March 9, 2021

Guangdong Transtek Medical Electronics Co., Ltd.
% Kevin Wang
Consultant
Chonconn Medical Device Consulting Co., Ltd.
Room 508, Block C, No. 1029 Nanhai Avenue, Nanshan District
Shenzhen, Guangdong 518067
China

Re: K202891
Trade/Device Name: Blood Pressure Monitor
Regulation Number: 21 CFR 870.1130
Regulation Name: Noninvasive Blood Pressure Measurement System
Regulatory Class: Class II
Product Code: DXN
Dated: December 16, 2020
Received: February 10, 2021

Dear Kevin Wang:

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K202891

Device Name
Blood Pressure Monitor

Indications for Use *(Describe)*
The Transtek Blood Pressure Monitor is digital monitors intended for use in measuring blood pressure and heartbeat rate with arm circumference ranging from 22cm to 45cm (about 8¾″-17½″).
The device can be used to detect irregular heartbeat.
It is intended for adult indoor use 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.

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510(K) Summary

Prepared in accordance with the requirements of 21 CFR Part 807.92

Prepared Date: 2020/10/09

1. Submission sponsor

Name: Guangdong Transtek Medical Electronics Co., Ltd.
Address: Zone B, No.105, Dongli Road, Torch Development District, Zhongshan, Guangdong, China
Contact person: Endless Chan
Title: RA Engineer
E-mail: Endless.Chan@transtekcorp.com

2. Submission correspondent

Name: Chonconn Medical Device Consulting Co., Ltd.
Address: Room 508, Block C, No. 1029 Nanhai Avenue, Nanshan District, Shenzhen, Guangdong, P. R. China 518067
Contact person: Kevin Wang
E-mail: kevin@chonconn.com
Tel: +86-755 33941160

3. Subject Device Information

Trade/Device Name	Blood Pressure Monitor
Model	LS802-GS
Common Name	Automatic Arm Blood Pressure Monitor
Regulatory Class	Class II
Product Code	DXN
Submission type	Traditional 510(K)

4. Predicate Device

1. Guangdong Transtek Medical Electronics Co., Ltd., TRANSTEK Blood Pressure Monitor under K131395.

The subject device has same intended use, same target patient population, same performance effectiveness, performance safety as the predicate devices and no question is raised regarding to effectiveness and safety. So, the conclusion is that the subject device is substantial equivalent to the predicate.

5. Device Description

Blood Pressure Monitor, Models LS802-GS is designed to measure the systolic and diastolic blood pressure and pulse rate of an individual by using a non-invasive technique in which an inflatable cuff is wrapped around the upper arm. Our method to define systolic and diastolic pressure is similar to the auscultatory method but uses an electronic pressure sensor rather than a stethoscope and mercury manometer. The sensor

converts tiny alterations in cuff pressure to electrical signals, by analyzing those signals to define the systolic and diastolic blood pressure and calculating pulse rate, which is a well-known technique in the market called the "oscillometric method".

The main components of the Blood Pressure Monitor is the main unit and cuff unit. ABS is used to outer housing of the main unit. The preformed cuff unit, which is applicable to arm circumference approximately between 220 and 450 mm, includes the inflatable bladder and nylon shell. The device consists of the microprocessor, the pressure sensor, the operation keys, the pump, the electromagnetic deflation control valve and the LCD.

The devices also compares the longest and the shortest time intervals of detected pulse waves to mean time interval and displays a warning signal with the reading to indicate the detection of irregular pulse rhythm when the difference of the time intervals is over 25%.

The devices embed an LTE Wireless network connections module that allows it to connect to receiving end. Once measurement is over, the LCD of device displays results, and the device will start to send out data such as systolic, diastolic, pulse, date, time with Wireless method and protocol.

6. Intended use & Indication for use

The Transtek Blood Pressure Monitor is digital monitors intended for use in measuring blood pressure and heartbeat rate with arm circumference ranging from 22cm to 45cm (about 8¾″-17½″). The device can be used to detect irregular heartbeat. It is intended for adult indoor use only.

7. Comparison to the Predicate Device

Features	**Subject Device LS802-GS**	**Predicate Device K131395 Model: LS802-B**	**Remark**
Applicant	Guangdong Transtek Medical Electronics Co., Ltd.	Guangdong Transtek Medical Electronics Co., Ltd.	/
Classification Regulation	21CRF 870.1130	21CRF 870.1130	Same
Classification and Code	Class II, DXN	Class II, DXN	Same
Common name	Automatic Arm Blood Pressure Monitor	Automatic Arm Blood Pressure Monitor	Same
Intended use	The Transtek Blood Pressure Monitor is digital monitors intended for use in measuring blood pressure and heartbeat rate with arm circumference ranging from 22cm to 45cm (about 8¾″-17½″). The device can be used to detect irregular heartbeat. It is intended for adult indoor use only.	Transtek Blood Pressure Monitor LS802-B, LS805-B and TMB-1018-BT are digital monitors intended for use in measuring blood pressure and heartbeat rate with arm circumference ranging from 22cm to 42cm (about 9-17 inches).	Different (1)

Features	Subject Device LS802-GS	Predicate Device K131395 Model: LS802-B	Remark
		These devices detect the appearance of irregular heartbeats during measurement and give a warning signal with readings. The Blood Pressure Monitor compares average blood pressure results to pre-established AHA (American Heart Association) hypertension guideline of 135/85 mmHg. Transtek Blood Pressure Monitor LS802-B, LS805-B and TMB-1018-BT are not intended to be a diagnostic device. Contact your physician if hypertensive values are indicated.	
Patient Populations	Adults	Adults	Same
Principle	Oscillometric method	Oscillometric method	Same
Target population	Adult	Adult	Same
Anatomical sites	Upper Arm	Upper Arm	Same
Where used (hospital, home, ambulance, etc.)	Home	Home	Same
Energy used and / or delivered	4 * 1.5V AA Battery, or by a DC 6V adapter	4 * 1.5V AA Battery, or by a DC 6V adapter	Same
Human factors	Blood pressure	Blood pressure	Same
Performance	Measuring systolic and diastolic blood pressure and pulse rate of adult individual, Including irregular pulse rhythm detection	Measuring systolic and diastolic blood pressure and pulse rate of adult individual, Including irregular pulse rhythm detection	Same
Biocompatibility	Cuff, according to ISO-10993	Cuff, according to ISO-10993	Same
Compatibility with the environment and other devices	Operation Environment: 5℃~ 40℃,15%~90%RH, Atmospheric: 70KPa~106KPa. Storage Environment: -20℃~60℃, ≤93%RH.	Operation Environment: 10℃~ 40℃, ≤85%RH, Atmospheric: 80KPa~106KPa. Storage Environment: -20℃~60℃, 10%~93%RH.	Different (2)

Features	Subject Device LS802-GS	Predicate Device K131395 Model: LS802-B	Remark
Electrical safety	According to IEC60601-1-2 According to IEC60601-1	According to IEC60601-1-2 According to IEC60601-1	Same
Blood Pressure Measurement	0mmHg ~ 299mmHg, 5℃ - 40℃ within ±3mmHg (0.4kPa)	0 ~ 300 mmHg, 15℃ - 25℃ within ±0.4 kPa (3 mm Hg) 10℃ - 40℃(out of 15℃-25℃) within ±0.7 kPa (5 mm Hg);	Different (3)
Pulse rate measurement	40-199 beat/minute, ±5%	40 ~ 199 beat/minute, ±5%	Same
Cuff Deflation	Automatic deflation	Automatic deflation	Same
Memory Size	60	60	Same
Wireless	LTE	Bluetooth	Different (4)

Justification of difference:

Different (1): The substantial difference of the intended use is the arm circumference ranging. The proposed device is wider than the predicate device. The proposed device was validated according to ISO 80601-2-30 and ISO 81060-2. The performance data can demonstrate this difference does not raise different questions of safety and effectiveness.

Different (2): Compared with the predicate device, the subject device requires less strict operation and storage environment. The IEC 60601-1-11 test report can demonstrate that the subject device can maintain the safety and performance within the operation and storage environment. Thus, this difference does not raise different questions of safety and effectiveness.

Different (3): The subject device's blood pressure measurement range is restricted to 299 mmHg for safety purpose. Thus, the different does not raise different questions of safety and effectiveness.

Different (4): The wireless module is different. However, the wireless function is same. The monitor can transmit the measurement result through wireless and display the measurement on the mobile application. Thus, this difference does not raise different questions of safety and effectiveness.

8. Performance Data

The following performance data were provided in support of the substantial equivalence determination.

Biocompatibility testing

The biocompatibility evaluation for the subject device was conducted in accordance with the FDA Guidance for Industry and Food and Drug Administration Staff: Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process". The battery of testing included the following tests:

- Cytotoxicity

- Sensitization
- Irritation

The subject device is considered surface contacting for a duration of exceed 24 hours but not 30 days.

Non-clinical data

The subject device has been tested according to the following standards:

- IEC 60601-1: Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and essential performance
- IEC 60601-1-2: Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests
- IEC 80601-2-30: Medical electrical equipment – Particular requirements for the basic safety and essential performance of automated non-invasive sphygmomanometers.
- IEC 60601-1-11: Medical electrical equipment -- Part 1-11: General requirements for basic safety and essential performance -- Collateral standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment
- IEC 60601-1-6: Medical Electrical Equipment - Part 1-6: General requirements for safety – Collateral Standard: Usability.
- IEC 62366-1: Medical devices – Application of usability engineering to medical devices.
- FDA Guidance for Non-Automated Sphygmomanometer.

Wireless testing:

- Bluetooth test according to FCC CFR Title 47 Part 15 Subpart C.
- ANSI C63.27L: 2017: American National Stand for Evaluation of Wireless Coexistence.
- AAMI TIR69: 2017 Risk management of radio-frequency wireless coexistence for medical devices and systems.
- Radio Frequency Wireless Technology in Medical Devices: Guidance for Industry and Food and Drug Administration Staff (August 14, 2013)

Reprocessing validation:

- AAMI TIR12: 2010-designing, testing, and labeling reusable medical devices for reprocessing in health care facilities: A guide for medical device manufactures
- AAMI TIR30: 2011-A compendium of processes, materials, test methods, and acceptance criteria for cleaning reusable medical devices
- Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling: Guidance for Industry and Food and Drug Administration Staff

Clinical data

This device was tested to ISO 81060-2: 2018 Non-invasive sphygmomanometers - Part 2: Clinical validation of automated measurement type. The study population consisted of 85 qualified healthy adult

subjects. All data's mean error and standard deviation of differences for systolic, diastolic pressure is not over the limits of ISO 81060-2: 2018, and the accuracy of subject device is better than predicate device. No adverse effect and/or complication is found in this study.

9. Conclusion

According to the 510(k) submission, the subject device and the predicate device has the same intended use, and the difference in technological features of the proposed devices and the predicate devices do not raise different questions regarding safety and effectiveness. Performance testing and compliance with voluntary standards demonstrate that the proposed device models are substantially equivalent to the predicate devices in terms of design, components, materials, principals of operation, biocompatibility, performance characteristics, and intended use.