated: September 15, 2022
Received: September 19, 2022

Dear Haiying Zhao:

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 D. 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

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)*
K221992

Device Name
Electronic Pulse Stimulator

Indications for Use *(Describe)*
The Electronic Pulse Stimulator MDTS100 is 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 and work activities.

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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Section II 510(k) Summary

This summary of 510(k) is being submitted in accordance with the requirements of 21 CFR 807.92.

There is no prior submission for the device.

3.1 Submitter Information

- **Manufacturer Name:**
  Establishment Registration Number: 3005569927
  Beijing Choice Electronic Technology Co., Ltd.
  2nd Floor, 3rd Floor and Room 410-412 4th Floor, No. 2 Building, No. 9 Shuangyuan Road , Shijingshan District BEIJING, 100041, P.R.China
- **Contact Person:**
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  Email: cc@choicemmed.com
- **Date prepared：June 24, 2022**

3.2 Proposed Device Information

Device Common Name: Transcutaneous Electrical Nerve Stimulator, OTC

Device Trade/Proprietary Name: Electronic Pulse Stimulator

Model: MDTS100

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

Regulation Number: 882.5890

Product Code: NUH

Class: Ⅱ

Panel: Neurology

3.3 Predicate Device

510(k) Number: K160508

Common Name: Transcutaneous Electrical Nerve Stimulator, OTC

Device Trade/Proprietary Name: Electronic Pulse Stimulator

Model: MDTS100

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

Product Code: NUH

Regulation Number: 882.5890

Device Class: Ⅱ

Panel: Neurology

Manufacturer: Beijing Choice Electronic Technology Co., Ltd.
Intended Use: The Electronic Pulse Stimulator MDTS100 is 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 and work activities.

3.4 Device Description

The Electronic Pulse Stimulator is powered by internal battery. It is intended for at home use in delivering electric pulses to tired and sore muscles. These pulses are generated by the device & delivered through electrode pads placed on the skin. The device has 7 stimulation modes: Mode1-Mode 7. These stimulation modes can be selected by pressing the MODE button on the front of the unit.
The device generates small pulses of electrical current. It transmits these pulses to the user's skin through adhesive electrode pads, which activates the nerves below and temporarily relieves pain related to soreness.
Its accessories include connecting wires, electrode pads, 2 AAA batteries.

The device is for over the counter use.

The device does not contain drug or biological products.

The device includes Bluetooth functionality, however, in this model of the device, the Bluetooth functionality is not used.

3.5 Comparison list of the technological characteristics

Table 2-1 Basic Unit Characteristics Comparison Table between the Proposed Device and Predicate Device

Comparison Elements			**Proposed Device**	**Predicate Device**	**Remark**
510(k) number			NA	K160508	/
Device Name/Model			Electronic Pulse Stimulator MDTS100	Electronic Pulse Stimulator MDTS100	/
Manufacturer			Beijing Choice Electronic Technology Co., Ltd.	Beijing Choice Electronic Technology Co., Ltd.	Same
Power Source(s)	-Method of Line Current Isolation		N/A for DC current	N/A for DC current	Same
	-Patient Leakage Current	-Normal condition	≤10μA	≤10μA	Same
		-Single fault condiction	≤50μA	≤50μA	Same
Average DC current through electrodes when device is on but no pulses are being applied(μA)			≤10μA	≤10μA	Same
Number of Output Modes			7	7	Same
Number of Output Channels	-Synchronous or Alternating?		Alternating	Alternating	Same
	-Method of Channel Isolation		No	No	Same

Regulated Current or Regulated Voltage?		Regulated Voltage	Regulated Voltage	Same
Software/Firmware/Microprocessor Control?		Yes	Yes	Same
Automatic Overload Trip		No	No	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)		20 minutes	20 minutes	Same
Compliance with Voluntary Standards?		Yes	Yes	Same
Compliance* with 21 CFR 898? (*Becomes mandatory beginning May 9, 2000)		Yes	Yes	Same
Weight		2.3 oz(Battery Excluded)	2.2 oz. (Battery Excluded)	Similar
Dimensions (in.) [W x H x D]		2.17x 5.12x0.79	2.17x 5.12x0.87	Similar
Housing Materials and Construction		Enclosure: ABS	Enclosure: ABS	Same

Table 2-2 Output Specification Comparison Table between the Proposed Device and Predicate Device

Comparison Elements	**Proposed Device**	**Predicate Device**	**Remark**
Waveform (e.g., pulsed monophasic, biphasic)	pulsed monophasic	pulsed monophasic	Same
Shape (e.g., rectangular, spike, rectified sinusoidal)	Rectangular	Rectangular	Same
Maximum Output Voltage (specify units) (+/-___20___%)	__150V____@ 500 Ω	___150V____@ 500 Ω	Same
	__160V____@ 2 kΩ	___160V___@ 2 kΩ	Same
	__165V_____@ 10 kΩ	___165V____@ 10 kΩ	Same
Maximum Output Current (specify units) (+/-_____%)	__300mA_____@ 500 Ω	___300mA____@ 500 Ω	Same
	__80mA_____@ 2 kΩ	____80mA___@ 2 kΩ	Same
	__16.5mA_____@ 10 kΩ	__16.5mA_____@ 10 kΩ	Same
Duration of primary (depolarizing) phase (μsec)	0 μsec	0 μsec	Same
Pulse Duration((μsec))	35 μsec	35 μsec	Same
Frequency(Hz)	0.9Hz~82Hz	0.9Hz~82Hz	Same
Net Charge (μC per pulse) (If zero, state method of achieving zero net charge.)	__42μC____ @ 500 Ω	___42μC____ @ 500 Ω	Same
Maximum Phase Charge, (μC)@500Ω	42μC	42μC	Same
Maximum Current Density, (mA/cm ²)	3.3mA/cm2@1.57″×1.57″Electrode Pad	3.3mA/cm2@1.57″×1.57″Electrode Pad	Same

Maximum Average Current (average absolute value), mA		2.8mA	2.8mA	Same
Burst Mode (i.e., pulse trains)	a. Pulses per burst	197	197	Same
	b. Bursts per second	0.185	0.185	Same
	c. Burst duration (seconds)	2.4s	2.4s	Same
	d. Duty Cycle [Line (b) x Line (c)]	0.44	0.44	Same
ON Time (seconds)		⩽1second	⩽1second	Same
OFF Time (seconds)		⩽1second	⩽1second	Same
Cybersecurity		FDA Guidance for Content of Premarket Submission for Management of Cybersecurity in Medical Device	/	Difference
Wireless Testing		Conform to FCC and wireless coexistence test	/	Difference

Conclusion:

The proposed device and the predicate device have same working principle, same performance specification. There are very small differences in the weight and dimensions of the two devices, which have no impact on the safety and effectiveness.

Compared with the predicate device, the proposed device has bluetooth function. We have conducted the wireless test and cybersecurity analysis to verify the basic safety and the essential performance. The Bluetooth function in this model of the device is not used.

3.6 Intended use

The Electronic Pulse Stimulator MDTS100 is 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 and work activities.

3.7 Testing

Biocompatibility Testing

The material in contact with the patient of the proposed device is self adhesive electrode, which has been conducted the biocompatibility test according to the requirement of the ISO 10993-1, ISO 10993-5, ISO 10993-10.

Electrical safety and electromagnetic compatibility (EMC)

The proposed device Electronic Pulse Stimulator MDTS100 is tested in accordance with IEC 60601-1, IEC 60601-1-2, IEC 60601-1-11, IEC 60601-2-10 to evaluate the electrical safety and EMC.

Performance Test-Bench

We have also conducted IEC 60601-2-10 and other performance tests including maximum output amplitudes, pulse durations, pulse repetition frequencies, maximum output current, supply voltage fluctuations, supply voltage fluctuations, Cleaning Test , High and Low Temperature & Humidity Test, Shelf-life Test as so on .

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 failure or latent flaw could indirectly result in minor injury to the patient or operator through incorrect or delayed information or through the action of a care provider.

Cybersecurity testing

Cybersecurity testing were conducted and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Postmarket Management of Cybersecurity in Medical Devices." Cybersecurity testing was performed because of the Bluetooth function. Please note that the Bluetooth function in this model of the device is not used.

Wireless Testing

We have conducted the FCC test and wireless coexistence for the proposed device MDTS100. The test reports are presented in ***Electromagnetic Compatibility and Electrical Safety***. Wireless testing was performed because of the Bluetooth function. Please note that the Bluetooth function in this model of the device is not used.

Clinical Testing

The clinical testing was not needed in this submission.

3.8 Determination of substantial equivalence

The proposed device of the Electronic Pulse Stimulator MDTS100 has the same classification information, same intended use, same design principle, same product design and specifications as the predicate device. So, the proposed device are Substantially Equivalent (SE) to the predicate device which is US legally market device.