November 28, 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: K232713
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: August 31, 2023
Received: September 5, 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)*
K232713

Device Name
Blood Pressure Monitor

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 16cm to 36cm (about 6⅓″-14⅕″), 22cm to 32cm (about 8¾″-12½″), 22cm to 42cm (about 8¾″-16½″) or 22cm to 45cm (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.

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 requirement of 21 CFR Part 807.92

Prepared Date: 08/31/2023

1. Submitter

Name: Guangdong Transtek Medical Electronics Co., Ltd.
Address: Zone A, No. 105, Dongli Road, Torch Development District, 528437 Zhongshan, Guangdong, China
Contact: Jerry Fan
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2. Subject Device

Trade/Device Name	Blood Pressure Monitor
Model	TMB-2266
Common Name	Blood Pressure Monitor
Classification	Class II
Product Code	DXN
Submission Type	Traditional 510(k)

3. Predicate Device

/	**Predicate Device**	**Reference Device**
Manufacturer:	Guangdong Transtek Medical Electronics Co., Ltd.	Guangdong Transtek Medical Electronics Co., Ltd.
Device Name / Model:	Blood Pressure Monitor / LS802-GS	Welch Allyn 901123 Digital Blood Pressure Device / ProBP™ 2000
510(k) Number:	K202891	K181832

4. Device Description

Blood Pressure Monitor TMB-2266 is designed to measure systolic pressure, diastolic pressure and pulse rate of population at or over 3 years old 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 HIPS material. As for accompanying cuffs, five types of cuffs have been clinically validated to be matched with the device, suitable for population aged at or over three and with arm circumference from 16cm~45cm. 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.

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 16cm to 36cm (about 6⅓″-14⅕″), 22cm to 32cm (about 8¾″-12½″), 22cm to 42cm (about 8¾″-16½″) or 22cm to 45cm (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.

6. Comparison to Predicate Device

Features	Subject Device	Predicate Device (K202891)	Reference Device (K181832)	Note
Model	**TMB-2266**	**LS802-GS**	**ProBP™ 2000**	/
Applicant	Guangdong Transtek Medical Electronics Co., Ltd.	Guangdong Transtek Medical Electronics Co., Ltd.	Guangdong Transtek Medical Electronics Co., Ltd.	Same
Device Name	Blood Pressure Monitor	Blood Pressure Monitor	Welch Allyn 901123 Digital Blood Pressure Device	Same
Product Code	DXN	DXN	DXN	Same
Classification	Class II	Class II	Class II	Same
Regulation #	21 CFR 870.1130	21 CFR 870.1130	21 CFR 870.1130	Same
Type of Use	OTC	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 16cm to 36cm (about 6⅓″-14⅕″), 22cm to 32cm (about 8¾″-12½″), 22cm to 42cm (about 8¾″-16½″) or 22cm to 45cm (about 8¾″-17¾″). The cuff with arm circumference range of 16~36cm is intended for children older than 6 years old or adults.	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.	The Welch Allyn ProBP 2000 Digital blood pressure device is intended for use in measuring blood pressure and heart rate in patients at least 3 years of age or older with arm circumferences between 15 cm to 55 cm (approximately 5.9 to 21.7 inches). The Welch Allyn ProBP 2000 automatically measures systolic and diastolic pressure and pulse rate. The	Similar, refer to Note[1]

	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.		device is intended to be used by clinicians and medically qualified personnel.	
Patient Population	Population at or over 3 years old	Adult	At least 3 years of age or older	Similar, refer to Note[2]
Principle	Oscillometric method	Oscillometric method	Oscillometric method	Same
Anatomical Site	Upper Arm	Upper Arm	Upper Arm	Same
Where used (hospital, home, ambulance, etc.)	Home	Home	Medical Institutions	Same
Power Supply	4*1.5V AAA batteries; Or by DC 5V adapter	4*1.5V AA Battery Or by DC 6V adapter	4*1.5V AA Battery Or by DC 6V adapter	Similar, refer to Note[3]
Human Factors	Blood pressure	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.	Measuring systolic and diastolic blood pressure and pulse rate of intended population, including irregular pulse rhythm detection.	Same
Cuff Deflation	Automatic 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)	0mmHg ~ 300mmHg, 5℃ - 40℃ within ±3mmHg (0.4kPa)	Same
Pulse Rate	40-199 beat/minute, ±5%	40-199 beat/minute, ±5%	40-199 beat/minute, ±5%	Same

Measurement				
Display	LCD	LCD	LCD	Same
Memory	2×199	60	99	Different, refer to Note[4]
Operation Environment	Temperature: 5℃~40℃; Relative Humidity: 15%~90% RH; Atmospheric: 700hPa~1060hPa	Temperature: 5℃~40℃; Relative Humidity: 15%~90% RH; Atmospheric: 70kPa~106kPa	Temperature: 5℃ to 40℃; Relative Humidity: ≤85% RH Atmospheric Pressure: 86kPa to 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	Temperature: -20℃ to 60℃ Relative Humidity: 10% RH - 93% RH Atmospheric Pressure: 50kPa - 106kPa	Same
Performance	Compliance with IEC 80601-2-30	Compliance with IEC 80601-2-30	Compliance with IEC 80601-2-30	Same
Clinical	Compliance with ISO 81060-2	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	All patient contact parts meet the requirements of ISO 10993-1/5/10	Same, refer to Note[5]
Electrical Safety	Compliance with IEC 60601-1 and IEC 60601-1-11	Compliance with IEC 60601-1 and IEC 60601-1-11	Compliance with IEC 60601-1	Same
EMC	Compliance with IEC 60601-1-2	Compliance with IEC 60601-1-2	Compliance with IEC 60601-1-2	Same
Wireless	Bluetooth	LTE	No wireless function	Different,

				refer to Note[6]

Justification for difference:

Note [1]:

The subject device shares a similar intended use with the predicate device and reference device. The substantial difference between the subject device and the predicate devices regarding the intended use lies in the arm circumference range. The subject device has the same intended population as reference device, though different from the predicate device. Used on its intended population, 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]:

The subject device has the same intended population as reference device, though different from the predicate device. Used on its intended population, 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]:

Same as the predicate device and reference device, the subject device can be powered either by battery or adapter, though there is tiny difference in the specifications of applicable battery and adapter. The subject device with its matched battery and adapter has been validated according to IEC 60601-1, IEC 60601-1-11, IEC 80601-2-30 and IEC 60601-1-2. As demonstrated in relevant test reports, the difference here does not raise any issues concerning safety and effectiveness.

Note [4]:

The subject device enjoys a larger memory room for storing measured data than both the predicate device and reference 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 IEC 80601-2-30. As demonstrated in relevant test reports, the difference here does not raise any issues concerning safety and effectiveness.

Note [5]:

The cuffs 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 the latest 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.

Note [6]:

The wireless module employed is different between the subject device and the predicate devices.

However, it serves the same purpose, that is to transfer measurement results. As for the wireless technology of the subject device, it has also been validated according to 47 CFR Part 15, Subpart C 15.247. As demonstrated in relevant test reports, the difference here does not raise any issues concerning 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

Clinical data

The device was tested according to ISO 81060-2:2018+A1:2020 Non-invasive sphygmomanometers – Part 2: Clinical validation of intermittent automated measurement type. Four clinical studies were performed on the device matching with different models of cuff. The study

population consisted of 87, 86, 86 and 102 qualified subjects respectively. For the first three studies, all subjects were adults. While for the last one, 65 subjects aged over 18 and 37 at the age of 3-12 were included. All data's mean error and standard deviation of differences in systolic, diastolic pressure is not beyond the limits set as per ISO 81060-2:2020. No adverse effect and/or complications are found in this study.

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.