December 6, 2020

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: K202599
Trade/Device Name: Transtek Wrist Blood Pressure Monitor
Regulation Number: 21 CFR 870.1130
Regulation Name: Noninvasive Blood Pressure Measurement System
Regulatory Class: Class II
Product Code: DXN
Dated: September 2, 2020
Received: September 8, 2020

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K202599

Device Name
Transtek Wrist Blood Pressure Monitor

Indications for Use *(Describe)*
The Transtek Blood Pressure Monitor is a digital monitor intended for use in measuring blood pressure and heartbeat rate with a wrist circumference ranging from 13.5cm to 23cm. 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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"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."

510(K) Summary

Prepared in accordance with the requirements of 21 CFR Part 807.92

Prepared Date: 2020/09/02

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: Nicole Hu

Title: RA Engineer

E-mail: nicole.hu@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	Transtek Wrist Blood Pressure Monitor
Model	TMB-2072
Common Name	Automatic Blood Pressure Monitor
Regulatory Class	Class II
Product Code	DXN
Submission type	Traditional 510(K)

4. Predicate Device

Guangdong Transtek Medical Electronics Co., Ltd., Transtek Wrist Blood Pressure Monitor, Model TMB-1014-BT under K123669.

5. Device Description

Transtek Wrist Blood Pressure Monitor, TMB-2072 is designed to measure the systolic and diastolic blood pressure and heartbeat rate of an individual by using a non-invasive technique in which an inflatable cuff is wrapped around the wrist. Measurement 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 heartbeat rate, which is a well-known technique in the market called the "Oscillometric method". Transtek Wrist Blood Pressure Monitor is single-mounted devices of the main unit and cuff unit. The preformed cuff unit, which is applicable to

wrist circumference approximately between 13.5 and 23 cm, includes the inflatable bladder and nylon shell. The device consists of the microprocessor, the pressure sensor, the operation keys, the pump and the electromagnetic deflation control valve. The subject device is powered by 3.7V Built-in rechargeable lithium-ion battery. The device 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 heartbeat when the difference of the time intervals is over 25%. Transtek Wrist Blood Pressure Monitor TMB-2072 embeds a Bluetooth module that allows it to connect to nearby BT receiving end. The mobile application displays results. And once measurement is over, the device will start transmission data by BT. Thus, users can receive, and display/storage, measurement data from TMB-2072 unit through their end devices that embedded BT module.

6. Intended use & Indication for use

The Transtek Blood Pressure Monitor is a digital monitor intended for use in measuring blood pressure and heartbeat rate with a wrist circumference ranging from 13.5cm to 23 cm.
It is intended for adult indoor use only.

7. Comparison to the Predicate Device

Features	**Subject Device TMB-2072**	**Predicate Device K123669 Model: TMB-1014-BT**	**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 a digital monitor intended for use in measuring blood pressure and heartbeat rate with a wrist circumference ranging from 13.5cm to 23 cm. It is intended for adult indoor use only.	Transtek Wrist Blood Pressure Monitor TMB-1014-BT is a digital monitor intended for use in measuring blood pressure and heartbeat rate in adult patient population with wrist circumference ranging from 13.5 cm to 21.5 cm (about 5 1/4-S8 1/2 inches). This device detects the appearance of irregular heartbeats during measurement and gives a warning	Different 1)

Features	Subject Device TMB-2072	Predicate Device K123669 Model: TMB-1014-BT	Remark
		signal with readings. The Wrist Blood Pressure Monitor compares average blood pressure results to pre-established AHA (American Heart Association) hypertension guideline of 135/85 mmHg. Transtek Wrist Blood Pressure Monitor, TMB-1014-BT is not intended to be a diagnostic device. Contact your physician if hypertensive values are indicated.	
Principle	Oscillometric method	Oscillometric method	Same
Target population	Adult	Adult	Same
Anatomical sites	Wrist	Wrist	Same
Where used (hospital, home, ambulance, etc.)	Home	Home	Same
Energy used and / or delivered	3.7V 420mAH Built-in rechargeable lithium-ion battery, 5V 1A USB AC Adaptor	2 × 1.5V AA Battery	Different 2)
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 Storage Environment: -20℃~60℃, ≤93%RH	Operation Environment: 5℃~ 40℃,15%~90%RH Storage Environment: -20℃~60℃, ⩽93%RH	Same
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, ±3mmHg	0mmHg-300mmHg, ±3mmHg	Different 3)
Pulse rate measurement	40-199 beats/minute, ±5%	40-199 beats/minute, ±5%	Same
Cuff Deflation	Automatic deflation	Automatic deflation	Same

Features	Subject Device TMB-2072	Predicate Device K123669 Model: TMB-1014-BT	Remark
Wireless	Bluetooth	Bluetooth	Same

Justification of difference:

Different 1): The wrist circumference is different. The clinical study of blood pressure can demonstrate the subject device can meet the requirement on this wrist range. The clinical study was conducted by ISO 81060-2. So, the different does not raise different questions of safety and effectiveness.

Different 2): The power supply is different. The subject device was tested accordance with IEC 60601-1. The clinical study can demonstrate the subject device can meet the requirement on this power supply. So, the different does not raise different questions of safety and effectiveness.

Different 3): The subject device's blood pressure is restricted to 299 mmHg for safety purpose. So, the different 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 not exceed 24 hours.

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

It has been shown in this 510(k) submission that the difference between the proposed devices and the predicate devices do not raise any questions regarding safety and effectiveness. Performance testing and compliance with voluntary standards demonstrate that the proposed are substantially equivalent to the relevant aspects of the predicate devices in terms of design, components, materials, principals of operation, biocompatibility, performance characteristics, and intended use.