May 15, 2020

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

Re: K200287
Trade/Device Name: BP-BT Kiosk
Regulation Number: 21 CFR 870.1130
Regulation Name: Noninvasive Blood Pressure Measurement System
Regulatory Class: Class II
Product Code: DXN
Dated: April 10, 2020
Received: April 14, 2020

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. 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,

LT Stephen Browning
Assistant Director
Division of Cardiac Electrophysiology, Diagnostics and Monitoring Devices
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)*
k200287

Device Name
BP-BT Kiosk

Indications for Use *(Describe)*

BP-BT Kiosk is designed to measure blood pressure (systolic and diastolic) and pulse rate in adult patients with arm circumference range between 6.7 inches (17.0 cm) to 16.5 inches (42.0 cm). Indication: Prescription use in medical or clinic environment only.Rx only.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

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510(k) Premarket Notification Number: date: January, 29,2020

510(k) Summary BP-BT Kiosk

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: Non-Invasive Blood Pressure measurement system
Device Name and Model: BP-BT Kiosk
Regulation number: 21CFR 870.1130
Product Codes: DXN
Device Class: Class II
Classification Name: Blood pressure monitor
Classification Panel: Cardiology

3. Predicate legally marketed device

A&D Medical TM-2657 Family of Digital Blood Pressure Monitors K151953. Applicant: A&D Engineering, Inc. Product Code: DXN

4. Device Description
BP-BT Kiosk has the same design as the predicated device with an inflatable cuff which is wrapped around the patient's upper arm. After the user pushes the "START" button, the cuff is first adapted to the arm size and then, inflated automatically by an internal pump. The systolic and diastolic blood pressures are also determined by oscillometric method. The deflation rate is controlled by an internal exhaust valve. There is a quick exhaust mechanism so that the cuff pressure can be completely released urgently. There is a maximum pressure safety setting at 300 mmHg. BP-BT Kiosk will not inflate the cuff higher than 300 mmHg. BP-BT Kiosk will turn on an irregular heartbeat indicator if an irregular heartbeat was detected during the measurement process. At the end of the measurement, the systolic and diastolic pressures with pulse rate are shown on the LCD and transmitted via Bluetooth wireless module. The cuff is also deflated automatically to 0 mmHg at the same time. The detail of summary of substantial equivalence is listed below.

5. Intended use and indications for use

BP-BT Kiosk is designed to measure blood pressure (systolic and diastolic) and pulse rate in adult patients with arm circumference range between 6.7 inches (17.0 cm) to 16.5 inches (42.0 cm). Indication : Prescription use in medical or clinic environment only. Rx only.

6. Performances, technical specifications and materials

Performances

The main purpose of the device is to measure the subject blood pressure and Pulse rate.

Technical specifications i.e. table of comparison with the predicate device

Patient contact materials:

The material in contact with the patient is the cuff. The Cuff material is nylon and latex free.

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7. Contra-indications

- Patients with any implanted electronic device (i.e. Pacemaker.).
- Patients with arterial catheters
- Patients with venous pulsations may cause erroneous reading in blood pressure (e.g. tricuspid valve regurgitation).
- Patients that have low blood perfusion. Using the blood pressure device may cause skin erosion and/or pressure necrosis.
- Patients that have double mastectomy procedure

8. Undesirable side effects:

No side effects or adverse reactions are known to date.

9. Substantial equivalence

Predicate legally marketed device:

A&D Medical TM-2657 Family of Digital Blood Pressure Monitors K151953. Applicant: A&D Engineering, Inc. Product Code: DXN

Table of comparison

Information	TM-2657 Family	BP-7000 Kiosk
Intended use	TM-2657, TM-2657P, TM-2657PBT, and TM-2657PRS are designed to measure blood pressure (systolic and diastolic) and pulse rate in adult patients with arm circumference range between 7.1 inches (18.0 cm) to 13.8 inches (35.0 cm).	BP-BT Kiosk is designed to measure blood pressure (systolic and diastolic) and pulse rate in adult patients with arm circumference range between 6.7 inches (17.0 cm) to 16.5 inches (42.0 cm).
Power Supply	100-240V AC 50/60Hz	AC 100-240V, 50-60Hz ; D.C.12V, 3.5A

Cuff design	Winding mechanism operated by geared motor	Winding mechanism operated by geared motor
Display Type	Display by LED	Display by LED
Communication	Wired – RS232C standard (TM-2655 Family). Wireless – Bluetooth 2.1 Standard (UA-767PBT)	Bluetooth serial port and USB interface..
Testing Bench	Type of protection against electric shock: Class I. BF Compliant with standards: 60601-1, 60601-1-2 80601-2-30. Clinical Test	Type of protection against electric shock: Class I. BF Compliant with standards: 60601-1, 60601-1-2 60601-2-30 Clinical Test
Measurement types	Systolic and diastolic Blood pressure Pulse rate Method : oscillometric	Systolic and diastolic Blood pressure Pulse Rate Method : oscillometric
Operating and storage environment	Operating: 10℃ to 40℃ with 15 % to 85% RH Storage: -20℃ to 60℃ with 10 -95% RH	Operating: 5℃ to 40℃ with15% to 80% RH Storage: -20 ℃ to 55 ℃ with ≤93%RH
External dimensions and weight	241 (W) x 330 (H) x 390 (D) mm Approx. 5.5 kg	387.7mm (L) × 244.1mm (W) × 340.2mm (H) Approx. 6 kg
Measurement ranges and Accuracy	Pressure: 0- 299 mmHg BP : +/- 3%, Pulse : +/- 5 %	Pressure: 0- 300 mmHg BP: ± 2 mmHg Pulse rate: ± 5 %
Target population	Adult general public	Adult general public
Where used	Over the counter	Prescription use in medical or clinic environment only.

10. Performances and Effectiveness

Performances and effectiveness are demonstrated by:

- CRC (Cyclic redundancy check) Coding was performing to demonstrate the software performance to accurately capture, store, and analyze the data measured by the hardware's.
- 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
- Testing comprises the Software verification and validation (SRS/SDS/STD/STR).
- Risk analysis and

Clinical Test.: 267 sets of data were measured by the blood pressure monitor and Mercury Blood pressure monitor

- The average deviation of systolic pressure: -0.19mmHg
- The standard deviation of systolic pressure: 1.56 mmHg
- The average deviation of diastolic pressure: 0.25mmHg
- The standard deviation of diastolic pressure: 1.65mmHg
- The error of pulse rate measured by blood pressure monitor was within ±5%.

The Following differences:

- The BP-BT Kiosk has a) a larger amplitude in arm circumference range and b) a D.C. converter 12V, 3.5A comparing to the predicate device.

Do not affect the performances and the effectiveness of the BP-BT s kiosk.

11. General Safety Concerns

The laboratory test reports, and clinical study of the BP-BT Kiosk have demonstrated the general safety of the device 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. Fourth Edition 2014
- ✓ 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
- ✓ Guidance for: Industry; FDA staff; and Content of Premarket Submissions for Software Contained in Medical Devices Document issued on: May 11, 2005
- ✓ ISO 14971: Medical devices — Application of risk management to medical devices. March 01, 2007

Conclusion

BP-BT Kiosk is equivalent in performance, technology, safety and efficacy to the legally marketed predicate device.

Premarket notification [510K] Number: k200287