February 9, 2022

Dalian Labtek Science & Development Co., Ltd.
℅ Doris Dong
Manager
Shanghai CV Technology Co., Ltd.
Room 903, No.19 Dongbao Road, Songjiang Area
Shanghai, Shanghai 201613
China

Re: K213313
Trade/Device Name: Veinoflow SCD (Model: LBTK-M-I 5006)
Regulation Number: 21 CFR 870.5800
Regulation Name: Compressible Limb Sleeve
Regulatory Class: Class II
Product Code: JOW
Dated: January 5, 2022
Received: January 10, 2022

Dear Doris Dong:

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,

Nicole Gillette
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K213313

Device Name
Veinoflow SCD

Indications for Use *(Describe)*
Veinoflow SCD, LBTK-M-I 5006 is a system to prevent DVT (Deep Vein Thrombosis) by improving the blood velocity of patients. LBTK-M-I 5006 is indicated for 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

[As required by 21 CFR 807.92]

1. Submission Information

510(k) Number:	K213313
Date:	September 8th, 2021
Type of 510(k) Submission:	Traditional 510(k)
Owner：	Dalian Labtek Science & Development Co., Ltd. 1-18-17, Liandong Street, Advanced Equipment Manufacturing Industry Park Economic-Technological Development Zone, Dalian, Liaoning, China, 116085 Tel: +86-411-84548445 E-mail: sales001@labtek-med.com
Contact:	Doris Dong [Consultant, from Shanghai CV Technology Co., Ltd.] Add: Room 903, No. 19 Dongbao Road, Songjiang Area, Shanghai, 201613 China E-mail: doris.d@ceve.org.cn Tel: 86 21-31261348 / Fax: 86 21-57712250

2. Device Description

Proprietary Name:	Veinoflow SCD
Model:	LBTK-M-I 5006
Common Name:	Intermittent Pneumatic Compression Device
Classification Name:	Compressible limb sleeve
Regulation Number:	21 CFR 870.5800
Product Code:	JOW
Device Class:	II
Review Panel:	Cardiovascular
Device Description:	Veinoflow SCD, Model LBTK-M-I 5006, is a pneumatic pump system that supplies compressed air to inflate garments that are attached to a patent's lower limbs. It consists of a pump controller, specially designed inflation and deflation garments for feet and legs, air supply tubes, and power line. The inflation and deflation garments have 3 types: ① leg garments, ② calf garments, ③ foot cuffs. The system offers sequential inflation and propels the vein blood from limb to heart, therefore enhancing the blood circulation. The controller can automatically detect the external garment type, and provides pressure correspondingly. The pressure value is preset and adjustable. The controller has a self test system, when there is any error, it will alarm both in visual and audio. All the leg garments, calf garments and foot cuffs are packaged in pairs. The controller can function properly in both situations either when connected to a one single leg garment/calf garment/foot cuff or one pair of leg garments/calf garments/foot cuffs, giving the end user more flexibility for prophylaxis options.
Indications for use:	Veinoflow SCD, LBTK-M-I 5006 is a system to prevent DVT (Deep Vein Thrombosis) by improving the blood velocity of patients. LBTK-M-I 5006 is indicated for Circulation Enhancement, Deep Vein Thrombosis Prophylaxis, Edema -Acute, Edema - Chronic, Extremity Pain Incident to Trauma or Surgery, Leg ulcers,

Venous Stasis / Venous Insufficiency.

3. Predicate Device

The Veinoflow SCD (LBTK-M-I 5006) is equivalent to the following:

Predicate Device	Manufacturer	510(k) Number
Veinoflow SCD, LBTK-M-I 5001	Dalian Labtek Science & Development Co., Ltd.	K123830

4. Substantial Equivalence to Predicate device

More Detailed comparison data is included in "Section 10 - Substantial Equivalence Discussion" of this 510(k) submission.

	New Device	**Predicate Device**	**Remark**
510(k) Number	To be assigned	K123830	--
Device Name	Veinoflow SCD	Veinoflow SCD	--
Model	LBTK-M-I 5006	LBTK-M-I 5001	--
Manufacturer	Dalian Labtek Science & Development Co., Ltd.	Dalian Labtek Science & Development Co., Ltd.	Same
Product Code	JOW	JOW	Same
Class	II	II	Same
Indications for use	Veinoflow SCD, LBTK-M-I 5006 is a system to prevent DVT (Deep Vein Thrombosis) by improving the blood velocity of patients. LBTK-M-I 5006 is indicated for Circulation Enhancement, Deep Vein Thrombosis Prophylaxis, Edema -Acute, Edema - Chronic, Extremity Pain Incident to Trauma or Surgery, Leg ulcers, Venous Stasis / Venous Insufficiency.	Veinoflow SCD system, Model LBTK-M-I 5001 is a system to prevent DVT (Deep Vein Thrombosis) by improving the blood velocity of patients. LBTK-M-I 5001 is indicated for Circulation Enhancement, Deep Vein Thrombosis Prophylaxis, Edema -Acute, Edema - Chronic, Extremity Pain Incident to Trauma or Surgery, Leg ulcers, Venous Stasis / Venous Insufficiency.	Same
Prescription or OTC	Prescription	Prescription	Same
Components	Pump controller, multi-cavity leg garments, calf garments, foot cuffs, battery, air tubes and power line	Pump controller, multi-cavity thigh-calf garments, calf garments, foot cuffs, battery, air supply tubes, power line	Same
Compression Type	Leg garments & Calf garments: Sequential, Gradient Foot Cuffs: Uniform	Thigh-calf garments & calf garments: Sequential, Gradient Foot Cuffs: Uniform	Same
Case Materials	ABS	ABS	Same
Controller Dimensions	Length: 185mm; Width: 165mm; Height: 250mm	Length: 240mm; Width: 140mm; Height: 263mm	Similar Note 1
Controller Weight	2.5kg	3.5kg	
Deflation time	2~3s	2~3s	Same
Default	60s	48s	Similar

inflatable interval time			Note 2
Adjustable inflatable interval time	24s, 48s, 60s	24s, 48s, 60s	Same
Default Pressure	Leg garments & Calf garments: 40mmHg Foot Cuffs: 130mmHg	Thigh-calf garments & calf garments: 40mmHg Foot Cuffs: 130mmHg	Same
Adjustable pressure	Leg garments & Calf garments: 30~60mmHg (10mmHg per step) Foot Cuffs: 120~140mmHg (10mmHg per step)	Thigh-calf garments & calf garments: 30~60mmHg (10mmHg per step) Foot Cuffs: 120~140mmHg (10mmHg per step)	Same
Mode of Operation	Continuous	Continuous	Same
Bed Hook	Yes	Yes	Same
Power Cord Storage	Yes	Yes	Same
Power Cord	Hospital Grade Plug	Hospital Grade Plug	Same
Power Requirement	AC 100-240V, 50/60 Hz	AC 100-240V, 50/60 Hz	Same
Battery	DC11.1V 5000mAh, Lithium Ion	14.8V, 3100mAhr, Lithium Ion	Similar Note 3
Shipping Unit	Each	Each	Same
Standards	ISO 10993-5, ISO 10993-10, IEC 60601-1, and IEC 60601-1-2	ISO 10993-5, ISO 10993-10, IEC 60601-1, and IEC 60601-1-2	Same
Non-sterile	Non-sterile	Non-sterile	Same
Microprocessor Control?	Yes	Yes	Same

Summary of the technological characteristics of the device compared:

Note 1:

The weight, dimensions and appearance of the proposed device are different from the predicate device K123830, these differences don't affect the performance of the device, and the proposed device has passed the tests of ANSI AAMI ES60601-1 and IEC 60601-1-2. Therefore, these differences don't raise any new safety and effectiveness issues.

Note 2:

The default inflation interval of the proposed device is 60s, and the default inflation interval of the predicate device is 48s. However, the adjustable inflation interval time value of the proposed device and predicate device is the same (24s, 48s, 60s), and the user can adjust the inflation interval time as needed. Therefore, the difference in the default inflation interval time doesn't raise any safety and effectiveness issues.

Note 3:

The battery used is different from the predicate device, but the battery used by the proposed device has passed the test of the IEC 62133-2 standard. Therefore, this difference doesn't raise any safety or effectiveness issues.

5. Non-clinical Testing

The conclusions drawn from the non-clinical testing below demonstrate that the Veinoflow SCD is substantially equivalent to the predicate device K123830. The Veinoflow SCD has been tested and conforms to international consensus standards:

Electrical safety:

• ANSI AAMI ES60601-1: 2005/(R)2012 And A1:2012, C1:2009/(R)2012 And A2:2010/(R)2012 (Consolidated Text) Medical Electrical Equipment - Part 1: General Requirements For Basic Safety And Essential Performance (IEC 60601-1:2005, MOD);

EMC:

• ANSI AAMI IEC 60601-1-2:2014, Medical Electrical Equipment -- Part 1-2: General Requirements For Basic Safety And Essential Performance -- Collateral Standard: Electromagnetic Disturbances -- Requirements And Tests;

Additional safety testing:

• IEC 62133-2 Edition1.0 2017-02 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;

Biocompatibility testing:

• ISO 10993-5:2009/(R) 2014, Biological Evaluation Of Medical Devices -- Part 5: Tests For In Vitro Cytotoxicity. (Biocompatibility)

• ISO 10993-10 Third Edition 2010-08-01, Biological Evaluation Of Medical Devices - Part 10: Tests For Irritation And Skin Sensitization. (Biocompatibility)

6. Conclusion

The data included in this submission demonstrate that the modified Veinoflow SCD (Model: LBTK-M-I 5006) is substantially equivalent to the cleared primary predicate device, the K123830, Veinoflow SCD (Model: LBTK-M-I 5001).