March 31, 2022

Shenzhen Future Electronic Co., Ltd
℅ You Yijie
Manager
Qimmiq Medical Consulting Service Co., Ltd.
RM.1711, Building K
NO.101 Science Ave International Creative Valley
Guangzhou, Guangdong 510663
China

Re: K213745
Trade/Device Name: Air Compression Therapy Device, model: ST-502
Regulation Number: 21 CFR 890.5650
Regulation Name: Powered Inflatable Tube Massager
Regulatory Class: Class II
Product Code: IRP
Dated: February 2, 2022
Received: February 2, 2022

Dear You Yijie:

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)*

K213745

Device Name
Air Compression Therapy Device, model: ST-502

Indications for Use *(Describe)*

The Air Compression Therapy Device(model: ST-502) is indicated for the temporary relief of minor muscle aches and pains and for temporary increase in circulation to the treated areas in people who are in good health. The Air Compression Therapy Device (model: ST-502) simulates kneading and stroking of tissues by using an inflatable garment.

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 – K213745

1. Submitter's Information

Establishment Registration Information

Name: SHENZHEN FUTURE ELECTRONIC CO., LTD.
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Contact Person of applicant

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Contact Person of the Submission:

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Email: Jet.you@qimmiq-med.com

Date prepared: Nov. 15, 2021

2. Device Information

Trade Name:	Air Compression Therapy Device
Model:	ST-502
Classification name:	Massager, Powered Inflatable Tube
Review panel:	Physical Medicine
Product code:	IRP
Regulation Class:	II
Regulation Number:	21CFR890.5650

3. Predicate Device Information

Predicate device:

510(k) submitter/holder:	Shenzhen Dongjilian Electronics Co., Ltd.

510(K) Number:	K193354
Trade Name:	Air Compression Therapy Device
Model:	S9019
Classification name:	Massager, Powered Inflatable Tube
Review panel:	Physical Medicine
Product code:	IRP
Regulation Class:	II
Regulation Number:	21CFR890.5650

4. Device description

Air Compression Therapy Device, model: ST-502 is a powered inflatable tube massager. The Air Compression Therapy Device, model: ST-502 is consists of an air pump, air pressure sensor, leg sleeves and adapter. The air pump, air pressure sensor and control components are protectively housed in a plastic case of the control unit. The control unit is connected to the dedicated leg sleeves via a series of hoses; each leg sleeve has 3 compression chambers. The Air Compression Therapy Device, model: ST-502 utilizes the pneumatically controlled leg sleeves actuated by an electronically controlled air pump unit.

The “Power” button, “Intensity” button, “Mode” button and LED indicators/displays provide for user interface. There is also a port for connecting the AC adapter plug.

The leg sleeves consist of air pipes and three airbags encased inside a soft medical fabric for increased patient comfort and biocompatibility compliance.

In operation, the user simply turns the power on via the “Power” button. And the user presses the “Intensity” button, “Mode” button to adjust the pressure intensity and working mode of the device as the needs of users.
The compression massage direction is from foot room and push up the thighs. By inflating the air chambers sequentially and then deflating as one cycle, the pressure can be adjusted to avoid any discomfort to the patient. The leg sleeves work under the action of sensor and microprocessor. Software controls the timing and pressure reflected by the sensor, cycling airflow into and out of the sleeves to compress body.
During in the working condition, once the leg sleeves pressure of the airbags reach the proper level(240mmHg), the device is turned off, and the leg sleeves deflates to the ambient pressure through a valve inside the plastic case.

Environment of use of the device: Clinics, hospital, athlete training, and home environments

Principle of operation:

The control unit is connected to the leg sleeves via hose. The control unit contains an air pump, pressing “Power” button to begin normal treatment status, the air pump will pump air into leg sleeves with stetted rhythm though air pipe, the sleeve fits on the low limbs and provide therapy.

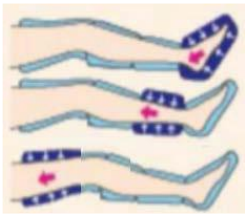
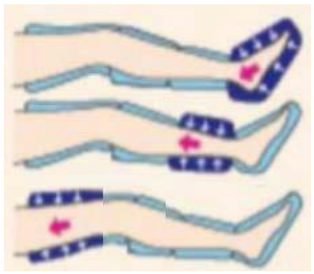
5. Indications for Use

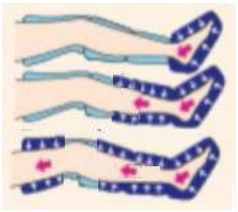
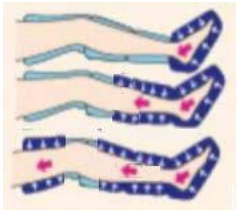
The Air Compression Therapy Device (model: ST-502) is indicated for the temporary relief of minor

muscle aches and pains and for temporary increase in circulation to the treated areas in people who are in good health. The Air Compression Therapy Device (model: ST-502) simulates kneading and stroking of tissues by using an inflatable garment.

6. Summary of technological characteristics of device compared to the predicate devices (K193354)

SE Comparisons	**Subject device (Air Compression Therapy Device, model: ST-502)**	**Primary predicate device (Shenzhen Dongjilian Electronics Co.,Ltd. Air Compression Therapy Device, Model: S9019)**	**Discussion of difference**
510K Number	K213745	**K193354**	***/***
Classification	21 CFR890.5650	21 CFR890.5650	**Same**
Product Code	IRP	IRP	**Same**
FDA Class	II	II	**Same**
Indications for Use	The Air Compression Therapy Device (model: ST-502) is indicated for the temporary relief of minor muscle aches and pains and for temporary increase in circulation to the treated areas in people who are in good health. The Air Compression Therapy Device (model: ST-502) simulates kneading and stroking of tissues by using an inflatable garment.	The Air Compression Therapy Device is indicated for the temporary relief of minor muscle aches and pains and for temporary increase in circulation to the treated areas in people who are in good health. The Air Compression Therapy Device simulates kneading and stroking of tissues by using an inflatable garment.	**Same**
Over-The-Counter Use	Yes	Yes	**Same**
Model	ST-502	S9019	***/***
Treatment area/Structure of Sleeves	Low limbs (Foot, calf and upper leg)	Low limbs (Foot, calf and upper leg)	**Same**
Environment of Use	Clinics, hospital, athlete training, and home environments	Clinics, hospital, athlete training, and home environments	**Same**
Patient Population	Adult	Adult	**Same**
Power source	100-240V, 50-60Hz	100~240V 50/60Hz	**Same**
Power Consumption	12w	12W	**Same**
SW/Firmware/ Microprocessor Control	Microprocessor	Microprocessor	**Same**
Therapy Time	20 mins	20 minutes	**Same**
Output pressure range	0~240 mmHg	0~240 mmHg	**Same**

Air pressure Level /Compression levels	3 levels settings: low level:150mmHg; Medium level:185mmHg; High Level: 215mmHg	3 levels settings: low level:150mmHg; Mid level:185mmHg; High Level: 215mmHg	**Same**
Pressure error range	±25mmHg	±25mmHg	**Same**
Inflation time	3-30s	3-30s	**Same**
Keep time	1-5s	1-5s	**Same**
Deflation time	1-5s	1-5s	**Same**
Mode types	Sequential/ Peristaltic	Sequential/ Peristaltic	**Same**
Cycle time	25 seconds to 3 minutes and 40 seconds	Range of 25 sec to 3 min 40 sec	**Same**
Number of chambers	3 Chambers	3 Chambers	**Same**
Number of treatment mode	3 modes	3 modes	**Same**
Modes (visual description)	M1: Start in the foot room and push up the thighs, the pressure gradually rises to a predetermined pressure level with each compression, then depressurizes and the pressure drops. Once the thighs are decompressed, the circulation begins again. Pattern 1 follow this stress sequence:  M2: Starting in the foot chamber, push up the thighs, and with each compression, the pressure gradually rises to a predetermined air pressure level, holding the air until the entire garment is compressed. All three parts decompress	**Mode 1**: Starting with the foot chamber and progressing up the thigh chamber, each section compresses and the pressure gradually rises to the pre-determined air pressure level, then decompresses and the air pressure drops. Once the thigh section decompresses, the cycle begins again. Mode 1 follows this pressure sequence:  **Mode 2:** Starting with the foot chamber and progressing up the thigh, each section compresses and the pressure gradually rises to the pre-determined air pressure level, holds the air until the entire garment is compressed. All three sections then	**Same**

	simultaneously, air pressure drops, and the circulation begins again. Pattern 2 follow this pressure sequence:  M3: It consists of two phase. Phase 1: It works as a pattern 1 method, and after phase 1 is completed, it continues to phase 2 (working as a pattern 2 method) until phase 2 is completed, and then continues to the next cycle without interruption. The pressure sequence of mode 3 is combined with mode 1 and mode 2.	decompress simultaneously and the air pressure drops, then cycle begins again. Mode 2 follows this pressure sequence  Mode 3: include two stage, stage 1: it works according to the method of mode 1, after the stage 1 is completed, it go to stage 2(working according to the method of mode 2) without interruption time until finish the stage 2, then enter next cycle without interruption . Mode1 ⇄ Mode2 The pressure sequence of mode 3 combines mode 1 and mode 2.	
Noise level	⩽65db	⩽ 65dB	**Same**
Sleeve Material	Material of memory cloth: 100% polyester material Velcro(loops): nylon70%, polyester 30% Velcro (hooks): 100% nylon	Nylon with a Polyurethane laminate	**Different** (Discussion is indicated in D1)
Housing Materials	Molded ABS enclosure	Molded ABS enclosure	**Same**
Patient contact	Non-conductive attachments	Non-conductive attachments	**Same**
Size and appearance	L215*W65*H51mm	10.2×5.9×25.6 （in）	**Different** (Discussion is indicated in D2)

			
Weight	1400g (approximately:3.08 pounds) (machine+right/left wrap) 1600g (approximately:3.52 pounds) (main unit+ leg sleeves +adapter)	4.6 pounds	**Different** (Discussion is indicated in D3)
Size and appearance of sleeves (leg part)	 Leg: One size: L720*W270mm	 Leg: One size：73*26cm	**Similar** (Discussion is indicated in D4)
Safety Features	The “Power” button allows user to stop therapy session at any time	Standby button allows user to stop therapy session at any time	**Similar** (Discussion is indicated in D5)
Operating environment	Temperature: 5℃~40℃ Humidity:15%-93%, non-condensing Atmospheric pressure: 70kPa-106kPa	Temperature: 5℃-40℃, Humidity:5%-90% no-condensing	**Similar** (Discussion is indicated in D6)
Transportation & Storage environment	Temperature:-20℃~55℃ Humidity:5%-90%, non-condensing Atmospheric pressure: 75kPa-106kPa	Temperature: -20℃~55℃; Humidity:5%-90% noncondensing Atmospheric Pressure:75kPa-106kPa	**Same**
Standards	ANSI AAMI ES60601-1:20051/(R)2012 and A1:2012,	ES 60601-1; IEC60601-1-2; ISO 10993-5:	**Same**

	C1:20091(R)2012 and A2:2010(R)2012 IEC 60601-1-2 Edition 4.0 2014; ANSI AAMI HA 60601-1-11:2015 ISO 10993-5 Third edition 2009-06-01: ISO 10993-10 Third Edition 2010-08-01;	ISO 10993-10; IEC 60601-1-11	

The discussion of differences exist between the subject and predicate devices is listed in following:

D1: The subject device has been validated for cytotoxicity per ISO 10993- 5 and Irritation as well as Sensitization per ISO 10993-10 with positive results, therefore, the material difference of subject device with predicate device S9019 (K193354) do not raise new questions of safety and effectiveness.

D2: The dimensions between subject device and predicate device S9019 (K193354) are the difference, but the subject device and predicate device S9019 (K193354) are both complied with ANSI/AAMI ES60601-1 and IEC 60601-1-2, so the differences do not affect the safety and effectiveness so the difference will not affect the safety and effectiveness.

D3: The weight of subject device is difference with predicate device S9019 (K193354) but the subject device and predicate device S9019 (K193354) are both complied with ANSI/AAMI ES60601-1 and IEC 60601-1-2, so the difference will not affect the safety and effectiveness.

D4: The size of sleeves (leg part)" of subject device is similar with the predicate device S9019 (K193354). The treatment effect of the Air Compression Therapy Device depends on the treatment pressure, treatment time, chamber number and treatment site, and the subject device and predicate device S9019 (K193354) are the same with treatment pressure, treatment time, chamber number and treatment site. So the difference will not affect the safety and effectiveness.

D5: Just the name of button is difference, the subject device can be stopped therapy session at any time through the "Power" button by user. This difference betweet subject device predicate device S9019 (K193354) will not affect the safety and effectiveness.

D6: Humidity of transportation & storage of subject device is similar with predicate device S9019 (K193354). But the subject device and predicate device S9019 (K193354) are both complied with ANSI/AAMI ES60601-1-11, so the differences do not affect the safety and effectiveness so the difference will not affect the safety and effectiveness.

7. Discussion of Non-Clinical Tests Performed for Safety and effectiveness are as follows

The recognized consensus standards for safety of medical electrical equipment: ANSI AAMI ES60601-1, ANSI AAMI HA 60601-1-11 for safety, IEC 60601-1-2 for electromagnetic compatibility, ISO 10993-5 and ISO 10993-10 for biological compatibility and IEC 62304 for software verification are complied. See below table for details:10993-1

Standards	Standards Name
ANSI AAMI ES60601-1:2005/(R)2012 and A1:2012	Medical Electrical Equipment - Part 1: General Requirements For Basic Safety And Essential Performance
IEC 60601-1-2 Edition 4.0 2014	Medical Electrical Equipment -- Part 1-2: General Requirements For Basic Safety And Essential Performance -- Collateral Standard: Electromagnetic Disturbances -- Requirements And Tests
ANSI AAMI HA 60601-1-11: 2015	Medical Electrical Equipment - Part 1-2: General Requirements for Basic Safety And Essential Performance - Collateral Standard: Electromagnetic Disturbances - Requirements And Tests
ISO 10993-5 Third edition 2009-06-01	Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
ISO 10993-10 Third Edition 2010-08-01	Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization
ISO 10993-1 Fifth edition 2018-08	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
IEC 62304 Edition 1.1 2015-06 CONSOLIDATED VERSION	Medical device software - Software life cycle processes

Software verification and validation was performed for the subject device in accordance with Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices - Guidance for Industry and FDA Staff, May 2005.

8. Discussion of Clinical Accuracy Testing Performed

There was no clinical testing performed.

9. Conclusions

Based on performance testing, comparison and analysis, the subject device Air Compression Therapy Device, model ST-502 is substantially equivalent to the predicate devices.