December 20, 2023

Guangdong Transtek Medical Electronics Co., Ltd.
Jerry Fan
RA Manager
Zone A, No. 105, Dongli Road, Torch Development District
Zhongshan, Guangdong 528437
China

Re: K233130
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: September 15, 2023
Received: September 27, 2023

Dear Jerry Fan:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Stephen C. Browning -S

LCDR 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)*
K233130

Device Name
Blood Pressure Monitor

Indications for Use *(Describe)*
The Blood Pressure Monitor is a digital monitor intended for use in measuring blood pressure and pulse rate with a wrist circumference ranging from 13.5cm to 21.5cm (about 5⅓″-8½″).
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 requirement of 21 CFR Part 807.92

Prepared Date: 09/15/2023

1. Submitter

Name: Guangdong Transtek Medical Electronics Co., Ltd.
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Contact: Jerry Fan
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2. Subject Device

Trade/Device Name	Blood Pressure Monitor
Model	TMB-2285-BT
Common Name	Blood Pressure Monitor
Classification	Class II
Product Code	DXN
Submission Type	Traditional 510(k)

3. Predicate Device

Manufacturer:	Zhongshan Transtek Electronics Co., Ltd.
Device Name/Model:	Blood Pressure Monitor / TMB-1014-BT
510(k) Number:	K123669
Classification	Class II
Product Code	DXN

4. Device Description

Blood Pressure Monitor TMB-2285-BT is designed to measure systolic pressure, diastolic pressure and pulse rate of adult population by a non-invasive technique, with an inflatable cuff wrapped around the wrist. The method to define systolic and diastolic pressure is similar to auscultatory method, though it uses an electronic pressure sensor rather than a stethoscope and mercury manometer. The sensor converts tiny alternations of cuff pressure into electrical signals. Based on analysis of these signals, the systolic and diastolic blood pressure is defined, and the pulse rate is calculated. This is an extensively used technique applied in blood pressure monitors, also known as "oscillometric method".

The main components of the Blood Pressure Monitor include main unit and wrist cuff. For the outer housing of the main unit, it's made of ABS material. The cuff model is WC1321-04, suitable for adults with wrist circumference of 13.5cm to 21.5cm. The cuff is consisted of fabric and an inflatable bladder inside. For critical electronic components, there is PCB, thermistor, pressure pump, motor, release valve and pressure sensor.

The device also enjoys a function of detecting irregular pulse rate. When measurements were performed, the monitor will record all pulse intervals and calculate the average. If two or more pulse

intervals were recorded, and the difference between each interval and the average is larger than ±25% of the average; or if four or more pulse intervals were recorded, and the difference between each interval and the average is larger than ±15% of the average, the irregular pulse symbol will be displayed along with measurement results.
An embedded Bluetooth wireless connection module in the device allows it to connect with matching receiving ends. When a measurement is done, the results will be displayed on LCD, and the measured data will be transferred to the APP via Bluetooth.

5. Indications for use

The Blood Pressure Monitor is a digital monitor intended for use in measuring blood pressure and pulse rate with a wrist circumference ranging from 13.5cm to 21.5cm (about 5⅓″-8½″).
It is intended for adult indoor use only.

6. Comparison to Predicate Device

Elements of Comparison	**Subject Device**	**Predicate Device (K123669)**	**Judgement**
Model	**TMB-2285-BT**	**TMB-1014-BT**	**/**
Company	Guangdong Transtek Medical Electronics Co., Ltd.	Zhongshan Transtek Electronics Co., Ltd.	/
Device Name	Blood Pressure Monitor	TRANSTEK Wrist Blood Pressure Monitor	/
Product Code	DXN	DXN	Same
Classification	Class II	Class II	Same
Regulation #	21 CFR870.1130	21 CFR870.1130	Same
Type of Use	OTC	OTC	Same
Intended Use / Indication for Use	The Blood Pressure Monitor is a digital monitor intended for use in measuring blood pressure and pulse rate with a wrist circumference ranging from 13.5cm to 21.5cm (about 5⅓″-8½″). 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 – 8 1/2 inches). This device detects the appearance of irregular heartbeats during	Similar, refer to Note[1]

		measurement and gives a warning 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.	
Patient Population	Adult	Adult	Same
Working principle	Oscillometric method	Oscillometric method	Same
Anatomical Site	Wrist	Wrist	Same
Where used (hospital, home, ambulance, etc.)	Home	Home	Same
Power Supply	Battery (2*AAA, 3V DC)	Battery (2*AAA, 3V DC)	Same
Human Factors	Blood pressure	Blood pressure	Same
Measurement Items	Measuring systolic and diastolic blood pressure and pulse rate of adult individual.	Measuring systolic and diastolic blood pressure and pulse rate of adult individual.	Same
Cuff Deflation	Automatic deflation with air pump	Automatic deflation with air pump	Same
Deflation of pressure	Automatic air release	Automatic air release	Same
Measurement perimeter of wrist	13.5cm~21.5cm	13.5cm~21.5cm	Same

Blood Pressure Measurement Range	0~299mmHg ±3mmHg (5℃~40℃); ±5mmHg (0℃~45℃ [out of 5℃~40℃])	0~300mmHg ±3mmHg (5℃~40℃); ±5mmHg (0℃~45℃ [out of 5℃~40℃])	Similar, refer to Note[2]
Pulse Rate Measurement	40~199 beat/minute, ±5% of reading	40~199 beat/minute, ±5% of reading	Same
Display	LCD	LCD	Same
Memory	199*2	60	Different, refer to Note[3]
Operation Environment	Temperature: 5℃~40℃ Relative humidity: 15%~90%, non-condensing, but not requiring a water vapor partial pressure greater than 50hPa Atmospheric: 700hPa ~1060hPa	Temperature: 5℃~40℃ Relative humidity: ≤80% Atmospheric: 86~106kPa	Similar, refer to Note[4]
Transport and Storage Environment	Temperature: -20℃~60℃ Relative humidity: ≤93%, non-condensing, at a water vapor pressure up to 50hPa Atmospheric pressure: 500hPa ~ 1060hPa	Temperature: -20℃~60℃ Relative humidity: 10~93%	Similar, refer to Note[5]
Performance	Compliance with IEC 80601-2-30	Compliance with IEC 80601-2-30	Same
Clinical	Compliance with ISO 81060-2	Compliance with ISO 81060-2	Same
Biocompatibility	All patient contact parts meet the requirements of ISO 10993-1/5/10/23	All patient contact parts meet the requirements of ISO 10993-1/5/10	Similar, refer to Note[6]
Electrical Safety	Compliance with IEC 60601-1 and IEC 60601-1-11	Compliance with IEC 60601-1 and IEC 60601-1-11	Same
EMC	Compliance with IEC 60601-1-2	Compliance with IEC 60601-1-2	Same
Wireless technology	Bluetooth	Bluetooth	Same

Justification for difference:

Note [1]:

The intended use of the subject device is essentially same as that of the predicate device, that is to measure blood pressure and pulse rate of adult population with a wrist circumference of 13.5cm to 21.5cm. There is only difference in expression. Besides, the safety and effectiveness of the subject device used on its intended population has also validated according to IEC 60601-1, IEC 60601-1-11, IEC 60601-1-2, IEC 80601-2-30 and ISO 81060-2. As demonstrated in relevant test reports, the difference here does not raise any issues concerning safety and effectiveness.

Note [2]:

There is a tiny difference regarding blood pressure measuring range of the subject device and predicate device, but the accuracy tolerance is same. The blood pressure measurement function as well as its accuracy has been validated according to IEC 80601-2-30 and ISO 81060-2. As demonstrated in relevant test reports, the difference here does not raise any issue concerning safety and effectiveness.

Note [3]:

The subject device enjoys a larger memory room for storing measured data than the predicate device. This difference, however, won't affect the normal measuring function of the devices. Besides, the subject device has also been validated according to IEC 60601-1, IEC 60601-1-2 and ISO 80601-2-30. As demonstrated in relevant test reports, the difference here does not raise any issues concerning safety and effectiveness.

Note [4]:

There is tiny difference regarding operation environment between the subject device and predicate device. The subject device has been validated to normally work at the claimed operation environment according to IEC 60601-1, IEC 60601-1-11 and IEC 80601-2-30. As demonstrated in relevant test reports, the difference her does not raise any issue concerning safety and effectiveness.

Note [5]:

There is tiny difference regarding transport and storage environment between the subject device and predicate device. The subject device has been validated to be safely transported and stored at the claimed environment according to IEC 60601-1, IEC 60601-1-11 and IEC 80601-2-30. As demonstrated in relevant test reports, the difference her does not raise any issue concerning safety and effectiveness.

Note [6]:

The wrist cuff of both the subject and predicate device are in compliance with international

standards of compatibility. The difference displayed above is caused by the update of standards. The new cuffs are tested and proved to meet requirements of ISO 10993-5/10/23, in terms of cytotoxicity, sensitization and irritation respectively. As demonstrated in relevant test reports, the difference here does not raise any issues concerning safety and effectiveness.

7. Performance Data

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

Biocompatibility testing:

The biocompatibility evaluation for the 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 biocompatibility testing includes the following tests:

- Cytotoxicity
- Sensitization
- Irritation

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

Non-clinical data

The device has been tested according to 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 requirement for basic safety and essential performance – Collateral standard: Electromagnetic compatibility – Requirements and tests
- IEC 80601-2-30: Medical electrical equipment – Particular requirements for 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
- FDA Guidance for Non-Automated Sphygmomanometer

Wireless testing

- 47 CFR Part 15, Subpart C
- Radio Frequency Wireless Technology in Medical Devices: Guidance for Industry and Food and Drug Administration Staff (August 14, 2013)

Clinical data

The device was tested according to ISO 81060-2:2018+A1:2020 Non-invasive sphygmomanometers – Part 2: Clinical validation of automated measurement type. The clinical study aimed to validate the accuracy of TMB-2285-BT blood pressure monitor with cuff WC1321-

04. 258 datasets were collected from 86 subjects. There are 86 adult subjects with aged 55.7±11.5, 58.1% male and 41.9% female. The mean differences between reference BPs and device readings were -0.27±3.18/-0.80±2.51mmHg for systolic BP (SBP)/diastolic BP (DBP) of criterion 1, and -0.27±2.60/-0.80±2.06mmHg for SBP/DBP of criterion 2. TMB-2285-BT with cuff ranging from 13.5-21.5cm fulfilled both validation criteria 1 and 2 of the ISO 81060-2:2018/Amd.1:2020.

8. Conclusion

With performance testing results and compliance with voluntary standards, a conclusion can be drawn that the proposed subject device is substantially equivalent to the predicate device.