March 19, 2020

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: K191856
Trade/Device Name: Compression Therapy Device (Model: LGT-2201DVT)
Regulation Number: 21 CFR 870.5800
Regulation Name: Compressible Limb Sleeve
Regulatory Class: Class II
Product Code: JOW
Dated: February 12, 2020
Received: February 18, 2020

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,

Fernando Aguel
Assistant Director
DHT2B: Division of Circulatory Support,
Structural and Vascular Devices
OHT2: Office of Cardiovascular 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)*
K191856

Device Name
Compression Therapy Device (Model: LGT-2201DVT)

Indications for Use *(Describe)*
Compression Therapy Device (Model: LGT-2201DVT) is intended to prevent DVT (Deep Vein Thrombosis) by improving the blood velocity of patients.
LGT-2201DVT is Circulation Enhancement, Deep Vein Thrombosis Prophylaxis, Edema -Acute, Edema - Chronic, Extremity Pain Incident to Trauma or Surgery, Leg Ulcers, Venous Stasis / Venous Insufficiency.

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 870.1130.

1. Submitter Information

Sponsor Name: Guangzhou Longest Science & Technology Co., Ltd.

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Application Correspondent:

Guangzhou KEDA Biological Tech Co., Ltd.

Contact person: Jet Li

Email: med-jl@foxmail.com

Tel: +86-20-22325619

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:	Compressible limb sleeve
Trade Name:	Compression Therapy Device ***Model: LGT-2201DVT***
Classification Name:	sleeve, limb, compressible
Review Panel:	Cardiovascular
Product Code:	JOW
Regulation Number:	870.5800
Regulation Class:	II

3. Predicate Device Information

Sponsor:	DAESUNG MAREF CO.,LTD

Common Name:	Intermittent Pneumatic Compression system
Trade Name:	DVT-4000
510(k) number:	K160180
Review Panel:	Cardiovascular
Product Code:	JOW
Regulation Number:	870.5800
Regulation Class:	II

4. Device Description

Compression Therapy Device LGT-2201DVT a compression therapy device comprised of intermittent pneumatic controller, sleeves and connectable hose. The working principle is the air inflating and deflating the sleeve sequentially to develop the circulating pressure on the human body. Squeezing the proximal and distal of the limbs to promote blood circulation lymphatic system and improve body microcirculation. Besides, prevent thrombus, reduce limbs drops and this kind disease which is related to blood and lymph circulation directly or indirectly.

5. Intended Use / Indication for Use

Compression Therapy Device (Model: LGT-2201DVT) is intended to prevent DVT (Deep Vein Thrombosis) by improving the blood velocity of patients.
LGT-2201DVT is Circulation Enhancement, Deep Vein Thrombosis Prophylaxis, Edema - Acute, Edema - Chronic, Extremity Pain Incident to Trauma or Surgery, Leg Ulcers, Venous Stasis / Venous Insufficiency.

6. Test Summary

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

- IEC 60601-1, Medical Electrical Equipment - Part 1: General Requirements for Safety, 1988+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
- ISO 10993-5, Biological evaluation of medical devices -- Part 5: Tests for In Vitro cytotoxicity, 2009
- ISO 10993-10, Biological evaluation of medical devices -- Part 10: Tests for irritation and skin sensitization, 2010

- 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

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 and new questions of safety or effectiveness.

Elements of Comparison	Subject Device	Predicate Device	Verdict
Manufacturer	Guangzhou Longest Science & Technology Co., Ltd	DAESUNG MAREF CO.,LTD	--
Product Name	Compression Therapy Device	DVT-4000	--
Intended Use	Compression Therapy Device (Model: LGT-2201DVT) is intended to **prevent DVT (Deep Vein Thrombosis)** by improving the blood velocity of patients. LGT-2201DVT is Circulation Enhancement, Deep Vein Thrombosis Prophylaxis, Edema - Acute, Edema - Chronic, Extremity Pain Incident to Trauma or Surgery, Leg Ulcers, Venous Stasis / Venous Insufficiency.	DVT-4000 is a system to **prevent DVT (Deep Vein Thrombosis)** by improving the blood velocity of patients. DVT-4000 is Circulation Enhancement, Deep Vein Thrombosis Prophylaxis, Edema - Acute, Edema - Chronic, Extremity Pain Incident to Trauma or Surgery, Leg Ulcers, Venous Stasis / Venous Insufficiency	SE
Type of use	Prescription Use	Prescription Use	SE
Size (L X W XH)	27 x14.8 x 12.8 cm	21.4 x18.1 x18.6 cm	Similar Note 1
Weight	2.3kg	2.0 kg	Similar Note 1
Input rating	AC 100-240 V 50/60Hz	AC 100-240 V 50/60Hz	SE
IEC classification	Class II , Type BF	Class II , Type BF	SE
Input power	90VA	60-80VA	Similar Note 2
Battery Voltage	11.1V /6500mAh, lithium battery	14.4V/2600mAh	Similar Note 2
Pressure range	30 - 150mmHg	20 - 140±10mmHg	Similar Note 3

Elements of Comparison	Subject Device	Predicate Device	Verdict
Setting Time	1min~99hours or continuous	1min~999hours	SE
Mode of Operation	Continuous	Continuous	SE
Applied part	Compression sleeves	Compression sleeves	SE
Electrical, Mechanical and Thermal Evaluation	IEC 60601-1 IEC 60601-1-2 IEC62133	IEC 60601-1 IEC 60601-1-2 IEC62133	SE
Biocompatibility Evaluation	All the patient contracting materials are evaluated by the biocompatibility standard ISO 10993 -5, -10.	All the patient contracting materials are evaluated by the biocompatibility standard ISO 10993 -5, -10.	SE

Note 1

Although there is a bit difference of the size and weight between the predicate device and subject device, they are all complied with the IEC 60601-1.Thus the differences do not affect the safety and effectiveness.

Note 2

The little difference of the input power does not affect the safety and effectiveness for the predicate device and subject device are complied with the IEC 60601-1. And although there is a bit difference of the battery, the LGT-2201DVT battery is verified in accordance with IEC62133.So the differences do not affect the safety and effectiveness.

Note 3

Although there is a bit difference of the Pressure range between the predicate device and subject device, they are all complied with the IEC 60601-1.Thus the differences do not affect the safety and effectiveness.

8. Conclusion

The subject device Compression Therapy Device, model: LGT-2201DVT has same intended use, principle of operation and similar technological characteristics as the predicate device. Although there are some specification that are different between two device, the subject device has undergone safety and performance tests, and the results complied with the test requests. Therefore, the difference between the Compression Therapy Device, model: LGT-2201DVT and the predicate device did not raise any problem

of substantial equivalence. Thus the subject device is substantially equivalent to the predicate device.

9. Summary Prepared Date

12 February 2020