November 22, 2023

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

Re: K232621
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 28, 2023
Received: August 29, 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)*
K232621

Device Name
Blood Pressure Monitor

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) 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.

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.

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510(K) Summary

Prepared in accordance with the requirements of 21 CFR Part 807.92

Prepared Date: 2023/10/19

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	Traditional 510(K)

4. Predicate Device Information

	Predicate Device 1 (Primary)	**Predicate Device 2**	**Predicate Device 3**
Sponsor	Guangdong Transtek Medical Electronics Co., Ltd.	Guangdong Transtek Medical Electronics Co., Ltd.	MICROLIFE INTELLECTUAL PROPERTY GMBH
Device Name	Blood Pressure monitor	Welch Allyn 901123 Digital Blood Pressure Device	Microlife Upper Arm Automatic Digital Blood Pressure Monitor
Model	LS802-GS	ProBP™ 2000	BP3KV1-5W
510(k) Number	K202891	K181832	K222979
Product Code	DXN	DXN	DXN
Regulation Class	Class II	Class II	Class II

The Predicate Devices have not been subject to a design-related recall.
The Predicate Device 2 is to reference the safety and effectiveness of population at least 3 years of age or older, and the Predicate Device 3 is to reference the safety and effectiveness of adults with conditions of diabetes, pregnancy, or pre-eclampsia.

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 450 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) 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.

7. Comparison to the Predicate Device & Reference Device

Features	Subject Device	Predicate Device 1 (Primary)	Predicate Device 2	Predicate Device 3	Remark
Applicant	Guangdong Transtek Medical Electronics Co., Ltd.	Guangdong Transtek Medical Electronics Co., Ltd.	Guangdong Transtek Medical Electronics Co., Ltd.	MICROLIFE INTELLECTUAL PROPERTY GMBH	/
Trade name	Blood pressure monitor	Blood pressure monitor	Welch Allyn 901123 Digital Blood Pressure Device	Microlife Upper Arm Automatic Digital Blood Pressure Monitor	/
Model	TMB-2092-G	LS802-GS	ProBP™ 2000	BP3KV1-5W	/
510(k) Number	Applying	K202891	K181832	K222979	/
Classification Regulation	21CRF 870.1130	21CRF 870.1130	21CRF 870.1130	21CRF 870.1130	/
Classification and Code	Class II, DXN	Class II, DXN	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) 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	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″) 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	The Upper Arm Blood Pressure Monitor, Model BP3KV1-5W is a device intended to measure the systolic and diastolic blood pressure and pulse rate of an adult individual by using a non-invasive oscillometric technique in which an inflatable cuff is wrapped around the upper arm for a circumference	Similar Note 1

Features	Subject Device	Predicate Device 1 (Primary)	Predicate Device 2	Predicate Device 3	Remark
	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.		rate. The device is intended to be used by clinicians and medically qualified personnel.	range from 22 to 52cm. The device is suitable for use by adults, including adults with conditions of diabetes, pregnancy, or pre-eclampsia. The device detects the appearance of irregular heartbeat during measurement and gives a warning signal with the reading once the irregular heartbeat is detected. The device can be used in connection with a smart phone via Bluetooth or with a personal computer (PC) via USB. The measurement data can be transferred to a smart phone running the Microlife Connected Health+ mobile software (App) or a PC running the Microlife BP Analyzer+ (BPA+) software.	
Patient	at least 3 years of age or older	Adults	at least 3 years of age or older	adults with conditions of	Similar

Features	Subject Device	Predicate Device 1 (Primary)	Predicate Device 2	Predicate Device 3	Remark
Populations				diabetes, pregnancy, or pre-eclampsia	Note 1
Principle	This product uses the Oscillometric Measuring method to detect blood pressure. Before every measurement, the unit establishes a "zero pressure" 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.	This product uses the Oscillometric Measuring method to detect blood pressure. Before every measurement, the unit establishes a "zero pressure" 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.	The subject device uses the Oscillometric Measuring method to detect blood pressure. The device detects blood pressure measurement on the inflation. Before every measurement, the unit establishes a "zero pressure" equivalent to the air pressure. Then it starts inflating the cuff with the inflation rate 7mmHg/s, meanwhile, the device detects pressure oscillations generated by beat-to-beat pulsatile. Then the measurement finishes, and the device starts deflating. Deflation occurs in step intervals based on the cuff pressure. The deflation step range is about 6-12 mmHg. Higher cuff pressure corresponds to the larger pressure deflation step.	Oscillometric method	Same
Anatomical sites	Upper Arm	Upper Arm	Upper Arm	Upper Arm	Same
Where used (hospital, home,	Home	Home	Medical Institutions	Home	Same

Features	Subject Device	Predicate Device 1 (Primary)	Predicate Device 2	Predicate Device 3	Remark
ambulance, etc.)					
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	Battery mode: 6VDC (4 AA batteries) AC adapter mode: Input 100–240V, 50–60Hz, 400mA; Output 6VDC, 1A	4 AA batteries, Or AC adapter 6 V DC 600 mA	Same
Human factors	Blood pressure	Blood pressure	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 adult individual, including irregular pulse rhythm detection	Measuring systolic and diastolic blood pressure and pulse rate and adult patients at least 3 years of age or older.	The device intended to measure the systolic and diastolic blood pressure and pulse rate of an adult, who with conditions of diabetes, pregnancy, or preeclampsia. The device detects the appearance of irregular heartbeat during measurement and gives a warning signal with the reading once the irregular heartbeat is detected.	Same
Biocompatibility	Cuff, according to ISO-10993	Cuff, according to ISO-10993	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: 70KPa~106KPa.	Temperature: 5℃ to 40℃; Relative Humidity: ≤85% RH Atmospheric Pressure: 86kPa to 106kPa	+10℃to +40℃ at RH 15% to 90%	Same
Storage and	Temperature: -4°F to +140°F (-	Temperature: -20°C to +60°C	Temperature: -20℃ to 60℃	- 20℃to +55℃	Same

Features	Subject Device	Predicate Device 1 (Primary)	Predicate Device 2	Predicate Device 3	Remark
transportation environment	20°C to +60°C) Relative humidity: ≤93%, non-condensing, at a water vapour pressure up to 50hPa Atmospheric pressure: 500hPa to 1060hPa	A relative humidity range of ≤ 93 %, non-condensing, at a water vapour pressure up to 50hPa An atmospheric pressure range of 500 hPa to 1060 hPa	Relative Humidity: 10% RH - 93% RH Atmospheric Pressure: 50kPa - 106kPa	at RH 15% to 90%	
Electrical safety	According to IEC60601-1-2 According to IEC60601-1	According to IEC60601-1-2 According to IEC60601-1	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 (0.4kPa)	0mmHg ~ 299mmHg, 5℃ - 40℃ within ±3mmHg (0.4kPa)	0mmHg ~ 300mmHg, 5℃ - 40℃ within ±3mmHg (0.4kPa)	0 to 299mmHg 10℃ - 40℃ within ± 3 mmHg or 2% of reading >200mmHg	Same
Pulse rate measurement	40-199 beat/minute, ±5%	40 ~ 199 beat/minute, ±5%	40 ~ 199 beat/minute, ±4%	40 to 199 beats/minute ± 5 % of the reading	Same
Cuff Deflation	Automatic deflation	Automatic deflation	Automatic deflation	Automatic deflation	Same
Memory Size	500	60	99	99*2	Different(1)
Wireless	GSM, LTE	LTE	No wireless function	Bluetooth	Similar Note 2

Justification of difference:

Note 1: The substantial differences of the intended use are the patient populations and arm circumference ranging. Both subject device and predicate device 1 (K202891) are suitable for home use environment, and both subject device and predicate device 2 (K181832) are suitable for children over three years old, and the arm circumference of predicate device 2 (K181832) is 15-55cm, which can cover the arm circumference of the subject device from 16-45cm, and both subject device and predicate device 3 (K222979) are suitable for adults with larger than 22cm arm circumference, adults with conditions of diabetes, pregnancy, or pre-eclampsia. Meanwhile, all four of them are intended to be operated by adults. Both the subject device and the predicate device are intended to be operated by adults. 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 predicate devices do not raise different questions of safety and effectiveness.

Note 2: Both the predicate device 1(K202891) and subject device use the cellular module, they can transmit the measurement results through wireless. The subject device has more GSM functions than the predicate device, which can be used as network compensation. The subject device has been verified according to IEC 60601-1, IEC 60601-1-11, IEC 60601-1-2, ISO 80601-2-30 and ISO 81060-2. Thus, this difference does not raise different questions of safety and effectiveness.

Different (1): Although the memory sizes are different between subject device and predicate device 1(K202891), the function is similar and they all meet the requirements of standard IEC 60601-1, IEC 60601-1-2 and ISO 80601-2-30. This difference does not affect the normal measuring function of the blood pressure monitor. Thus, this difference 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:

- 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

This device was tested to ISO 81060-2:2018/Amd.1:2020 Non- invasive sphygmomanometers —Part 2: Clinical investigation of intermittent automated measurement type AMENDMENT 1. Four clinical studies of this device consisted of 138 general adult subjects, 36 child subjects aged between three years and twelve years, 90 diabetic patients and 91 pregnant women.

The first clinical study (AC1636-01)

The clinical study aimed to validate the accuracy of TMB-2092-G blood pressure monitor with cuff AC1636-01. 261 datasets were collected from 88 subjects. There are 36 child subjects with aged 9.8±5.1, 52 adult subjects with aged 52.6±28.2. The mean differences between reference BPs and device readings were 0.25±3.02/0.96±2.54mmHg for systolic BP (SBP)/diastolic BP (DBP) of criterion 1, and 0.25± 2.55/0.96±2.32mmHg for SBP/DBP of criterion 2. TMB-2092-G with armbands of 16.0-36.0 cm fulfilled both validation criteria 1 and 2 of the ISO 81060-2:2018/Amd.1:2020.

The second clinical study (AC2245-021)

The clinical study aimed to validate the accuracy of TMB-2092-G blood pressure monitor with cuff AC2245-021. 258 datasets were collected from 86 subjects with aged 49.1±18.5. The mean differences between reference BPs and device readings were -1.1±3.51/-0.2±3.70mmHg for systolic BP (SBP)/diastolic BP (DBP) of criterion 1, and -1.1± 2.22/-0.2±2.82mmHg for SBP/DBP of criterion 2. TMB-2092-G with armbands of 22.0-45.0 cm fulfilled both validation criteria 1 and 2 of the ISO 81060-2:2018/Amd.1:2020.

The third clinical study (diabetes)

The purpose of the clinical study is to validate the accuracy of SUT (TMB-2092-G with cuff AC2245-021) in subjects with diabetes. 268 valid BP dataset pairs were collected from 90 diabetics. The mean differences between reference BPs and TMB-2092-G readings were -1.11 ± 3.50/-1.24± 3.21mmHg for systolic BP (SBP)/diastolic BP (DBP) of criterion 1, and -1.11 ±3.19/-1.24±3.01 mm Hg for SBP/DBP of criterion 2. TMB-2092-G BP monitor with cuff of 22-45cm for diabetics fulfilled both criteria 1 and 2 of the ISO 81060-2:2018/Amd.1:2020.

The fourth clinical study (pregnant)

The purpose of the clinical study is to validate the accuracy of SUT (TMB-2092-G with cuff AC2245-021) in subjects with pregnant. 270 valid datasets were collected from 91 subjects with 12-40 weeks pregnant (38.5% normotensive pregnant patients, 30.8% hypertensive pregnant and 30.8% pre-eclampsia).The mean differences between reference BPs and TMB-2092-G readings were -2.74 ±5.61/0.13 ±4.48 mmHg for systolic BP (SBP)/diastolic BP (DBP) for criterion 1 and -2.74 ±5.11/0.13 ±4.02 mmHg for systolic BP (SBP)/diastolic BP (DBP) for criterion 2. The TMB-2092-G with cuff of 22-45cm intended use for pregnant fulfilled validation criteria 1and criteria 2 of the ISO 81060-2:2018/Amd.1:2020.

Summary

Based on the clinical performance in the clinical studies, the blood pressure monitor model TMB-2092-G was found to have a safety and effectiveness profile that is similar to the predicate devices.

9. Conclusion

Performance testing and compliance with voluntary standards demonstrate that the proposed subjected device is substantially equivalent to the predicate device.