December 19, 2017

LD Technology LLC
Albert Maarek
Quality Manager
100 N. Biscayne Blvd Suite 502
Miami, Florida 33132

Re: K173696
Trade/Device Name: TBL-ABI System
Regulation Number: 21 CFR 870.2780
Regulation Name: Hydraulic, Pneumatic, Or Photoelectric Plethysmographs
Regulatory Class: Class II
Product Code: JOM
Dated: November 3, 2017
Received: December 1, 2017

Dear Albert Maarek:

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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/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

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: January 31, 2017
See PRA Statement below

510(k) Number
K173696

Device Name: TBL-ABI System

Indications for Use *(Describe)*

The TBL-ABI is indicated for use on adult subjects at risk of having or developing peripheral arterial disease (PAD).
TBL-ABI is intended for rapid measurement of ankle-brachial pressure index (ABPI) or ankle-brachial index (ABI) in adults and pulse volume recording (PVR) / volume plethysmography in adults.
It is suitable for use in wound care assessment, for assessing symptomatic PAD, and as a screening device for PAD. It may also be used on patients with venous or arterial ulcers prior to the application of compression therapy.
TBL-ABI can be used on patients with unilateral lower limb amputation.
The TBL-ABI System is intended to be used to spot-check patients. The TBL-ABI provides information regarding patient risk. The physician has the responsibility of making proper judgments based on this information.

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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510(k) Premarket Notification Number: 173696
Date of preparation: November 04 ,2017

510(k) Summary
TBL-ABI device

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of 21 CFR §807.92

1. Submitter's Identification:
Manufacturer: L.D TECHNOLOGY
Address:
100 N. Biscayne Blvd, Suite 502
Miami, FL, 33132, USA
Tel: 305-379-9900
E mail: albert.ldteck@gmail.com

2. Device Name / Classification
Trade name: Patient monitor
Device Name and Model: TBL-ABI
Regulation number: 21CFR 870.2780
Product Code: JOM
Device Class: Class II
Classification Name: Hydraulic, pneumatic, or photoelectric plethysmograph
Classification Panel: Cardiology

3. Predicate legally marketed devices
TM-ABI k143152 Applicant: LD TECHNOLOGY LLC. Product Code: JOM.

4. Device Description
TBL-ABI System comprises:
- 3 Bluetooth blood pressure devices with attached cuffs.
- Software installed on a computer

It is intended to measure a patient's Ankle Brachial Index (ABI) and provide Pulse Volume Recording (PVR) / volume plethysmography.
This is done through an automated process.
The operator places the three devices with different color-coded electronic boxes on the right or left arm, and on each leg as described in the instructions for use, and the devices connect to the computer via Bluetooth.
Once the devices are connected, the operator clicks start on the software to start the measurement. The devices will then automatically control the inflation & deflation of the cuffs and monitor the variations in individual pressures to determine values to be used for the calculation of the ABI

values for both the left and right of the patient.
TBL-ABI uses pneumo-plethysmography in order to obtain physiologic measurements from the patient's limbs.
Measurements are conducted as a single occurrence on the three limbs, thus eliminating any requirement to rest the patient between measurements.
The test period takes approximately 3 minutes.
ABI values, as well as the Pulse Volume recording (PVR), are displayed on the software installed in a computer. The results are saved in a backup file and can also be printed.

5. Intended use and indications for use
The TBL-ABI is indicated for use on adult subjects at risk of having or developing peripheral arterial disease (PAD).
TBL-ABI is intended for the rapid measurement of ankle-brachial pressure index (ABPI), or ankle-brachial index (ABI), and pulse volume recording (PVR) / volume plethysmography in adults. It is suitable for use in wound care assessment, for assessing symptomatic PAD, and as a screening device for PAD. It may also be used on patients with venous or arterial ulcers prior to the application of compression therapy.
TBL-ABI can be used on patients with unilateral lower limb amputation.
The TBL-ABI System is intended to be used to spot-check patients. The TBL-ABI provides information regarding patient risk. The physician has the responsibility of making proper judgments based on this information.
*Prescription Use: Federal law restricts the use of this device to sale by or on the order of a physician

6. Performances, technical specifications and materials
Performances
TBL-ABI comprises 3 portable medical devices, powered by internal Li-Po battery. Each device has a rechargeable battery, and a Bluetooth connection with the software installed in a computer. Each device has a different box color.
The front panel of each device has an on/off button to connect the Bluetooth.,
The main purpose of the TBL-ABI is to measure ABI, SYS and DIA of all limbs. It also allows for checking measurement history.

Technical specifications i.e. table of comparison with the predicate device
Patient contact materials:
The materials in contact with the patient are the cuffs.
The Cuff material is lycra fabric, raised fabric.

7. Contra-indications
- **Patients undergoing external defibrillation.**
- **Patients connected to electronic life support devices, or any implanted electronic device.**
- Patients moving or undergoing long term monitoring.
- Do not use this device in the presence of:
  - Magnetic resonance imaging (MR or MRI) equipment. MRI equipment may deliver induced current to the device.

- Strong electromagnetic sources, such as electro surgery equipment.
- Computed Tomography (CT) equipment.
- WIFI router at distance less than 10 feet and in the same room.
- Cellphones at distance less than 10 feet.
- Microwaves ovens, cables and connectors associated with satellite dishes, nearby power
- lines or power stations, cordless telephones, wireless speakers, some monitors and
- displays, cameras, baby monitors.

The distance between hardware and the computer must be less than 10 feet and in the same room.

- Arterial catheters, or with an AV fistula or pressure dressing.
- Venous pulsations may cause erroneous reading in blood pressure (e.g. tricuspid valve regurgitation).
- Take caution with patients that have low perfusion. Using the blood pressure device may cause skin erosion and/or pressure necrosis.

8. Undesirable side effects:
No side effects or adverse reactions are known to date.

9. Substantial equivalence
Predicate legally marketed device: TM-ABI, K143152. Applicant: LD TECHNOLOGY LLC. Product Code: JOM.

Substantial Equivalence Discussion

- ✓ Step 1: **Does the new device have the same indication statement?** Yes

Device Modifications are not affected the intended use of the device.

- ✓ Step 3: **The new device has the same intended use and may be "substantially equivalent**." Yes
- ✓ Step 5: **Does the new device have the same technological characteristics, e.g. design, materials, etc.?**

Similarities:

- ✓ Same intended use
- ✓ Scientific Background (oscillometric measurement of the blood pressure and PVR)
- ✓ Placement of the cuff
- ✓ Power supply using a rechargeable battery
- ✓ Classification Degree of protection against electric shocks
- ✓ Operating mode

Device Modifications:

- ✓ The TBL-ABI and predicate device have different dimension and weight
- ✓ The TBL-ABI and predicate device use a battery with different voltage and intensity rate.

- ✓ The TBL-ABI cuffs are in different material and are directly attached to each device versus cuffs connected with tubes for TM-ABI.
- ✓ The TBL-ABI has a maximal pressure of 270 mmHg versus 299 mmHg for TM-ABI
- ✓ The TM-ABI has small difference in temperature and humidity conditions for storage and working environment
- ✓ The TBL-ABI uses 3 Bluetooth devices versus one USB connection device for TM-ABI

Rationale for the Device modifications:

- ✓ Bluetooth communication
- ✓ Cuffs attached to 3 electronic boxes with pump
  Allow to remove the tubes and the patient feel more comfortable and it is more convenient for the technician.

Step 6**: If it has new technological characteristics, could they affect safety or effectiveness? Discussion why any differences between the subject and predicate(s) do not impact safety and effectiveness [see section 513(i) (1) (A) of the FD&C Act and 21 CFR 807.87(f)] See "**

Does the change in communication to the software affect the safety or effectiveness?

The Bluetooth communication is safe, and we use the same CRC coding test as the previous USB communication. CRC (Cyclic redundancy check) Coding was performing to demonstrate the software performance to accurately capture, store, and analyze the data measured by the hardware. Testing of the Bluetooth has been performed.

Do the other changes affect the safety or effectiveness?

The fact that the TBL-ABI has:

- ✓ A different dimension and weight
- ✓ Battery with lower voltage and intensity rate
- ✓ Different cuff material and cuffs directly attached to the device
- ✓ A small lower maximal blood pressure value
- ✓ A small difference in temperature and humidity environment

do not affect the performances and the effectiveness of the TBL-ABI system compared to the predicate device as shown by the laboratory testing (60601-1-1-1, 60601-1-2, IEC 80601-2-30, ISO 10993 and IEC 62133) and testing performed comparing the results of 2 devices as well as the cybersecurity risk assessment.

Table of comparison

Information	TBL-ABI	TM-ABI K143152
Intended use	The TBL-ABI is indicated for use on adult subjects at risk of having or developing peripheral arterial disease (PAD). TBL-ABI is intended for the rapid measurement of ankle-brachial pressure index (ABPI), or ankle-brachial index (ABI), and pulse volume recording (PVR) / volume plethysmography in adults. It is suitable for use in wound care assessment, for assessing symptomatic PAD, and as a screening device for PAD. It may also be used on patients with venous or arterial ulcers prior to the application of compression therapy. TBL-ABI can be used on patients with unilateral lower limb amputation.	The TM-ABI is indicated for use on adult subjects at risk of having or developing peripheral arterial disease (PAD). TM-ABI is intended for the rapid measurement of ankle-brachial pressure index (ABPI), or ankle-brachial index (ABI), and pulse volume recording (PVR) / volume plethysmography in adults. It is suitable for use in wound care assessment, for assessing symptomatic PAD, and as a screening device for PAD. It may also be used on patients with venous or arterial ulcers prior to the application of compression therapy. TM-ABI can be used on patients with unilateral lower limb amputation.
Dimensions/weight	For each device: Width: 60mm, height: 30mm, depth:132mm Weight: 260g	width: 250 mm, height: 730mm, depth: 200 mm, weight: 0.60kg
Power Supply	Output: 3.7 V DC. Battery type: rechargeable lithium polymer Capacity: 530 mAh, number of measurements per charge: 60	Output: 5V DC. Battery type: rechargeable lithium polymer Capacity: 2,300mAh, number of measurements per charge: 30
Applied parts in contact with the patient	3 cuffs lycra fabric raised fabric ISO 10993- 10 2010. ISO 10993-10, 2012 and ISO 10993-5, 2009	3 cuffs, nylon and bladders ISO 10993-10: 2010
Testing Bench	Type of protection against electric shock: Class II. BF Compliant with standards: 60601-1, 60601-1-2 80601-2-30.	Type of protection against electric shock: Class II. BF Compliant with standards: 60601-1, 60601-1-2 80601-2-30.
Measurement types	Using the pneumo-plethysmographic method: Right and left Ankle brachial pressure index Systolic blood Diastolic blood pressure	Using the pneumo-plethysmographic method: Right and left Ankle brachial pressure index Systolic blood Diastolic blood pressure
Measurement ranges	Pressure: 0 to 270 mmHg	Pressure: 0 to 299 mmHg
Limit values of measurement errors	Pressure: ± 3mmhg Ankle brachial pressure index: ± 0.1	Pressure: ± 3mmhg Ankle brachial pressure index: ± 0.1

Cuffs inflation and deflation	Automatic inflation using an air pump and deflation using an electromagnetic valve.	Automatic inflation using an air pump and deflation using an electromagnetic valve.
Temperature and humidity range	working environment: 5 to 40°C, 15 to 80% relative air humidity, IPX21 protection, transport and storage: -20 to 55°C, up to 85% relative air humidity.	working environment: 10 to 40°C, 30 to 85% relative air humidity, IPX0 protection, transport and storage: 0 to 60°C, up to 85% relative air humidity.
Target population	Adult	Adult
Where used	Clinical environment	Clinical environment
PC Data transmission	Bluetooth version 4.0	USB

10. Non-clinical, Performances and Effectiveness

CRC (Cyclic redundancy check) Coding was performing to demonstrate the software performance to accurately capture, store, and analyze the data measured by the hardware.
Testing comprises:

1. Calibration tests
2. Bluetooth testing and Cybersecurity risk design
3. Laboratory tests
4. Software verification (SRS/SDS/STD/STR)

11. General Safety Concerns

The laboratory test reports of the TBL-ABI System and Bluetooth communication technology testing have demonstrated the general safety of the system compared to the legally marketed predicate device.

12. Standards

- ✓ IEC 60601-1: Medical electrical equipment – Part 1: General requirements for basic safety and essential performance. Third Edition December 2006
- ✓ IEC60601-1-2: Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility – Requirements and tests. Third Edition 05/17/2007
- ✓ IEC 80601-2-30: Medical electrical equipment – Part 2-30: Particular requirements for the basic safety and essential performance of automated non-invasive sphygmomanometers. 10/31/2010 Second Edition
- ✓ ISO 10993-10: Tests for irritation and skin sensitization.2010 and 2012
- ✓ ISO 10993-5: Biological evaluation of medical devices. 2009
- ✓ IEC 62133: 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. 2nd Edition.2012.
- ✓ Guidance for: Industry; FDA staff; and Content of Premarket Submissions for Software Contained in Medical Devices Document issued on: May 11, 2005
- ✓ Wireless Medical device FDA Guidance. 2014.

- ✓ Cybersecurity FDA Guidance. 2013.
- ✓ ISO 14971: Medical devices — Application of risk management to medical devices. March 01, 2007

Conclusion
TBL-ABI is equivalent in performance, technology, safety and efficacy to the legally marketed predicate device.
Signature:

Albert MAAREK

Premarket notification [510K] Number: 173696