October 29, 2019

Guangzhou Longest Science & Technology Co., Ltd.
℅ Jet Li
Regulation Manager
Guangzhou KEDA Biological Tech Co., Ltd.
6F, No.1 TianTai Road, Science City, LuoGang District
Guangzhou, CN

Re: K191862
Trade/Device Name: Compression Therapy Device Model LGT-2200SP
Regulation Number: 21 CFR 890.5650
Regulation Name: Powered Inflatable Tube Massager
Regulatory Class: Class II
Product Code: IRP
Dated: September 1, 2019
Received: September 5, 2019

Dear Jet Li:

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,

For Vivek Pinto, Ph.D.
Director (Acting)
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K191862

Device Name
Compression Therapy Device
Model: LGT-2200SP

Indications for Use *(Describe)*
Compression Therapy Device LGT-2200SP is intended for the temporary relief of minor muscle aches and pains and for the temporary increase in circulation to the treated areas, it can simulate 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

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA and 21 CFR 890.5650, and there were no prior submissions for the subject device.

1. Submitter Information

Sponsor: GUANGZHOU LONGEST SCIENCE&TECHNOLOGY CO., LTD.

Address: 5&6f, Building B4, No.11, Kaiyuan Avenue, Science City Guangzhou Hi-Tech Industrial Development Zone, Guangzhou Guangdong, CHINA 510530

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Application Correspondent: Jet Li

Company: Guangzhou KEDA Biological Technology Co., Ltd

E-mail: med-jl@foxmail.com

Phone: 86-18588874857

Address: 6F, No.1 TianTai road, Science City, LuoGang District, GuangZhou City, China

2. Subject Device Information

Type of 510(k) submission: Traditional

Common Name: Compression Therapy Device

Model: LGT-2200SP

Classification Name: Powered inflatable tube massager

Review Panel: Physical Medicine

Product Code: IRP

Regulation Number: 21 CFR 890.5650

Regulation Class: 2

3. Predicate and Reference Device Information

1) Primary Predicate Device

Sponsor: NormaTec Industries

Trade/Device Name: NormaTec Pulse and NormaTec Pulse Pro

510K number: K160608

Regulation Number: 21 CFR 890.5650

2) Secondary Predicate Device

Sponsor: Rapid Reboot Recovery Products, LLC

Device Name: Rapid Reboot Compression Therapy System

510(k) number: K182668

Regulation Number: 21 CFR 890.5650

3) Reference Device

Sponsor: XIAMEN SENYANG CO., LTD.

Device Name: Pressure Therapy System, model: Pt 1002

510(k) number: K161907

Regulation Number: 21 CFR 890.5650

4. Device Description

Compression therapy device LGT-2200SP is a powered inflatable tube massager, comprised of an air compressor with intermittent pneumatic controller, 4-chamber sleeves covered with Polyether Nylon Fabric, and a connectable hose for connecting the device to the sleeves. The case of main unit body is made from ABS plastic

The device can be powered by an external power supply, or be powered by an internal lithium ion battery. The sleeves have 4-chambers and different applicable body areas, such as the Arm/ Leg/ Waist, hip and thigh/ Calf and foot. The sleeves can be inflating and deflating sequentially to apply the circulating pressure on the target body areas which controlled by the main unit.

The device simulates manual kneading and stroking of tissues by sequential inflated sleeves, to temporarily relieve minor muscle aches and/or pains and to temporarily increase circulation to the treated areas. It is to be used by adults who are in good health.

5. Intended Use/Indication for use

Compression Therapy Device LGT-2200SP is intended for the temporary relief of minor muscle aches and pains and for the temporary increase in circulation to the treated areas, it can simulate kneading and stroking of tissues by using an inflatable garment.

6. Test Summary

Compression Therapy Device has been evaluated the safety and performance by lab bench testing according to the following standards:

- ⊠ ANSI/AAMI ES60601-1, Medical Electrical Equipment - Part 1: General Requirements for Safety, 2005+A1:2012

- ⊠ IEC 60601-1-2, Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests, 2014

- ⊠ 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, Edition 2.0 2015-01

- ⊠ IEC 62133-2:2017, Secondary cells and batteries containing alkaline or other non-acid electrolytes - Safety requirements for portable sealed secondary cells, and for batteries made from them, for use in portable applications- Part 2: Lithium systems

- ⊠ ISO 10993-5: 2009 Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity

- ⊠ ISO 10993-10: 2010 Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization

- ⊠ Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices.

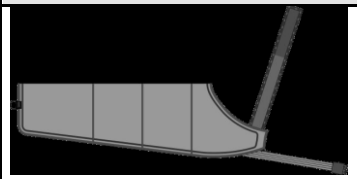
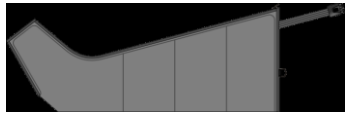
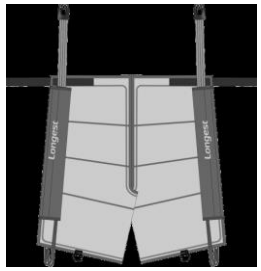
7. Comparison to Predicate Device

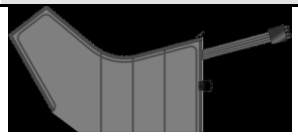
Compare with predicate device, the subject device is very similar in design principle, intended use, indications for use, functions, material and the applicable standards. The differences between subject device and predicate device do not raise any new questions of safety or effectiveness.
See the below form.

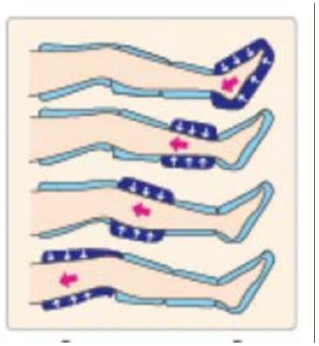
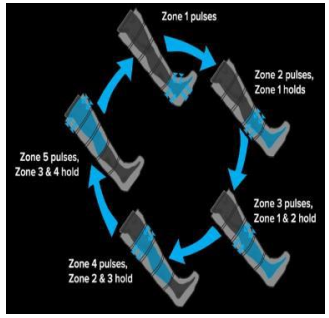
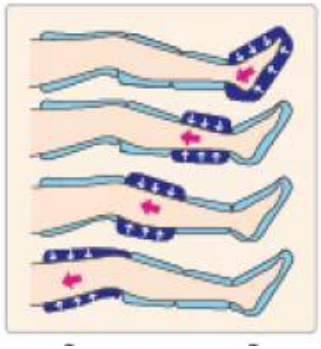
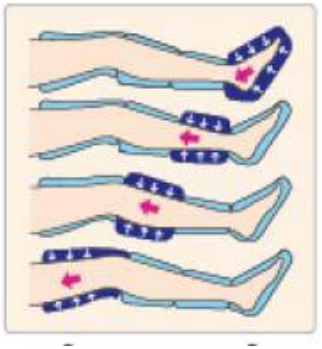
Elements of comparison	Subject Device	Predicate Device (Primary)	Predicate Device (II)	Predicate Device (III)	Verdict
Manufacturer	GUANGZHOU LONGEST SCIENCE&TECHNOLOGY CO., LTD.	NormaTec Industries	Rapid Reboot Recovery Products, LLC	XIAMEN SENYANG CO., LTD.	--
510K number	TBD	K160608	K182668	K161907	--
Product Name	Compression Therapy Device LGT-2200SP	NormaTec Pulse and NormaTec Pulse Pro	Rapid Reboot Compression Therapy System	Pressure Therapy System, Pt 1002	--
Classification Name	Powered inflatable tube massager	Powered inflatable tube massager	Powered inflatable tube massager	Powered inflatable tube massager	SE
Regulation Class	2	2	2	2	SE
Regulation Number	21 CFR 890.5650	21 CFR 890.5650	21 CFR 890.5650	21 CFR 890.5650	SE
OTC & Rx	OTC	OTC	OTC	Rx	--
Indications for Use					
Indications for Use	Compression Therapy Device LGT-2200SP is intended for the temporary relief of minor muscle aches and pains and for the temporary increase in circulation to the treated areas, it can simulate kneading and stroking of tissues by using an inflatable garment.	The NormaTec Pulse and Pulse Pro is an air pressure massager intended to temporarily relieve minor muscle aches and/or pains, and to temporarily increase circulation to the treated areas.	The Rapid Reboot Compression Therapy System is intended for the temporary relief of minor muscle aches and pains and for the temporary increase in circulation to the treated areas in people who are in good health. The Rapid Reboot Compression Therapy System simulates kneading and stroking of tissues	The device is indicated for use by medical professionals and patient at home, who are under medical supervision, in treating many conditions, such as: Primary lymphedema, edema following trauma and sport injuries, post immobilization edema, venous insufficiencies, lymphedema.	Minor different Note 1

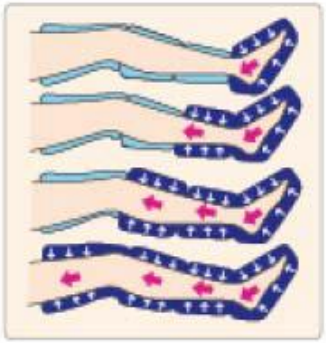
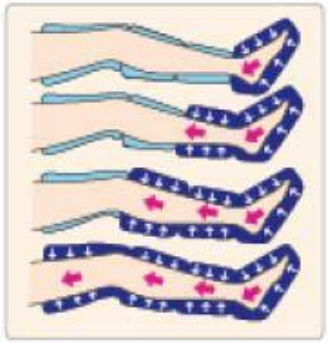
Elements of comparison	Subject Device	Predicate Device (Primary)	Predicate Device (II)	Predicate Device (III)	Verdict
			by using an inflatable garment.		
Device design					
Power Source	AC100-240V, 50/60Hz Battery 11.1V, 6500mAh meet IEC 62133	12 VDC via an IEC 60601-1 compliant power supply (100-240 VAC input) Optional Integrated rechargeable battery	110 V, 60Hz	110 V, 60Hz	Minor different Note 2
Power consumption	90VA	14W	30W	30W	Minor different Note 2
Dimensions (W*H*D)	270*148*129mm	4"*5" *9"	10" x 6.5" x 5"	260*170*130mm	Minor different Note 2

Elements of comparison	Subject Device	Predicate Device (Primary)	Predicate Device (II)	Predicate Device (III)	Verdict
Photo					Minor different Note 2
Weight	2.0 Kg(4.4pounds)	3.6 pounds	5.8 pounds	5.8 pounds	Minor different Note 2
Housing Materials	Molded ABS enclosure	Molded ABS enclosure	Molded ABS enclosure	Molded ABS enclosure	SE
Sleeves	4-chamber Arm Sleeve: 97.0*28.7 cm	Leg:	Leg: X-Short: 14” x 41” Short: 14” x 43” Medium: 14” x 45”	Small Leg Cuff:90X30cm Large Leg Cuff:110X30cm	Minor different

Elements of comparison	Subject Device	Predicate Device (Primary)	Predicate Device (II)	Predicate Device (III)	Verdict
	 4-chamber Leg Sleeve: S: 94.2*35.85 cm M: 106.2*39.0 cm L: 116.0*44.8 cm  4-chamber Waist, Hip and Thigh Sleeve: 71.3*71.8 cm  4-chamber Calf and Foot Sleeve: 61.0*30.1 cm	 Arm:  Hip: 	Long: 14” x 48” X-Long: 14” x 52”  Hip: Regular: 26” x 32” Large: 26” 35”  Arm: Regular: 18” x 38” Long: 18” x 44”		Note 3

Elements of comparison	Subject Device	Predicate Device (Primary)	Predicate Device (II)	Predicate Device (III)	Verdict
					
Number of Chambers	4-chamber	5 or less	4 Chambers	4 Chambers for each unit	SE
Sleeve Materials	Polyether Nylon Fabric	200 denier nylon with a polyurethane laminate/extrusion	Nylon with a Polyurethane laminate	Thermoplastic Urethane	Minor different Note 3
Mode of Compression	Sequential	Sequential	Sequential	Sequential	SE
Device Pressure range	30-150mmHg	30-110 mmHg	0-200 mmHg	0-250mmHg	Minor different Note 4

Elements of comparison	Subject Device	Predicate Device (Primary)	Predicate Device (II)	Predicate Device (III)	Verdict
Treatment Time	1min-99min, default as 30min, step of 5min	Stays on until the user turns it off or can be set up to turn off in a range of 10mins to continuous	User determines therapy time. Choose from 10, 20, or 30 minute session time, with option to add additional 10 minutes to any therapy time.	0 – 30mins	Minor different Note 5
Work Mode	 SEQUENTIAL: ①→②→③→④ SQUEEZE: ①②→③④ FLUSH: ①→①②→①②③→①②③④ FLOW: ④→③→②→① RELEASE: ③④→①② WAVE: SEQUENTIAL+SEQUENTIAL+FLOW	Sequential  NormaTec Pulse 	Model A  Model B	Model A  Model B	Minor different Note 6

Elements of comparison	Subject Device	Predicate Device (Primary)	Predicate Device (II)	Predicate Device (III)	Verdict
					
Patient contact	Non-conductive appliances	Non-conductive appliances	Non-conductive appliances	Non-conductive appliances	SE
Software/Firmware/Microprocessor Control	Microprocessor	Microprocessor	Microprocessor	Microprocessor	SE
Technology	Compressor and valve system which sequentially inflates cells of appliance	Compressor and valve system which sequentially inflates cells of appliance	Compressor and valve system which sequentially inflates cells of appliance	Compressor and valve system which sequentially inflates cells of appliance	SE
FDA-Recognized Standards					
Electrical safety, EMC	ANSI/AAMI ES60601-1 IEC 60601-1-2 IEC 60601-1-11 IEC 62133 ISO 10993-5 ISO 10993-10	ES 60601-1 IEC 60601-1-2; IEC 60601-1-11	IEC 60601-1:2014; IEC 60601-1-2:2014; EN ISO 10993-5:2009 EN ISO 10993-10:2010	IEC 60601-1 IEC 60601-1-2 ISO10993-5 ISO10993-10	Minor different Note 7

Note 1

Although there is a little difference about the description of indication for use, the meanings are the same. This difference does not affect the safety and effectiveness.

Note 2

Although the subject device design and specification parameter between the predicate devices and subject device are different, they are both complied with ANSI/AAMI ES60601-1. So the minor differences on such parameters (power, dimensions, appearance) do not affect the safety and effectiveness.

Note 3

Although the device provides four kind sleeves for different areas, which have minor difference about size and appearance, the sleeve chamber number are the same and the applicable body areas are included in the predicate devices (I to III), and the material of sleeves is also complied with ISO 10993-5 and ISO 10993-10. Therefore, the difference would not raise adversely impact on safety and effectiveness.

Note 4

Although the pressure range of subject device is different to the predicate devices, the range is smaller and contained by the predicate device (II), so the difference of pressure range would not raise adversely impact on safety and effectiveness.

Note 5

Although the treatment time range of subject device is 1 to 99mins, which seems to be longer than the predicate devices, the default value is 30min which is suitable for daily use. And the treatment time is optionally set by user with 5mins step, which is more exact to the predicate device (I&II), so the difference of pressure range would not raise adversely impact on safety and effectiveness.

Note 6

Although the subject device provides six kinds of work mode, the SEQUENTIAL and FLUSH mode are the same with the predicate device, while the other work modes of subject device just have difference about the inflatable order of the different chambers. The treatment pressure range are the same under different work modes, so the difference of pressure range would not raise adversely impact on safety and effectiveness.

Note 7

The subject device references more sufficient safety standards than the predicate devices, and the safety of the device is verified via tests.

7. Summary for clinical test

Clinical performance is not deemed necessary.

8. Conclusion

The subject device Compression Therapy Device has all features of the predicate devices for intended use. Thus, the subject device is substantially equivalent to the predicate devices.

9. Summary Prepared Date

21 Oct. 2019