December 13, 2021

Shenzhen OSTO Technology Company Limited
% Cassie Lee
Official Correspondent
Guangzhou GLOMED Biological Technology Co., Ltd.
2231, Building 1, Rui Feng Center, Kaichuang Road,
Huangpu District
Guangzhou, Guangdong 510663
China

Re: K211942
Trade/Device Name: Heating Lumbar Therapy Cushion (Model: AST-622, AST-622B, AST-623, AST-623B)
Regulation Number: 21 CFR 890.5850
Regulation Name: Powered muscle stimulator
Regulatory Class: Class II
Product Code: NGX, NUH, IRT
Dated: December 6, 2021
Received: December 10, 2021

Dear Cassie Lee:

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,

Heather Dean, PhD
Assistant Director, Acute Injury Devices Team
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)*
K211942

Device Name
Heating Lumbar Therapy Cushion (Model: AST-622, AST-622B, AST-623, AST-623B)

Indications for Use *(Describe)*
PMS(1 ~ 2): It is intended to stimulate healthy muscles in order to improve and facilitate muscle performance.
TENS(3 ~ 5): To be 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 work activities by applying current to stimulate nerve.

Heating: The Heating Lumbar Therapy Cushion is intended for temporary relief of minor aches and pains.

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 for K211942

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

1. Submitter's Information

- 510(k) Owner's Name: Shenzhen OSTO Technology Company Limited
- Establishment Registration Number: 3011564440
- Address: No.43 Longfeng Road, Xinsheng Community, Longgang Street, Longgang District, Shenzhen City, Guangdong Province, China
- Tel: +86-755-29769546
- Fax: +86-755-29769540
- Contact Person: Li Yang (General Manger)
- Email: annaosto@163.com

2. Application Correspondent:

- Contact Person: Ms. Cassie Lee
- Guangzhou GLOMED Biological Technology Co., Ltd.
- Address: 2231, Building 1, Rui Feng Center, Kaichuang Road, Huangpu District, Guangzhou, Guangdong, China
- Tel: +86 20 8266 2446
- Email: regulatory@glomed-info.com

3. Subject Device Information

- Common Name: Powered Muscle Stimulator for Muscle Conditioning, and heating for pain relief, blood circulation, and muscle performance
- Trade Name: Heating Lumbar Therapy Cushion (Model: AST-622, AST-622B, AST-623, AST-623B)
- Classification Name: Stimulator, Nerve, Transcutaneous, Over-The-Counter
- Review Panel: Physical Medicine
- Product Code: NGX, NUH, IRT
- Regulation Number: 890.5850
- Regulation Class: II

4. Predicate Device Information

Predicate Device 1 Information

- Common Name: Transcutaneous electrical nerve stimulator for pain relief
- 510(k) Number: K190783
- Sponsor: Shenzhen OSTO Technology Company Limited
- Trade Name: Health Expert Electronic Stimulator (model: AST-300L)
- Classification Name: Stimulator, Nerve, Transcutaneous, Over-the-Counter
- Review Panel: Neurology, Physical Medicine
- Product Code: NUH, NGX
- Regulation Number: 882.5890, 890.5850
- Regulation Class: II

Predicate Device 2 Information

- Common Name: Transcutaneous Electrical Nerve Stimulation (TENS) unit, Powered Muscle Stimulation (PMS) unit, and heating for pain relief, blood circulation, and muscle performance
- 510(k) Number: K200561
- Sponsor: JKH Health Co., LTD
- Trade Name: StimPlus Patch
- Classification Name: Stimulator, Nerve, Transcutaneous, Over-The-Counter
- Review Panel: Neurology
- Product Code: NUH, NGX, NYN, IRT
- Regulation Number: 882.5890
- Regulation Class: II

4. Device Description

The Heating Lumbar Therapy Cushion is a portable TENS/PMS device. The device is equipped with a remote control, an adapter, a pair of electrode pads and electrode wire. The electrode wire is used to connect the electrode pads to the main unit.

The device has 5 stimulate modes and one heating mode, through the stainless steel plate to provide users with lower back stimulation and heat generation to warm and comfortable lower back muscles. In addition, it is equipped with a pair of electrode pads, which can be used to stimulate different parts of the body (the shoulder, waist, back, arm and leg).

The principle of operation of the subject device is:

PMS: A powered muscle stimulator for muscle conditioning is a device used for other than medical purposes to apply an electrical current to electrodes on a person's skin to temporarily affect the stimulated muscle's contractile properties, force output, and/or fatigue resistance. This device is not intended for use in patients with medical conditions and is intended only for muscle conditioning purposes.

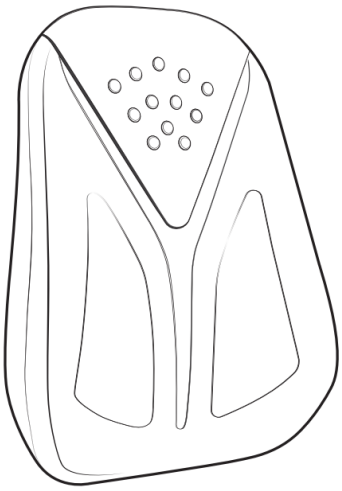
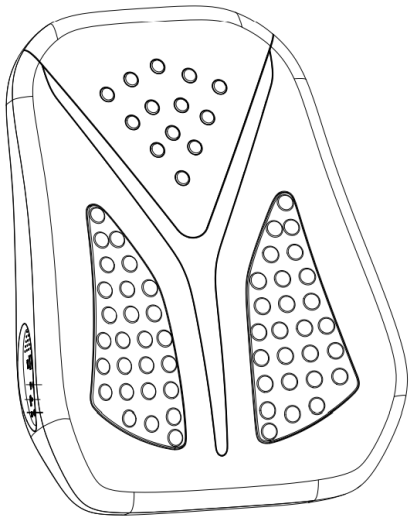
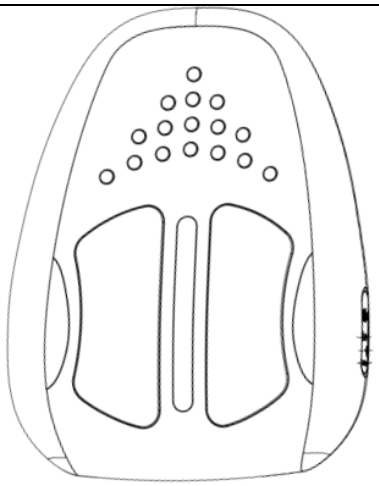
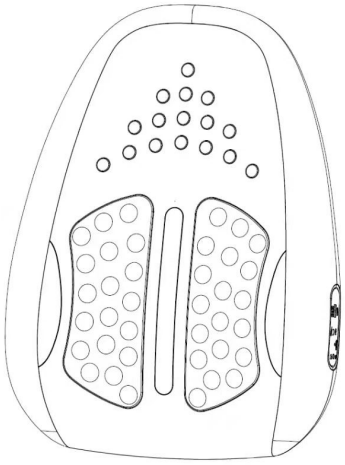
TENS: The electrodes placed on the skin send small-scale, low-voltage electrical pulses to specific nerves. The purpose is to change the way neurons send signals and prevent pain signals from reaching the brain to relieve pain.

All the functions of the device can only be controlled by the remote control, which should connected to the main unit through a wire. The remote controller has the component of ON/OFF Key, Mode Selection key (left and right), Intensity Modification keys (increase and decrease) and an LCD screen. And the LCD screen can show stimulation mode, stimulation intensity, heating intensity and time remaining of an application mode. The device has 5 stimulation modes, each with 50 stimulation intensity and one heating Mode, heating mode has 3 levels, namely level 1 (37°C), level 2 (40°C), and level 3 (43°C).

The stainless steel plate provides users with lower back stimulation and heat to warm and comfort the muscles of the lower back. The stimulation function and heating function can be used separately or simultaneously. When used with a pair of electrode pads, it must be used simultaneously with the main unit stimulation mode, otherwise the electrode pads will be invalid.

The equipment has four models: AST-622, AST-622B, AST-623, AST-623B, the four models differ only in appearance. Please refer to the photographs as below:

Model	Appearance	Model	Appearance

AST-622		AST-622B	
AST-623		AST-623B	

5. Intended Use / Indications for Use

PMS(1 ~ 2): It is intended to stimulate healthy muscles in order to improve and facilitate muscle performance.
TENS(3 ~ 5): To be 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 work activities by applying current to stimulate nerve.
Heating: The Heating Lumbar Therapy Cushion is intended for temporary relief of minor aches and pains.

6. Test Summary

6.1 Non-Clinical Tests Performed

Non-Clinical tests were performed on the subject device in order to validate the design and to assure conformance with the following voluntary design standards in connection with medical device electrical safety, and electromagnetic compatibility:

- Electrical safety test according to IEC 60601-1, IEC 60601-1-11 and IEC 60601-2-10 standards
- Electromagnetic compatibility test according to IEC 60601-1-2 standard
- Usability test according to IEC 62366 standard
- Software verification and validation test according to the requirements of the FDA “Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices”

- The waveform test has also been conducted to verify the output specifications of the device according to “Guidance for Transcutaneous Electrical Nerve Stimulator for Pain Relief Intended for Over the Counter Use and Guidance for Powered Muscle Stimulator for Muscle Conditioning”.
- Biocompatibility test according to ISO 10993-5 and ISO 10993-10 standards

6.2 Discussion of Clinical Tests Performed

There were no Clinical Tests.

7. Comparison to predicate device and conclusion

The technological characteristics, features, specifications, materials, mode of operation, and intended use of Heating Lumbar Therapy Cushion (Model: AST-622, AST-622B, AST-623, AST-623B) is substantially equivalent to the predicate devices quoted above.

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 1	Predicate Device 2	Remark
Device Name	Heating Lumbar Therapy Cushion (Model: AST-622, AST-622B, AST-623, AST-623B)	Health Expert Electronic Stimulator Model: AST-300L	PL-029K29, PL-029K30, and PL-029Q	--
510(k) Number	K211942	K190783	K200561	--
Intended Use	PMS(1 ~ 2): It is intended to stimulate healthy muscles in order to improve and facilitate muscle performance. TENS(3 ~ 5): To be 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 work activities by applying current to stimulate nerve. Heating: The Heating Lumbar Therapy Cushion is intended for temporary relief of minor aches and pains.	PMS (Mode 1~8) It is intended to stimulate healthy muscles in order to improve and facilitate muscle performance. TENS (Mode 9~25) 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.	TENS: PL-029K29, PL-029K30, and PL-029Q 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-029K29, PL-029K30, and PL-029Q are also intended for symptomatic relief and management of chronic, intractable pain and relief of pain associated with arthritis. PMS: PL-029K29, PL-029K30, and PL-029Q are used to stimulate healthy muscles in order to	SE

Elements of Comparison	Subject Device	Predicate Device 1	Predicate Device 2	Remark
			improve and facilitate muscle performance. To 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 or diseases. PL-029K29, PL-029K30, and PL-029Q are also intended to temporarily increase local blood circulation in the healthy muscles of lower extremities. Heating: PL-029K30 and PL-029Q is intended for temporary relief of minor aches and pains.	
Treatment site	Shoulder, waist, back, arm and leg	Shoulder, waist, back, back of the neck, arm, leg, and foot	Arms, abdomen, shoulder, waist, back, and leg	SE
Principle of Operation	PMS: A powered muscle stimulator for muscle conditioning is a device used for other than medical purposes to apply an electrical current to electrodes on a person's skin to temporarily affect the stimulated muscle's contractile properties, force output, and/or fatigue resistance. This device is not intended for use in patients with medical conditions and is intended	PMS: A powered muscle stimulator for muscle conditioning is a device used for other than medical purposes to apply an electrical current to electrodes on a person's skin to temporarily affect the stimulated muscle's contractile properties, force output, and/or fatigue resistance. This device is not intended for use in patients with	PMS: A powered muscle stimulator for muscle conditioning is a device used for other than medical purposes to apply an electrical current to electrodes on a person's skin to temporarily affect the stimulated muscle's contractile properties, force output, and/or fatigue resistance. This device is not intended for use in patients with medical conditions and is intended only for	SE

Elements of Comparison		Subject Device	Predicate Device 1	Predicate Device 2	Remark
		only for muscle conditioning purposes; TENS: The electrodes placed on the skin send small-scale, low-voltage electrical pulses to specific nerves. The purpose is to change the way neurons send signals and prevent pain signals from reaching the brain to relieve pain.	medical conditions and is intended only for muscle conditioning purposes; TENS: The electrodes placed on the skin send small-scale, low-voltage electrical pulses to specific nerves. The purpose is to change the way neurons send signals and prevent pain signals from reaching the brain to relieve pain.	muscle conditioning purposes; TENS: The electrodes placed on the skin send small-scale, low-voltage electrical pulses to specific nerves. The purpose is to change the way neurons send signals and prevent pain signals from reaching the brain to relieve pain.	
Power Source(s)		Powered by adapter, 100-240VAC, 50-60Hz Output: 5Vdc, 2A Unit Input: 5Vdc, 2A	Adaptor Input: 100-240Vac, 50-60Hz, 0.1A Output: 5Vdc, 2A Unit Input: 5Vdc, 2A	Rechargeable or nonrechargeable battery	SE
-Method of Line Current Isolation		Type BF Applied Part	Type BF Applied Part	Battery Supply	SE
-Patient Leakage Current	NC	AC: 54.4uA, DC: 0	AC: 54.5, DC: 0.5□□	2.0μA	SE Note 1
	SFC	AC: 13.4uA, DC: 0	AC: 54.5, DC: 0.5□□	＜10.0μA	
Number of Output Channels:		1	2	1-2	SE
Number of Output Modes		For stimulation: 5 modes For heating: 1 mode	25	PL-029K29: 8 PL-029K30: 8 PL-029Q: 8	SE Note 2
Output Intensity Level		For stimulation: 50 levels For heating: 3 levels	99 steps	No publicly available	SE Note 1
Synchronous or Alternating		Synchronous	Synchronous	Synchronous	SE
Method of Channel Isolation		1	2	1	SE
Regulated Current or Regulated Voltage?		Voltage	Voltage Control	Voltage	SE
Software/Firmware/ Microprocessor Control?		Yes	Yes	Yes	SE

Elements of Comparison		Subject Device	Predicate Device 1	Predicate Device 2	Remark
Automatic Overload Trip		No	No	No	SE
Automatic No-Load Trip		No	No	Yes	SE
Automatic Shut Off		Yes	Yes	Yes	SE
User Override Control		Yes	Yes	Yes	SE
Indicator Display	On/Off Status	Yes	Yes	Yes	SE
	Low battery	No	No	Yes	SE
	Voltage / current level	Yes	Yes	No	SE
Timer Range		5-30 min	25 to 60 min	PL-029K29: 10~60 PL-029K30: 10~60 PL-029Q: 10~60	SE
Weight		Unit: 1704.5g Remote Controller: 73g	2.1Kg (Without accessories)	Not publicly available	SE Note 2
Dimensions(mm) [L x W x D]		Model AST-622 and AST-622B: 456mm×354mm×86.7mm Model AST-623 and AST-623B: 448.9mm×347.9mm×69.9mm Stainless steel: For AST-622: 224mm×96mm For AST-622B: 224mm×96mm For AST-623: 212mm×94mm For AST-623B: 212mm×94mm	429.2mm x 401mm x 152.8mm Foot Conductive Rubber: 254×98mm	PL-029K29: 150x80x12 PL-029K30: 80x55x20 PL-029Q: 148x81x29	SE Note 2
Housing Materials and Construction		Main unit: ABS Plastic, Stainless steel Red Transparent Plastic:	Main unit (Sole Massage Roller, Unit Housing,	Silicone & ABS	SE

Elements of Comparison	Subject Device	Predicate Device 1	Predicate Device 2	Remark
	ABS plastic Electrode Pads: White silica gel, Black conductive silicone, Transparent conductive adhesive silicone, Transparent PET silicone	Host keypads): ABS plastic Foot Conductive pad: Stainless steel Red Transparent Plastic: ABS plastic Electrode Pads: White silica gel, Black conductive silicone, Transparent conductive adhesive silicone, Transparent PET silicone		
Maximum skin temperature	43°C	40°C	PL-029K30: 43°C PL-029Q: 43°C	SE
Waveform	Symmetrical Biphasic	Pulsed, symmetric, biphasic	Biphasic	SE
Shape	Rectangular	Rectangular, with interphase interval	Rectangular	SE
Maximum Output Voltage	23.2V±10% @ 500Ω	44V±10% @ 500Ω	Mode 1: This mode cycles the following modes Mode 2: 36.4 Mode 3: 47.6 Mode 4: 57.6 Mode 5: 29.6 Mode 6: 29.6 Mode 7: 40.8 Mode 8: 24.0	SE Note 1
	39.2V±10% @ 2KΩ	80V±10% @ 2KΩ	Mode 1: This mode cycles the following modes Mode 2: 80.8 Mode 3: 96.0 Mode 4: 93.6 Mode 5: 66.4 Mode 6: 66.4 Mode 7: 86.4 Mode 8: 53.6	
	73.2V±10% @ 10KΩ	112V±10% @ 10KΩ	Mode 1: This mode cycles the following modes Mode 2: 134 Mode 3: 132 Mode 4: 108 Mode 5: 126	

Elements of Comparison	Subject Device	Predicate Device 1	Predicate Device 2	Remark
			Mode 6: 126 Mode 7: 129 Mode 8: 105	
Maximum Output Current	46.4mA±10% @ 500Ω	88mA±10% @ 500Ω	Mode 1: This mode cycles the following modes Mode 2: 72.8 Mode 3: 95.2 Mode 4: 115.2 Mode 5: 59.2 Mode 6: 59.2 Mode 7: 81.6 Mode 8: 48.0	SE Note 1
	19.6mA±10% @ 2KΩ	40mA±10% @ 2KΩ	Mode 1: This mode cycles the following modes Mode 2: 40.4 Mode 3: 48.0 Mode 4: 46.8 Mode 5: 33.2 Mode 6: 33.2 Mode 7: 43.2 Mode 8: 26.8	
	7.32mA±10% @ 10KΩ	11.2mA±10% @ 10KΩ	Mode 1: This mode cycles the following modes Mode 2: 13.4 Mode 3: 13.2 Mode 4: 10.8 Mode 5: 12.6 Mode 6: 12.6 Mode 7: 12.9 Mode 8: 10.5	
Pulse Duration	180μs	120μs	100μs	SE Note 1
Pulse frequency (Hz)	133Hz	77.3Hz	Mode 1: This mode cycles the following modes Mode 2: 62.5 Mode 3: 12.8~54.3 Mode 4: 1.19 Mode 5: 104.1 Mode 6: 104.1 Mode 7: 19.8 Mode 8: 156.2	SE Note 1
Net Charge (per pulse)	0μC @ 500Ω, Method: Balanced waveform	0μC @ 500Ω Method: Balanced	Not publicly available	SE

Elements of Comparison	Subject Device	Predicate Device 1	Predicate Device 2	Remark
		waveform		
Maximum Phase Charge(μC) at 500Ω	8.352μC @ 500Ω	10.56μC @ 500Ω	Mode 1: This mode cycles the following modes Mode 2: 14.6 Mode 3: 19.0 Mode 4: 23.0 Mode 5: 11.8 Mode 6: 11.8 Mode 7: 16.3 Mode 8: 9.6	SE Note 1
Maximum Current Density	4.44mA @ 500Ω	1.63mA @ 500Ω	Mode 1: This mode cycles the following modes Mode 2: 2.02 Mode 3: 2.64 Mode 4: 3.20 Mode 5: 1.64 Mode 6: 1.64 Mode 7: 3.26 Mode 8: 1.92	SE Note 1
Maximum Power Density	0.225mW/cm² @ 500Ω	0.0000266mW/cm² @ 500Ω	Mode 1: This mode cycles the following modes Mode 2: 0.92 Mode 3: 0.32~1.37 Mode 4: 0.04 Mode 5: 1.01 Mode 6: 1.01 Mode 7: 0.53 Mode 8: 1.44	SE Note 1
ON Time	2s	240 us	3.4~20	SE Note 2
OFF Time	2s	12700 us	1~2.5	SE Note 2
Biocompatibility	ISO 10993-5, ISO 10993-10	All user directly contacting materials are compliance with ISO10993-5 and ISO10993-10 requirements.	ISO 10993-5, ISO 10993-10	SE
Electrical Safety	IEC 60601-1, IEC 60601-1-11, IEC 60601-2-10	Comply with IEC 60601-1 and IEC 60601-2-10	IEC 60601-1, IEC 60601-2-10	SE
EMC	IEC 60601-1-2	Comply with IEC 60601-1-2	IEC 60601-1-2	SE

Comparison in Detail(s):

Note 1:

Although the "Power Source(s)", "Patient Leakage Current", "Output Intensity Level", "Maximum Output Voltage", "Maximum Output Current", "Pulse Duration", "Pulse frequency (Hz)", "Maximum Phase Charge(μC) at 500Ω", "Maximum Current Density" and "Maximum Power Density" of subject device are a little different from the predicate device, but they all meet the requirements by IEC 60601-1, IEC 60601-1-2 and IEC 60601-2-10 standards required. So the differences will not raise any safety or effectiveness issue.

Note 2:

Although the "Weight", "Dimensions(mm)", "Number of Output Modes", "ON Time" and "OFF Time" of subject device are a little different from the predicate device, but the differences will not raise any safety or effectiveness issue.

Comparison in Detail(s):

Note (a):

Although the “Pulse Duration”, “Pulse Frequency” “On time” and “Off time” of subject device are little different from the predicate device, they are very similar in waveform group, and are all comply with IEC 60601-1 and IEC 60601-2-10 requirements. So the differences of the function specifications will not raise any safety or effectiveness issue.

Note (b):

Although the “Maximum Output Voltage”, “Maximum Output Current”,“Maximum Phase Charge”,“Maximum Average Current”,“Maximum Current Density” and “Maximum Average Power Density” of subject device is little different from the predicate device, their maximum peak voltage are very similar, and are all comply with IEC 60601-1 and IEC 60601-2-10 requirements. So the differences of the function specifications will not raise any safety or effectiveness issue.

Finial Conclusion:

The subject devices "Heating Lumbar Therapy Cushion, model AST-622, AST-622B, AST-623, AST-623B" are Substantial Equivalent to the predicate device K190783 and K200561.

8. Date of the summary prepared: December 13, 2021