DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
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November 18, 2014

Wuhan Landing Medical Hi-Tech Co., Ltd
Yan Liu
Quality Manager
818 Gaoxin Rd East Lake High Tech Development Zone
Floors 1 & 2, Units B & C & D, Building No. B7 Med Equipment Park
Wuham, CH 430206

Re: K141390
Trade/Device Name: Intermittent pneumatic compression device
Regulation Number: 21 CFR 870.5800
Regulation Name: Compressible Limb Sleeve
Regulatory Class: Class II
Product Code: JOW
Dated: Undated
Received: September 15, 2014

Dear Yan Liu,

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
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: December 31, 2013
See PRA Statement on last page.

510(k) Number *(if known)*

K141390

Device Name

Intermittent pneumatic compression device

Indications for Use *(Describe)*

The LD Q-IPC III is a system to prevent DVT(Deep Vein Thrombosis) by improving the blood velocity of patients.

Leg Compression
The use of the product with Calf Cuff and Thigh Cuff is indicated for:
1. Deep vein thrombosis and pulmonary embolism prophylaxis.

Foot Compression
The use of the product with Foot Cuff is indicated for:
1. Circulation enhancement.
2. Deep vein thrombosis prophylaxis.
3. Edema-Acute.
4. Edema-Chronic.
5. Extremity pain incident to trauma or surgery.
6. Leg Ulcers.
7. 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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

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

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Wuhan Landing Medical Hi-Tech Co,LTD

Section 5 - 510(k) Summary

Date of Summary Preparation: 9/9/2014

1. Submitter's Identifications

Submitter's Name: Wuhan Landing Medical Hi-Tech Co., LTD
Address: Floors 1&2,Units B&C&D,Building No.B7 Medical Equipment Park,818 Gaoxin Road East Lake High Tech Development Zone 430206 Wuhan, Hubei,China
Contact Person: Yan Liu
Contact Email Address: fdalanding@sohu.com
Telephone: +86-27-59263677
Fax: +86-27-59368637

2. Correspondent's Identifications

Correspondent's Name: Wuhan Landing Medical Hi-Tech Co.,LTD
Address: Floors 1&2,Units B&C&D,Building No.B7 Medical Equipment Park,818 Gaoxin Road East Lake High Tech Development Zone 430206 Wuhan, Hubei,China
Contact Person: Yan Liu
Contact Email Address: fdalanding@sohu.com
Telephone: +86-27-59263677
Fax: +86-27-59368637

3. Name of the Device

Device Classification Name: sleeve, limb, compressible
Product Name: Compressible limb sleeve
Trade Name: Intermittent pneumatic compression device
Model: LD Q-IPC III
Classification Panel: Cardiovascular
Product Code: JOW
Device Classification: Class II

4. The Predicate Devices

K123830 Veinoflow SCD, LBTK-M-I 5001

5. Device Description

The LD Q-IPC III Intermittent pneumatic compression device is a pneumatic compression device that noninvasively helps reduce the incidence of deep vein thrombosis, a potentially life threatening condition.
The LD Q-IPC III Intermittent pneumatic compression device consists of the controller, the Tubing Sets and single-patient used cuff. The cuff includes calf cuffs, thigh cuffs and foot cuffs.
The controller will deliver air to the cuffs and sequentially pressurize them. Cuffs will be

pressurized from the distal air chamber to the proximal air chamber. After the compression, the controller will allow an interval time for vein refilling, before the controller starts to pressurize the cuffs again. The cycles will be repeated throughout the time the unit is in use or for the duration of the default operating time.

6. Intended Use of Device

The LD Q-IPC III is a system to prevent DVT(Deep Vein Thrombosis) by improving the blood velocity of patients.

Leg Compression
The use of the product with Calf Cuff and Thigh Cuff is indicated for:
1. Deep vein thrombosis and pulmonary embolism prophylaxis.

Foot Compression
The use of the product with Foot Cuff is indicated for:
1. Circulation enhancement.
2. Deep vein thrombosis prophylaxis.
3. Edema-Acute.
4. Edema-Chronic.
5. Extremity pain incident to trauma or surgery.
6. Leg Ulcers.
7. Venous stasis /Venous insufficiency.

7. Summary of Substantial Equivalence

Table : The difference between LD Q-IPC III and Predicate Veinoflow SCD (K123830)

	New Device	Predicate Device
510(k) Number	K 141390	K123830
Product Code:	JOW	JOW
Proprietary Name:	Intermittent Pneumatic Compression Device	Veinoflow SCD, LBTK-M-I 5001
Manufacturer:	Wuhan Landing Medical Hi-Tech Co., Ltd	Dalian Labtek Science & Development Co., Ltd
Indication for use:	The LD Q-IPC III is a system to prevent DVT(Deep Vein Thrombosis) by improving the blood velocity of patients. LD Q-IPC III is indicated for Circulation enhancement, Deep vein thrombosis and pulmonary embolism 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 and pulmonary embolism prophylaxis, Edema-Acute, Edema-Chronic, Extremity pain incident to trauma or surgery, Leg Ulcers, Venous stasis /Venous insufficiency
Components	Pump controller, thigh cuffs, calf cuffs, foot cuffs, air supply tubes, power line	Pump controller, thigh cuffs, calf cuffs, foot cuffs, battery, air supply tubes, power line
Ingress of Water	Ordinary	Ordinary

protection		
Compression type	thigh cuffs & calf cuffs: Sequential, Gradient foot cuffs: Uniform	thigh cuffs & calf cuffs: Sequential, Gradient foot cuffs: Uniform
Compression time	Single thigh cuffs: 6s Compression Dual thigh cuffs: 12s Compression Single calf cuffs: 4s Compression Dual calf cuffs: 8s Compression Single foot cuffs: 2.5s Compression Dual foot cuffs: 5s Compression	Single thigh cuffs: 5.5s Compression Dual thigh cuffs: 11s Compression Single calf cuffs: 4s Compression Dual calf cuffs: 8s Compression Single foot cuffs: 2.5s Compression Dual foot cuffs: 5s Compression
Deflation time	2-3s	2-3s
Default inflatable Interval time	48s	48s
Adjustable inflatable interval time	24s, 48s, 60s	24s, 48s, 60s
Default Pressure	thigh cuffs & calf cuffs: 45 mmHg foot cuffs: 130 mmHg	thigh cuffs & calf cuffs: 40 mmHg foot cuffs: 130 mmHg
Adjustable Pressure	thigh cuffs & calf cuffs: 30-60 mmHg foot cuffs: 120-140 mmHg	thigh cuffs & calf cuffs: 30-60 mmHg foot cuffs: 120-140 mmHg
Mode of operation	Continuous	Continuous
Application mode	Single thigh cuffs Compression Dual thigh cuffs Compression Single calf cuffs Compression Dual calf cuffs Compression Single foot cuffs Compression Dual foot cuffs Compression	Single thigh cuffs Compression Dual thigh cuffs Compression Single calf cuffs Compression Dual calf cuffs Compression Single foot cuffs Compression Dual foot cuffs Compression Simultanous single thigh cuffs and single calf cuffs Compression
Bed Hook	Yes	Yes
Power cord storage	Yes	Yes
Audible/Visual Alarms	Low Pressure, High Pressure, Pump Error, Valve Error, System Error,	No garment, Pump Error, Valve Error, Temperature Error, Software Error, System Error, High Pressure, Low Pressure, Low Battery
Controll Dimensions	Length: 280mm; Width: 145mm; Height: 250mm	Length: 240mm; Width: 140mm; Height: 263mm
Controll Weight	3kg	3.5kg
Power Requirement	AC 100-240V, 60 VA, 50-60Hz	AC 100-240V, 50 VA, 50-60Hz
Battery	No	Yes
Shipping Unit	Each	Each
Standard	IEC60601-1 IEC60601-1-2	IEC60601-1 IEC60601-1-2

	ISO10993-1 ISO10993-5 ISO10993-10	ISO10993-1 ISO10993-5 ISO10993-10
Non-sterile	Non-sterile	Non-sterile
Microprocessor Control	Yes	Yes

8. Substantial Equivalence:

The proposed devices of LD Q-IPC III have the same classification information, same indications and intended use, same design principle, similar product design and specifications, same performance effectiveness, performance safety as the predicate device. The differences only exist in battery, default pressure, and audible/visual alarms. These differences are slight and do not influence the effectiveness and safety of the device.

9. Non-Clinical Tests Performed:

The following testing was performed on the LD Q-IPC III in accordance with the requirements of the design control regulations and established quality assurance procedures.

IEC60601-1:2005+CORR.1(2006)+CORR.2(2007),Medical electrical equipment-Part 1:General requirements for basic safety, and essential performance.

IEC60601-1-2:2007, Medical electrical equipment-Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility-Requirements and tests.

ISO10993-1: 2009, Biological evaluation of medical devices-Part 1:Evaluation and testing within a risk management process

ISO10993-5:2009, Biological evaluation of medical devices-Part 5: Tests for In Vitro cytotoxicity.

ISO10993-10:2010, Biological evaluation of medical devices-Part10: Tests for irritation and skin sensitization

In addition to the compliance of voluntary standards, the software verification has been carried out according to the FDA Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices.

10. Conclusion:

The proposed device LD Q-IPC III are determined to be Substantially Equivalent (SE) to the predicate device, Veinoflow SCD, LBTK-M-I 5001 in respect of safety and effectiveness.

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