August 21, 2024

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

Re: K241351
Trade/Device Name: Blood Pressure Monitor (TMB-2092-G)
Regulation Number: 21 CFR 870.1130
Regulation Name: Noninvasive Blood Pressure Measurement System
Regulatory Class: Class II
Product Code: DXN
Dated: May 11, 2024
Received: July 31, 2024

Dear Fan Jerry:

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)*

K241351

Device Name

Blood Pressure Monitor (TMB-2092-G)

Indications for Use *(Describe)*

This Blood Pressure Monitor is intended for use in measuring blood pressure and pulse rate in patients with arm circumferences from 16 to 36 cm (6.3 to 14.1 inch), 22 to 42cm (8.6 to 16.5 inch), 22 to 45cm (8.6 to 17.7 inch) or 40 to 52cm (15.7 to 20.5 inch).
Cuff model AC1636-01, arm circumference range is 16~36cm (6.3 to 14.1 inch), which is intended for children older than 3 years old or adults without conditions of diabetes, pregnancy, or pre-eclampsia.
Cuff model AC2245-021, arm circumference range is 22~45cm (8.6 to 17.7 inch), which is intended for adult population or those who with conditions of diabetes, pregnancy, or pre-eclampsia.
Cuff model AC2242-41 and cuff model AC4052-04, arm circumference range are 22~42cm (8.6 to 16.5 inch) and 40~52cm (15.7 to 20.5 inch) respectively, which are intended for adults without conditions of diabetes, pregnancy, or pre-eclampsia.
It is intended 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.

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."

510(K) Summary

Prepared in accordance with the requirements of 21 CFR Part 807.92

Prepared Date: 2024/7/31

1. Submission sponsor

Name: Guangdong Transtek Medical Electronics Co., Ltd.
Address: Zone A, No.105, Dongli Road, Torch Development District, Zhongshan, Guangdong, China
Contact person: Jerry Fan
Title: RA Manager
E-mail: gt-rateam@transtekcorp.com
Tel: +86-157 2866 8528

2. Submission correspondent

Name: Guangdong Transtek Medical Electronics Co., Ltd.
Address: Zone A, No.105, Dongli Road, Torch Development District, Zhongshan, Guangdong, China
Contact person: Jerry Fan
E-mail: gt-rateam@transtekcorp.com
Tel: +86-157 2866 8528

3. Subject Device Information

Trade/Device Name	Blood Pressure Monitor
Model	TMB-2092-G
Common Name	Blood Pressure Monitor
Regulatory Class	Class II
Product Code	DXN
Submission type	Special 510(k)

4. Predicate Device Information

	Predicate Device
Sponsor	Guangdong Transtek Medical Electronics Co., Ltd.
Device Name	Blood Pressure monitor
Model	TMB-2092-G
510(k) Number	K232621
Product Code	DXN
Regulation Class	Class II

The Predicate Device have not been subject to a design-related recall.

5. Device Description

The Blood Pressure Monitor 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 160mm and 520 mm, includes the inflatable bladder and polyester 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 embed a Cellular 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 rate, date and time by Wireless method and protocol.

6. Intended use & Indication for use

This Blood Pressure Monitor is intended for use in measuring blood pressure and pulse rate in patients with arm circumferences from 16 to 36 cm (6.3 to 14.1 inch), 22 to 42cm (8.6 to 16.5 inch), 22 to 45cm (8.6 to 17.7 inch) or 40 to 52cm (15.7 to 20.5 inch).

Cuff model AC1636-01, arm circumference range is 16~36cm (6.3 to 14.1 inch), which is intended for children older than 3 years old or adults without conditions of diabetes, pregnancy, or pre-eclampsia.

Cuff model AC2245-021, arm circumference range is 22~45cm (8.6 to 17.7 inch), which is intended for adult population or those who with conditions of diabetes, pregnancy, or pre-eclampsia.

Cuff model AC2242-41 and cuff model AC4052-04, arm circumference range are 22~42cm (8.6 to 16.5 inch) and 40~52cm (15.7 to 20.5 inch) respectively, which are intended for adults without conditions of diabetes, pregnancy, or pre-eclampsia.

It is intended indoor use only.

7. Comparison to the Predicate Device

Features	Subject Device	Predicate Device	Remark
Applicant	Guangdong Transtek Medical Electronics Co., Ltd.	Guangdong Transtek Medical Electronics Co., Ltd.	/
Trade name	Blood pressure monitor	Blood pressure monitor	/
Model	TMB-2092-G	TMB-2092-G	/
510(k) Number	Applying	K232621	/
Classification Regulation	21CRF 870.1130	21CRF 870.1130	/

Features	Subject Device	Predicate Device	Remark
Classification and Code	Class II, DXN	Class II, DXN	Same
Intended use	This Blood Pressure Monitor is intended for use in measuring blood pressure and pulse rate in patients with arm circumferences from 16 to 36 cm (6.3 to 14.1 inch), 22 to 42cm (8.6 to 16.5 inch), 22 to 45cm (8.6 to 17.7 inch) or 40 to 52cm (15.7 to 20.5 inch). Cuff model AC1636-01, arm circumference range is 16~36cm (6.3 to 14.1 inch), which is intended for children older than 3 years old or adults without conditions of diabetes, pregnancy, or pre-eclampsia. Cuff model AC2245-021, arm circumference range is 22~45cm (8.6 to 17.7 inch), which is intended for adult population or those who with conditions of diabetes, pregnancy, or pre-eclampsia. Cuff model AC2242-41 and cuff model AC4052-04, arm circumference range are 22~42cm (8.6 to 16.5 inch) and 40~52cm (15.7 to 20.5 inch) respectively, which are intended for adults without conditions of diabetes, pregnancy, or pre-eclampsia. It is intended indoor use only.	This Blood Pressure Monitor is intended for use in measuring blood pressure and pulse rate in patients with arm circumferences from 16 to 36 cm (6.3 to 14.1 inch) or 22 to 45cm (8.6 to 17.7 inch) . Cuff model AC1636-01, arm circumference range is 16~36cm (6.3 to 14.1 inch), which is intended for children older than 3 years old or adults without conditions of diabetes, pregnancy, or pre-eclampsia. Cuff model AC2245-021, arm circumference range is 22~45cm (8.6 to 17.7 inch), which is intended for adult population or those who with conditions of diabetes, pregnancy, or pre-eclampsia. It is intended indoor use only.	Different Note 1
Patient Populations	at least 3 years of age or older	at least 3 years of age or older	Same
Principle	This product uses the Oscillometric Measuring method to detect blood pressure. Before every measurement, the unit establishes a “zero pressure”	This product uses the Oscillometric Measuring method to detect blood pressure. Before every measurement, the unit establishes a “zero pressure”	Same

Features	Subject Device	Predicate Device	Remark
	equivalent to the atmospheric pressure. Then it starts inflating the arm cuff, meanwhile, the unit detects pressure oscillations generated by beat-to-beat pulsatile, which is used to determine the systolic and diastolic pressure, and also pulse rate.	equivalent to the atmospheric pressure. Then it starts inflating the arm cuff, meanwhile, the unit detects pressure oscillations generated by beat-to-beat pulsatile, which is used to determine the systolic and diastolic pressure, and also pulse rate.	
Anatomical sites	Upper Arm	Upper Arm	Same
Where used (hospital, home, ambulance, etc.)	Home	Home	Same
Energy used and / or delivered	Battery mode: 6VDC (4 * 1.5V batteries) AC adapter mode: Input 100–240V, 50–60Hz, 0.2A max; Output 6VDC, 1A	Battery mode: 6VDC (4 * 1.5V batteries) AC adapter mode: Input 100–240V, 50–60Hz, 0.2A max; Output 6VDC, 1A	Same
Human factors	Blood pressure	Blood pressure	Same
Performance	Measuring systolic and diastolic blood pressure and pulse rate of patients at least 3 years of age or older, including irregular pulse rhythm detection	Measuring systolic and diastolic blood pressure and pulse rate of patients at least 3 years of age or older, including irregular pulse rhythm detection	Same
Biocompatibility	Cuff, according to ISO-10993	Cuff, according to ISO-10993	Same
Operation Environment	Temperature: 5℃~ 40℃ Relative Humidity: 15%~90%RH, Atmospheric Pressure: 70KPa~106KPa.	Temperature: 5℃~ 40℃ Relative Humidity: 15%~90%RH, Atmospheric Pressure: 70KPa~106KPa.	Same
Storage and transportation environment	Temperature: -4°F to +140°F (-20°C to +60°C) Relative humidity: ≤93%, non-condensing, at a water vapour pressure up to 50hPa Atmospheric pressure: 500hPa to 1 060hPa	Temperature: -4°F to +140°F (-20°C to +60°C) Relative humidity: ≤93%, non-condensing, at a water vapour pressure up to 50hPa Atmospheric pressure: 500hPa to 1 060hPa	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, 5℃ - 40℃ within ±3mmHg	0mmHg ~ 299mmHg, 5℃ - 40℃ within ±3mmHg	Same

Features	Subject Device	Predicate Device	Remark
	(0.4kPa)	(0.4kPa)	
Pulse rate measurement	40-199 beat/minute, ±5%	40 ~ 199 beat/minute, ±5%	Same
Cuff Deflation	Automatic deflation	Automatic deflation	Same
Memory Size	500	500	Same
Wireless	GSM, LTE	GSM, LTE	Same

Justification of difference:

Note 1:

The subject device has the same functions and principle with cleared device (K232621). The modification that was occurred is only add two cuff sizes, 22~42cm and 40~52cm, both of them are for the general population use. In addition, the subject device has been verified according to IEC 60601-1, IEC 60601-1-11 and IEC 60601-1-6, and it also has been validated according to ISO 80601-2-30 and ISO 81060-2. Thus, the differences between the subject device and the cleared device do 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:

- GSM and LTE test according to FCC 47 CFR Part22 subpart H, FCC 47 CFR Part24 subpart E, FCC 47 CFR Part27 subpart C.
- Radio Frequency Wireless Technology in Medical Devices: Guidance for Industry and Food and Drug Administration Staff (August 14, 2013)

Clinical data

Blood pressure monitor with its new cuff sizes are 22~42cm and 40~52cm, these clinical tests were performed and comply with the accuracy requirements of ANSI/AAMI/ISO 81060-2:2019 Non- invasive sphygmomanometers —Part 2: Clinical investigation of intermittent automated measurement type and ISO 81060-2:2018/Amd.1:2020 Non- invasive sphygmomanometers —Part 2: Clinical investigation of intermittent automated measurement type AMENDMENT 1. Two clinical studies of this device consisted of 172 general adult subjects.

The first clinical study (AC2242-41)

The clinical study aimed to validate the accuracy of TMB-2092-G blood pressure monitor with cuff AC2242-41. 258 datasets were collected from 86 subjects. There are 86 adult subjects with aged 51.8±14.9. The mean differences between reference BPs and device readings were -0.02 ±2.12/0.17±1.97 mmHg for systolic BP (SBP) / diastolic BP (DBP) of criterion 1, and -0.02±1.49/0.17±1.51 mmHg for SBP / DBP of criterion 2. TMB-2092-G with armbands of 22.0-42.0 cm fulfilled both validation criteria 1 and 2 of ANSI/AAMI/ISO 81060-2:2019 and ISO 81060-2:2018/Amd.1:2020.

The second clinical study (AC4052-04)

The clinical study aimed to validate the accuracy of TMB-2092-G blood pressure monitor with cuff AC4052-04. 258 datasets were collected from 86 subjects with aged 49.9±10.2. The mean differences between reference BPs and device readings were -0.56±1.58/-0.24±1.63 mmHg for systolic BP (SBP) / diastolic BP (DBP) of criterion 1, and -0.56±0.98/-0.24±1.12 mmHg for SBP/DBP of criterion 2. TMB-2092-G with armbands of 40.0-52.0 cm fulfilled both validation criteria 1 and 2 of ANSI/AAMI/ISO 81060-2:2019 and ISO 81060-2:2018/Amd.1:2020.

Summary

Based on the clinical performance in the clinical studies, the differences between the subject device and the cleared device do not raise different questions of safety and effectiveness.

9. Conclusion

The subject device is itself of the corresponding cleared device manufactured by Guangdong Transtek Medical Electronics Co., Ltd. (FDA 510(k) number: K232621). The addition of new arm-cuff range, 22~42cm and 40~52cm, will not affect the intended use or alter the fundamental scientific technology of the device. So, the conclusion is that the subject device is substantial equivalent to the cleared device.