May 31, 2024

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

Re: K240254
Trade/Device Name: Blood Pressure Monitor (TMB-2296-BT)
Regulation Number: 21 CFR 870.1130
Regulation Name: Noninvasive Blood Pressure Measurement System
Regulatory Class: Class II
Product Code: DXN
Dated: May 9, 2024
Received: May 9, 2024

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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K240254

Device Name

Blood Pressure Monitor (TMB-2296-BT)

Indications for Use *(Describe)*

This Blood Pressure Monitor is a digital monitor intended for use in measuring blood pressure and pulse rate with arm circumference ranging from 22cm to 32cm (about 8¾″-12½″) or 22cm to 42cm (about 8¾″-16½″).
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 requirement of 21 CFR Part 807.92

Prepared Date: 03/30/2024

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-2296-BT
Common Name	Blood Pressure Monitor
Classification	Class II
Product Code	DXN
Submission Type	Traditional 510(k)

3. Predicate Device

Manufacturer:	Guangdong Transtek Medical Electronics Co., Ltd.
Device Name / Model:	Blood Pressure Monitor / TMB-2266
510(k) Number:	K232713
Classification	Class II
Product Code	DXN

4. Device Description

Blood Pressure Monitor TMB-2296-BT is designed to measure systolic pressure, diastolic pressure and pulse rate of adult by a non-invasive technique, with an inflatable cuff wrapped around the upper arm. 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 cuff. For the outer housing of the main unit, it’s made of HI-121H material. The two types of cuffs have been clinically validated to be matched with the device, suitable for adults with arm circumference from 22cm~42cm. The cuff is consisted of fabric and an inflatable bladder inside. For critical electronic components, there is medical switch power supply, 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.

With the use of software (including APP) and Bluetooth communication module, the wireless software function and hardware function are solely intended to transfer, store, convert formats, or display medical device data and results (blood pressure and pulse rate readings), without controlling or altering the functions or parameters of any connected medical devices, which is not be intended for active patient monitoring, therefore, based on the FDA guidance titled "Medical Device Data Systems, Medical Image Storage Devices, and Medical Image Communications Devices" (issued on September 28, 2022.), this software function is belong to Non-device-MDDS, and the hardware function is belong to Device-MDDS, they are not subject to FDA laws and regulations applicable to devices.

5. Indications for use

This Blood Pressure Monitor is a digital monitor intended for use in measuring blood pressure and pulse rate with arm circumference ranging from 22cm to 32cm (about 8¾″-12½″) or 22cm to 42cm (about 8¾″-16½″) .

It is intended for adult indoor use only.

6. Comparison to Predicate Device

Item	Subject Device	Predicate Device	Note
510(k)	Applying	K232713	/
Model	TMB-2296-BT	TMB-2266	/
Device Name	Blood Pressure Monitor	Blood Pressure Monitor	Same
Product Code	DXN	DXN	Same
Classification	Class II	Class II	Same
Regulation #	21 CFR 870.1130	21 CFR 870.1130	Same
Type of Use	OTC	OTC	Same
Intended Use / Indication for Use	This Blood Pressure Monitor is a digital monitor intended for use in measuring blood pressure and pulse rate with arm circumference ranging from 22cm to 32cm (about 8¾″-12½″) or 22cm to 42cm (about 8¾″-16½″). It is intended for adult indoor use	This Blood Pressure Monitor is a digital monitor intended for use in measuring blood pressure and pulse rate with arm circumference ranging from 16cm to 36cm (about 6⅓″-14⅕″), 22cm to 32cm (about 8¾″-12½″), 22cm to 42cm (about 8¾″-16½″) or 22cm to 45cm	Similar, refer to Note 1.

	only.	(about 8¾″-17¾″). The cuff with arm circumference range of 16~36cm is intended for children older than 6 years old or adults. The cuffs with arm circumference range of 22~32cm or 22~42cm or 22~45cm, which are intended for adult population. It is intended indoor use only.	
Patient Population	Adult	Population at or over 6 years old	Similar, refer to Note 2.
Principle	Oscillometric method	Oscillometric method	Same
Anatomical Site	Upper Arm	Upper Arm	Same
Where used (hospital, home, ambulance, etc.)	Home	Home	Same
Power Supply	3.6V 1000mAH Built-in rechargeable li-polymer battery	4*1.5V AAA batteries; Or by DC 5V adapter	Similar, refer to Note 3.
Human Factors	Blood pressure	Blood pressure	Same
Measurement Items	Measuring systolic and diastolic blood pressure and pulse rate of intended population, including irregular pulse rhythm detection.	Measuring systolic and diastolic blood pressure and pulse rate of adult individual, including irregular pulse rhythm detection.	Same
Cuff Deflation	Automatic deflation	Automatic deflation	Same
Blood Pressure Measurement	0mmHg ~ 299mmHg, 5℃ - 40℃ within ±3mmHg (0.4kPa)	0mmHg ~ 299mmHg, 5℃ - 40℃ within ±3mmHg (0.4kPa)	Same
Pulse Rate Measurement	40-199 beat/minute, ±5%	40-199 beat/minute, ±5%	Same
Display	LCD	LCD	Same
Memory	2×199	2×199	Same
Operation Environment	Temperature: 5℃~40℃; Relative Humidity: 15%~90% RH; Atmospheric: 700hPa~1060hPa	Temperature: 5℃~40℃; Relative Humidity: 15%~90% RH; Atmospheric: 70kPa~106kPa	Same

Storage and transportation Environment	Temperature: -20℃~60℃; Relative humidity≤93%RH, non-condensing; Atmospheric: 500hPa~1060hPa	Temperature: -20℃~60℃; Relative humidity≤93%RH, non-condensing Atmospheric: 500hPa~1060hPa	Same
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 10993-1/5/10/23	Same
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	Bluetooth	Bluetooth	Same

Justification for difference:

Note 1:

The subject device shares a similar intended use with the predicate device, and the substantial difference between the subject device and the predicate device regarding the intended use lies in the arm circumference range and patient population. However, the range of the intended patient population of the subject device is within that of the predicate device, and used on its intended patient population with the intended arm circumference, the subject device with matched cuffs has also 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 issues concerning safety and effectiveness.

Note 2:

Although there are some differences between the intended patient population of the subject device and the predicate device, the range of the intended patient population of the subject device is within that of the predicate device, and used on its intended patient population with the intended arm circumference, the subject device with matched cuffs has also 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 issues concerning safety and effectiveness.

Note 3:

Although the power supply of subject device is different with predicate device,the subject device with its matched battery has been validated according to IEC 60601-1, IEC 60601-1-11, IEC 80601-2-30 and IEC 60601-1-2. Thus, the differences between the subject device and the predicate device do not raise different questions of safety and effectiveness.

Conclusion:

Based on the comparison and analysis in this submission, it can be concluded that: the subject device is substantially equivalent to the predicate device and reference device regarding 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 ISO 81060-2:2018/Amd.1:2020. Non-invasive sphygmomanometers – Part 2: Clinical validation of intermittent automated measurement type. Two clinical studies were performed on the device matching with different models of cuff. The study population consisted of 88 and 87 qualified subjects respectively. 262 datasets were collected from 88 subjects with aged 51.9±16.3. The mean differences between reference BPs and

device readings were 0.21 ± 2.59/0.66 ± 2.12mmHg for systolic BP (SBP)/diastolic BP (DBP) of criterion 1, and 0.21 ± 2.07/0.66 ± 1.76mmHg for SBP/DBP of criterion 2. 259 datasets were collected from 87 subjects with aged 59.3 ± 11.7. The mean differences between reference BPs and device readings were -1.62 ± 2.80/0.12 ± 3.01mmHg for systolic BP (SBP)/diastolic BP (DBP) of criterion 1, and -1.62 ± 2.35/0.12 ± 2.60mmHg for SBP/DBP of criterion 2. TMB-2296-BT fulfilled both validation criteria 1 and 2 of the ISO 81060-2:2018/Amd.1:2020.

8. Conclusion

Based on the information presented in this 510(k) premarket notification submission, a conclusion can be drawn that the proposed subject device is considered substantially equivalent to the predicate device. The differences between the subject device and the predicate devices were successfully tested with relevant standards and FDA guidance, and do not affect equivalent safety and effectiveness or raise new issues concerning safety and effectiveness.