Dalian Labtek Science & Development Co., Ltd.
Room 403, No. 35 Huoju Road, High-Tech Zone, Dalian, Liaoning, China 116085
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AUG 17 2012

Section 5
510(k) Summary
[As required by 21 CFR 807.92]

1. Submission Information:

510(k) Number:	K121718
Date:	May 10th, 2012
Type of 510(k) Submission:	Traditional
Basis for 510(k) Submission:	New device
Submitter/Manufacturer:	Dalian Labtek Science & Development Co., Ltd. Room 403, No. 35 Huoju Road, High-Tech Zone, Dalian, Liaoning, China
Contactor:	Doris Dong, Consultant Shanghai CV Technology Co., Ltd. E-mail: doris_d@126.com Tel: 86 21-31261348 / Fax: 86 21-37824346

2. Device Description:

Proprietary Name:	A-V Hand & Foot Pump, Model LBTK-M-I 1000
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
Indications for use:	A-V Hand & Foot Pump, Model LBTK-M-I 1000, is intended for use to enhance blood circulation in the arteries and veins in patents. The indications vary depending on whether pump is used with the foot pad or hand pad. A. Foot use - Acute Edema - Chronic Edema - Circulation Enhancement - Deep Vein Thrombosis and Pulmonary Embolism Prophylaxis - Leg Pain Incident to Trauma or Surgery - Leg Ulcers - Venous Stasis/Venous Insufficiency B. Hand use - Acute Edema - Chronic Edema - Circulation Enhancement - Pain Incident to Trauma or Surgery
Device Description:	A-V Hand & Foot Pump, Model LBTK-M-I 1000, consists of a pump controller connected by air supply hoses to specially designed inflation pads. The pump controller is microprocessor controlled, with a liquid crystal display, power switch, two air output sockets, function keys of "Left impulse

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	run/pause", "Pressure adjustment", "Left preset settings", "Increase key-press", "Decrease key-press", "Right preset settings", "Impulse interval control", "Right Impulse run/pause", and so on. The pulse pressure, pulse duration, and pulse interval can be displayed by the screen. The inflation pads include foot pad, hand pad and undercast foot pad. The pads have one air chamber, through which the air energy is transferred to the body. The pads are non-sterile and for single patient use only. The inflation pad is rapidly inflated by a controlled impulse of air from the controller. After each impulse the controller automatically allows the inflation pad to deflate. To deliver the impulse pressure effectively to the extremity, the inflation pad must be retained in the correct position. The system has built-in alarms and displays to alert attention to adjustment requirements and to assist with rapid troubleshooting.
Specifications:	Power supply: AC110V/0.2A/50-60Hz Length/Height/Width: 365mm/220mm/150mm Weight: 4kg Tubing length: 2m Tubing diameter: OD-8mm, ID-6mm Mode of operation: Rapid inflation and deflation, manual switch Number of channels: 2 Number of air chamber: 1 Inflation time: 0.2 seconds Impulse duration: 1 or 3 seconds adjustable Pulse interval: 20~50s for inflation foot pads; 12~20s for inflation hand pads Pressure: 60mmHg~200mmHg Inflation Pump Connector Design: Air pump → hoses → air cylinder → magnetic valve → airway tube → pads
Performance data:	The device has passed the following testing: 1) Biological compatibility test 2) Material anti-stretch test 3) Air chamber welding point anti-stretch test 4) Air leakage test 5) Air chamber maximum blast pressure test 6) Electromagnetic compatibility test
Standards:	ISO 10993-1: 2009: Evaluation and testing within a risk management process ISO 10993-5: 2009: Tests for cytotoxicity: In vitro methods; ISO 10993-10: 2010: Tests for Irritation and Sensitization; IEC 60601-1: 2005: Medical electrical equipment - Part 1: General requirements for basic safety and essential performance IEC 60601-1-2:2001 Medical electrical equipment - Part 1-2: Electromagnetic compatibility Requirements and tests

3. Substantial Equivalence:

Detailed comparison data is included in "Section 9 - Substantial Equivalence Discussion" of this 510(k) submission.

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	New Device	Predicate Device
510(k) Number:	K121718	K964425
Product Code:	JOW	JOW
Proprietary Name:	A-V Hand & Foot Pump, Model LBTK-M-1 1000	A-V IMPULSE SYSTEM MODEL 6060
Manufacturer:	Dalian Labtek Science & Development Co., Ltd.	NOVAMEDIX SERVICES LTD
Indications for use:	A. Foot use - Acute Edema - Chronic Edema - Circulation Enhancement - Deep Vein Thrombosis and Pulmonary Embolism Prophylaxis - Leg Pain Incident to Trauma or Surgery - Leg Ulcers - Venous Stasis/Venous Insufficiency B. Hand use - Acute Edema - Chronic Edema - Circulation Enhancement - Pain Incident to Trauma or Surgery	For lower extremities: - Acute Edema - Chronic Edema - Circulation Enhancement - Deep Vein Thrombosis Prophylaxis - Leg Pain Incident to Trauma or Surgery - Leg Ulcers - Venous Stasis/Venous Insufficiency For upper extremities: - Acute Edema - Chronic Edema - Circulation Enhancement - Pain
Components:	Pump controller, air supply hoses, inflation pads	Pump controller, air supply hoses, inflation pads
Working principle:	Imitate natural physiological "foot pump" and "hand pump" to increase the speed of venous return and artery supply	Imitate natural physiological "foot pump" and "hand pump" to increase the speed of venous return and artery supply
Mode of operation:	Rapid inflation and deflation, manual switch	Rapid inflation and deflation, manual switch
Maximum number of times Reprocessed:	not reusable or reprocessable	not reusable or reprocessable
Performance: - Number of channels: - Inflation time: - Impulse duration: - Inflate frequency:	 2 0.2 seconds 1 or 3 seconds adjustable 12-50 seconds	 2 0.4 seconds 1 or 3 seconds adjustable 12-50 seconds

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- Pressure: - Compression cycle time:	60mmHg~200mmHg 12s~50s adjustable	60mmHg~200mmHg 12s~50s adjustable
Specifications: - Length/Height/Width: - Weight: - Tubing length: - Power supply: - Fuse: - Number of chambers:	 365mm/220mm/150mm 4kg 2mm AC110V/0.2A/50-60Hz T1Ax20mm(Antisurge) 1	 260mm/162mm/234mm 3.4kg 2m 120V/0.6A/60Hz T1Ax20mm(Antisurge) 1
Standards:	ISO 10993-5: 2009: Tests for cytotoxicity: In vitro methods; ISO 10993-10: 2010: Tests for Irritation and Sensitization; IEC 60601-1-2:2001 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance collateral standard: Electromagnetic compatibility Requirements and tests	UL 544: UL Standard for Safety Medical and Dental Equipment
Validation testing:	1) Biological compatibility test 2) Material anti-stretch test 3) Air chamber welding point anti-stretch test 4) Air leakage test 5) Air chamber maximum blast pressure test 6) Electromagnetic compatibility test	The Controller is built and tested toUL544.
Non-sterile:	Non-sterile	The inflation foot pads are in non-sterile and sterile forms.
Microprocessor Control?	Yes	Yes
Differences:	The two devices have different outline dimensions, inflation time, compliant standards, validation tests, and so on.	
Similarities:	The two devices have same components, working principle, intended use, safety features, and so on.	
Conclusion:	Since the new device A-V Hand & Foot Pump, Model LBTK-M-I 1000, has same components, working principle, intended use, and safety features with the predicate device, they are substantial equivalent. Any difference in technological characteristics does not raise any new safety and effectiveness issues. The conclusion drawn from the testing is that the device is as safe and effective as the predicate device.	

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4. Safety and Effectiveness of the device:

A. Safety:

A-V Hand & Foot Pump is a non-invasive medical device that applies brief pressure pulses to the palm of the hand or sole of the foot. Rather than altering or manipulating normal body functions, the A-V Hand & Foot Pump seeks to mimic the natural pumping mechanisms that already exist in the venous plexus systems in the hand and foot. Accordingly, the A-V Hand & Foot Pump is intrinsically safe. Apart from the intrinsic safety of the physiological mechanism of the A-V Hand & Foot Pump, the product's components are designed to minimize potential risks to patients during product use. In particular, the product is equipped with the following safety features:

① In the event of power failure or malfunction of the generator, the venting valve automatically opens so that any pressure in the pads is released.

② Audio and visual alarms are activated if inflation pads pressure either exceeds or fails to achieve recommended levels.

③ Relevant contraindications, numerous warnings concerning proper use and maintenance, are contained in the instruction manual.

④ The product's labeling indicates that the device is restricted to sale by or on the order of a physician.

⑤ Software validation and other safety features.

B. Effectiveness

A-V Hand & Foot Pump, Model LBTK-M-I 1000, is similar to the predicate device in intended use and mode of operation. A-V Hand & Foot Pump, Model LBTK-M-I 1000, is a manually operated device and does not raise any new issue of safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

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Dalian Labtek Science & Development Co., Ltd.
c/o Ms. Doris Dong
Shanghai CV Information Technology Co., Ltd.
Rm 1706 Yuesha Building, No. 128 Songle Rd.
Songjiang, Shanghai

Re: K121718
Trade/Device Name: A-V Hand & foot Pump, Model LBTK-M-I 1000
Regulation Number: 21 CFR 870.5800
Regulation Name: Compressible Limb Sleeve
Regulatory Class: Class II
Product Code: JOW
Received: June 11, 2012

Dear Ms. 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. 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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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,

M J Hillebrenner

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K121718

Section 4
Indications for Use Statement

510(k) Number (if known): K121718

Device Name: A-V Hand & Foot Pump, Model LBTK-M-I 1000

Indications for Use:
A-V Hand & Foot Pump, Model LBTK-M-I 1000, is intended for use to enhance blood circulation in the arteries and veins in patents. The indications vary depending on whether pump is used with the foot pad or hand pad.

A. Foot use
- Acute Edema
- Chronic Edema
- Circulation Enhancement
- Deep Vein Thrombosis and Pulmonary Embolism Prophylaxis
- Leg Pain Incident to Trauma or Surgery
- Leg Ulcers
- Venous Stasis/Venous Insufficiency

B. Hand use
- Acute Edema
- Chronic Edema
- Circulation Enhancement
- Pain Incident to Trauma or Surgery

Prescription Use ✓ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K121718