July 16, 2025

Cemho Medical Technology (Guangdong) Co., Ltd.
℅ Yijie You
Manager
Qimmiq Medical Consulting Service Co., Ltd
RM.406, Building C, Run Science Park
No.18 Shenzhou Road, Huangpu
Guangzhou, Guangdong 510663
China

Re: K251102
Trade/Device Name: Automatic Blood Pressure Monitor (CH-S691L, CH-B607, CH-B606, CH-S692L, CH-S602, CH-W701L, CH-S693L, CH-B601L, CP-B01, CH-S603)
Regulation Number: 21 CFR 870.1130
Regulation Name: Noninvasive blood pressure measurement system
Regulatory Class: Class II
Product Code: DXN
Dated: April 11, 2025
Received: April 11, 2025

Dear Yijie You:

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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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)*
K251102

Device Name
Automatic Blood Pressure Monitor (model: CH-S691L, CH-B607, CH-B606, CH-S692L, CH-S602, CH-W701L, CH-S693L, CH-B601L, CP-B01, CH-S603)

Indications for Use *(Describe)*
The Automatic Blood Pressure Monitor is designed to measure blood pressure (systolic and diastolic) and pulse rate in adult patients with arm circumference range between 7.1 inches (18.0 cm) to 16.5 inches (42 cm).

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

[As required by section 21 CFR 807.92(c)]

1. 510(k) owner (Applicant)

Establishment Registration number:		3021355406
Name:		Cemho Medical Technology (Guangdong) Co., Ltd.
Address:		Cemho Medical Industrial Park, West of Xinghe Line, Dongguan Shijie (Xingning) Industrial Transfer Industrial Park, Xingning, Meizhou City, Guangdong Province, P.R. China
Contact Person	**Name:**	Gang HONG
	Address:	Cemho Medical Industrial Park, West of Xinghe Line, Dongguan Shijie (Xingning) Industrial Transfer Industrial Park, Xingning, Meizhou City, Guangdong Province, P.R. China
	TEL:	+86-13760152657
	Email:	honggang@cemho.com

2. Submission Correspondent (Authorized representative)

Name:	You Yijie
Company Name	Qimmiq Medical Consulting Service Co., Ltd
Address:	RM.406, Building C, Run Science Park, No.18 Shenzhou Road, Huangpu, Guangzhou, Guangdong 510663 P.R. China
TEL:	(+86)020-82245821
FAX:	(+86)020-82245821
Email:	jet.you@qimmiq-med.com

3. Device Information

Purpose of the application: 510(K) submission
Submission Type: Traditional 510(K)
The reason for the 510(k): It is a new device

Trade Name: Automatic Blood Pressure Monitor
Model: CH-S691L, CH-B607, CH-B606, CH-S692L, CH-S602, CH-W701L, CH-S693L, CH-B601L, CP-B01, CH-S603
Common name of the device: Automatic Blood Pressure Monitor

Classification name: System, Measurement, Blood-Pressure, Non-Invasive

Regulation name:	Noninvasive blood pressure measurement system
Review panel:	Cardiovascular
Product code:	DXN
Regulation Class:	II
Regulation Number:	21 CFR 870.1130

4. Predicate Device Information

510(k) submitter/holder:	A&D Engineering, Inc.
510(K) Number:	K151953
Trade name:	A&D Medical TM-2657 Family of Digital Blood Pressure
Model:	TM-2657P
Review Panel:	Cardiovascular
Product Code:	DXN
Regulation Class:	II
Regulation Number:	21 CFR 870.1130

5. Device description

The Automatic Blood Pressure Monitor (models: CH-S693L, CH-B601L, CP-B01, CH-S603, CH-S691L, CH-B607, CH-B606, CH-S692L, CH-S602, CH-W701L) is a kiosk-type, automated, single upper-arm cuff oscillometric BP monitor developed for measurement of BP and pulse rate in healthcare facility/hospital or at home.

It is designed for BP measurements on either the right or left upper arm and has a fixed tubular (Arm barrel) opening to insert the user's arm, with an integral single-arm cuff, which when inflated surrounds the upper arm. It is suitable for arm circumference range 18~42 cm. The device has an elbow groove to ensure correct positioning of the arm and measures BP during inflation. A wide LED screen presents systolic and diastolic BP, heart rate and time of measurement. After the user pushes the start button, the cuff is inflated automatically by an internal pump, the systolic and diastolic blood pressures are determined by oscillometric method.

Principle of operation:

The product uses the Oscillometric Measuring method to detect blood pressure.

When the user presses the "START" button to initiate the measurement, the winding mechanism, driven by a geared motor, begins to operate. It stops winding when it starts to encounter resistance from the arm. At this point, the cuff is adapted to the arm size. Subsequently, the cuff is automatically inflated by an internal pump to reach a pressure above systolic pressure, no blood flow occurs through the artery. As the cuff is deflated below the systolic pressure, the reducing pressure exerted on the artery allows blood to flow through it and sets up a detectable vibration in the arterial wall. When the cuff pressure falls below the patient's diastolic pressure, blood flows smoothly through the artery in the usual pulses, without any vibration being set up in the wall. Vibrations occur at any point where the cuff pressure is sufficiently high that the blood has to push the arterial wall open in order to flow through the artery. The vibrations are transferred from the arterial wall, through the

air inside the cuff, into a transducer in the monitor that converts the measurements into electrical signals. Hence when 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 pulse rate.

6. Indications for Use

The Automatic Blood Pressure Monitor is designed to measure blood pressure (systolic and diastolic) and pulse rate in adult patients with arm circumference range between 7.1 inches (18.0 cm) to 16.5 inches (42 cm).

7. Summary of technological characteristics of device compared to the predicate devices (K151953)

SE Comparisons	**Subject device** (Automatic Blood Pressure Monitor, model: CH-S691L, CH-B607, CH-B606, CH-S692L, CH-S602, CH-W701L, CH-S693L, CH-B601L, CP-B01, CH-S603)	**Predicate device** (A&D Medical TM-2657 Family of Digital Blood Pressure, Model: TM-2657P)	**Discussion of difference**
510K Number	/	**K151953**	**/**
Model	CH-S691L, CH-B607, CH-B606, CH-S692L, CH-S602, CH-W701L, CH-S693L, CH-B601L, CP-B01, CH-S603	TM-2657P	**/**
Classification	21CFR 870.1130	21CFR 870.1130	**Same**
Product Code	DXN	DXN	**Same**
FDA Class	II	II	**Same**
Indications for Use	The Automatic Blood Pressure Monitor is designed to measure blood pressure (systolic and diastolic) and pulse rate in adult patients with arm circumference range between 7.1 inches (18.0 cm) to 16.5 inches (42 cm).	TM-2657, TM-2657P, TM-2657PBT, and TM-2657PRS are designed to measure blood pressure (systolic and diastolic) and pulse rate in adult patients with arm circumference range between 7.1 inches (18.0 cm) to 15.7 inches (40 cm).	**Same**
Patient Population	Adult	Adult	**Same**
Design	table type	table type	**Same**
Design Method	Oscillometric	Oscillometric	**Same**
Measurement Site	Upper Arm	Upper Arm	**Same**
Cuff Circumference	18cm~42cm	18cm~40cm	**Different** (Discussion is indicated in D1)
Pressure Sensor design	Resistance type pressure sensor	Capacitance type pressure transducer	**Different** (Discussion is indicated in D2)

Pressurization Source	Automatic Internal air Pump	Automatic internal air pump	**Same**
Cuff Design	Winding mechanism operated by geared motor	Winding mechanism operated by geared motor	**Same**
Air Pressure Control Method	Rubber valve with ceramic valve	Rubber valve with electrical control valve	**Different** (Discussion is indicated in D3)
Exhaust Method	Automatic rapid exhaust by electromagnetic valve	Automatic rapid exhaust by electromagnetic valve	**Same**
Display Type	3-digit display by LED	3-digit display by LED	**Same**
Cuff Attachment Method	By plastic hose connected to monitor	By plastic hose connected to monitor	**Same**
Measurement Item	SYS, DYS, Pulse Rate	SYS, DYS, Pulse Rate	**Same**
NIBP Clinical test	ISO 81060-2 Third edition 2018-11 Amendment 1 2020-01	BS EN1060-4:2004, BHS:1993	**Different** (Discussion is indicated in D4)
Pressure display range	0-295mmHg	0-299 mmHg	**Different** (Discussion is indicated in D5)
Minimum display resolution	1 mmHg	1 mmHg	**Same**
Blood Pressure Measurement Range	**SYS:** 55mmHg ~ 255 mmHg **DIA:** 25mmHg~200mmHg	**SYS:** 40-270 mmHg **DIA:** 20-200 mmHg	**Different** (Discussion is indicated in D6)
Blood Pressure Measurement Accuracy	±3 mmHg	± 3%	**Different** (Discussion is indicated in D7)
Pulse Measurement Range	40~199 beats/min	30 ~ 240 beats/min	**Different** (Discussion is indicated in D8)
Pulse rate measurement accuracy	±5%	±5%	**Same**
Operating Environment	**Ambient temperature:** +5℃~ +40℃ **Relative humidity (RH):** 15%~90% **Atmospheric pressure:** 70 kPa~106kPa	**Ambient temperature:** +10℃~ +40℃ **Relative humidity (RH):** 15%~85%	**Different** (Discussion is indicated in D9)
Storage Environment	**Ambient temperature:** -25℃~+55℃ **Relative humidity (RH):** 15%~93% **Atmospheric pressure:** 70 kPa~106kPa	**Ambient temperature:** -20℃~+60℃ **Relative humidity (RH):** 10%~95%	**Different** (Discussion is indicated in D10)
Printer function	NA	Thermometer Printer	**Different** (Discussion is indicated in D11)

IHB (Irregular Heartbeats Detection)	NA		More than +/-25% to the mean interval of all pulse intervals	**Different** (Discussion is indicated in D12)
Connectivity	**NA**		Wired - RS232C standard (TM-2655 Family) Wireless - Bluetooth 2.1 Standard (UA-767PBT)	**Different** (Discussion is indicated in D13)
Software Level Concern	Moderate		Moderate	**Same**
Performance	IEC 80601-2-30: Edition 2.0 2018-03		IEC80601-2-30:2009+CI:2010	**Different** (Discussion is indicated in D14)
Electrical Safety	ANSI AAMI ES60601-1:2005/(R)2012 & A1:2012 C1:2009/(R)2012 & A2:2010/(R)2012 (Cons. Text) [Incl. AMD2:2021]		IEC 60601-1:2006	**Different** (Discussion is indicated in D15)
EMC	IEC 60601-1-2: 2014+AMD1:2020		AAMI/ANSI/IEC 60601-1-2:2007	**Different** (Discussion is indicated in D16)
Material of Patient contact components	**Shell**: PC (Accounting for 70%) + ABS-H1214FRA (Accounting for 30%) **Display cover**: PMMA **Memory/ Start & Stop/ Set button**: PC (Accounting for 70%) + ABS-H1214FRA (Accounting for 30%)		Not public	**Different** (Discussion is indicated in D17)
Patient Interface	Cuff, button		Cuff, button	**Same**
Dimensions	**For models CH-S691L, CH-B607, CH-B606**	Approx. 283 (W) × 244 (D) × 244 (H) mm	241 (W) x 330 (H) x 390 (D) mm	**Different** (Discussion is indicated in D18)
	For models CH-S692L, CH-S602, CH-W701L	Approx. 283 (W) × 244 (D) × 244 (H) mm		
	For models CH-S693L, CH-B601L, CP-B01, CH-S603	Approx. 189 (W) × 268 (D) × 233 (H) mm		
Weight	**For models CH-S691L, CH-B607, CH-B606**	Approx. 2 kg (4.4 lbs)	Approx. 5.5 kg	**Different** (Discussion is indicated in D19)
	For models CH-S692L, CH-S602, CH-W701L	Approx. 2 kg (4.4 lbs)		
	For models CH-S693L, CH-B601L, CP-B01, CH-S603	Approx. 1.5 kg (3.3 lbs)		
User Interface	Cuff, button		Cuff, button	**Same**

Software	Embedded	Embedded	**Same**

The discussion of differences exist between the subject and predicate devices is listed in following:

D1: The difference of Cuff Circumference between subject device and predicate device is that the intended Cuff Circumference range of subject device is 18~42 cm and predicate device is 18~40 cm, this difference is addressed through clinical trial conducted with subject device according to ISO 81060-2 Third edition 2018-11 Amendment 1 2020-01, the results of clinical trial meet the requirements of ISO 81060-2 Third edition 2018-11 Amendment 1 2020-01, therefore, the difference of subject device with predicate device TM-2657P (K151953) will not affect the safety and effectiveness.

D2: The difference of Pressure Sensor between subject device and predicate device is that the intended Pressure Sensor of subject device is Resistance type pressure sensor and predicate device is Capacitance type pressure transducer, this difference is addressed through clinical trial conducted with subject device according to ISO 81060-2 Third edition 2018-11 Amendment 1 2020-01, the results of clinical trial meet the requirements of ISO 81060-2 Third edition 2018-11 Amendment 1 2020-01, therefore, the difference of subject device with predicate device TM-2657P (K151953) will not affect the safety and effectiveness.

D3: The Air Pressure Control Method of subject device is different with predicate device predicate device, this difference is addressed through clinical trial conducted with subject device according to ISO 81060-2 Third edition 2018-11 Amendment 1 2020-01, the results of clinical trial meet the requirements of ISO 81060-2 Third edition 2018-11 Amendment 1 2020-01, therefore, the difference of subject device with predicate device TM-2657P (K151953) will not affect the safety and effectiveness.

D4: The NIBP clinical test standard of the subject device is different from that of the predicate device regarding the standard version. The subject device meets the state-of-the-art standard version for clinical investigation of non-invasive sphygmomanometers, while the predicate device does not. Therefore, this difference does not raise new questions of safety and effectiveness.

D5: The difference of Pressure display range between subject device and predicate device is that the Pressure display range of subject device is 0-295mmHg and predicate device is 0-299mmHg, this tiny difference is addressed through clinical trial conducted with subject device according to ISO 81060-2 Third edition 2018-11 Amendment 1 2020-01, the results of clinical trial meet the requirements of ISO 81060-2 Third edition 2018-11 Amendment 1 2020-01, therefore, the difference of subject device with predicate device TM-2657P (K151953) will not affect the safety and effectiveness.

D6: The difference of Blood Pressure Measurement Range between subject device and predicate device is that the Blood Pressure Measurement Range of subject device is SYS: 55mmHg ~ 255 mmHg & DIA: 25mmHg~200mmHg and predicate device is SYS: 40-270 mmHg & DIA: 20-200 mmHg, the Blood Pressure Measurement Range of subject device is in the range of predicate device and meets the requirements of IEC 80601-2-30: Edition 2.0 2018-03, and this difference is also addressed through clinical trial conducted with subject device according to ISO 81060-2 Third edition 2018-11 Amendment 1 2020-01, the results of clinical trial meet the requirements of ISO 81060-2 Third edition 2018-11 Amendment 1 2020-01, therefore, the difference of subject device with predicate device TM-2657P (K151953) will not affect the safety and effectiveness.

D7: The difference of Blood Pressure Measurement Accuracy between subject device and predicate device is that the Blood Pressure Measurement Accuracy of subject device is ±3 mmHg and predicate device is ± 3%, the Blood Pressure Measurement Accuracy of subject device meets the requirements of IEC 80601-2-30: Edition 2.0 2018-03, and this difference is also addressed through clinical trial conducted with subject device according to ISO 81060-2 Third edition 2018-11 Amendment 1 2020-01, the results of clinical trial meet the requirements of ISO 81060-2 Third edition 2018-11 Amendment 1 2020-01, therefore, the difference of subject device with predicate device TM-2657P (K151953) will not affect the safety and effectiveness.

D8: The difference of Pulse Measurement Range between subject device and predicate device is that the Pulse Measurement Range of subject device is 40~199 beats/min and predicate device is 30 ~ 240 beats/min, the Pulse Measurement Range of subject device is in the range of predicate device, and this difference is also addressed through clinical trial conducted with subject device according to ISO 81060-2 Third edition 2018-11 Amendment 1 2020-01, the results of clinical trial meet the requirements of ISO 81060-2 Third edition 2018-11 Amendment 1 2020-01, therefore, the difference of subject device with predicate device TM-2657P (K151953) will not affect the safety and effectiveness.

D9: The operating Environment of subject device are different with predicate device TM-2657P (K151953), the difference introduces risks mitigated by testing in accordance with IEC 60601-1-11 and ANSI AAMI ES60601-1 provided in this submission, therefore the difference does not raise new questions of safety and effectiveness.

D10: The Storage Environment of subject device is different with predicate device TM-2657P (K151953), the difference introduces risks mitigated by testing in accordance with IEC 60601-1-11 and ANSI AAMI ES60601-1 provided in this submission, therefore the difference does not raise new questions of safety and effectiveness.

D11: The subject device does not have Printer function which will not raise new questions of safety and effectiveness.

D12: The subject device does not have IHB (Irregular Heartbeats Detection) function which will not raise new questions of safety and effectiveness.

D13: The subject device does not have Connectivity function which will not raise new questions of safety and effectiveness.

D14: The standard IEC 80601-2-30 of the subject device is different from that of the predicate device regarding the standard version. The subject device meets the state-of-the-art standard version for IEC 80601-2-30. Therefore, this difference does not raise new questions of safety and effectiveness.

D15: The standard IEC 60601-1 of the subject device is different from that of the predicate device regarding the standard version. The subject device meets the state-of-the-art standard version for IEC 60601-1. Therefore, this difference does not raise new questions of safety and effectiveness.

D16: The standard IEC 60601-1-2 of the subject device is different from that of the predicate device regarding the standard version. The subject device meets the state-of-the-art standard version for IEC 60601-1-2.

Therefore, this difference does not raise new questions of safety and effectiveness.

D17: The Material of Patient contact components of subject device has been validated for Cytotoxicity though testing against ISO 10993- 5, for Sensitization and Irritation though testing against ISO 10993-10 and ISO 10993-23 tested and all test results are positive, the difference of subject device with predicate device TM-2657P (K151953) do not raise new questions of safety and effectiveness.

D18: The Dimensions of subject device is different with predicate device predicate device TM-2657P (K151953) will not affect the safety and effectiveness.

D19: The Weight of subject device is tiny different with predicate device predicate device TM-2657P (K151953) will not affect the safety and effectiveness.

8. Discussion of Non-Clinical Tests Performed

The recognized consensus standards for safety of medical electrical equipment: ANSI AAMI ES60601-1:2005/(R)2012 & A1:2012 C1:2009/(R)2012 & A2:2010/(R)2012 (Cons. Text) [Incl. AMD2:2021], IEC 60601-1-11:2015/2020, IEC 60601-1-2: 2014+AMD1:2020 for electromagnetic compatibility, IEC 80601-2-30: Edition 2.0 2018-03, ISO 81060-2 Third edition 2018-11 Amendment 1 2020-01 for performance, IEC 62304 Edition 1.1 2015-06 for software verification and ISO 10993-5:2009 for Cytotoxicity endpoints, ISO 10993-10:2021 and ISO 10993-23:2021 for Sensitization and Irritation endpoints are complied. See below table for details:

Standards	**Standards Name**
ANSI AAMI ES60601-1:2005/(R)2012 & A1:2012 C1:2009/(R)2012 & A2:2010/(R)2012 (Cons. Text) [Incl. AMD2:2021]	Medical Electrical Equipment - Part 1: General Requirements For Basic Safety And Essential Performance
IEC 60601-1-2: 2014+AMD1:2020	Medical Electrical Equipment - Part 1-2: General Requirements For Basic Safety And Essential Performance -- Collateral Standard: Electromagnetic Disturbances - Requirements And Tests
IEC 60601-1-11:2015/2020	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 80601-2-30: Edition 2.0 2018-03	Medical electrical equipment - Part 2-30: Particular requirements for the basic safety and essential performance of automated non-invasive sphygmomanometers
ISO 81060-2 Third edition 2018-11 Amendment 1 2020-01	Non-invasive sphygmomanometers - Part 2: Clinical investigation of intermittent automated measurement type
ISO 10993-5:2009	Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
ISO 10993-10:2021	Biological evaluation of medical devices - Part 10: Tests for skin sensitization

ISO 10993-23:2021	Biological evaluation of medical devices - Part 23: Tests for irritation
IEC 62304 Edition 1.1 2015-06	Medical device software - Software life cycle processes

- **Electrical safety and electromagnetic compatibility (EMC)**
  Electrical safety and EMC testing were conducted on the subject device CH-S691L, CH-B607, CH-B606, CH-S692L, CH-S602, CH-W701L, CH-S693L, CH-B601L, CP-B01, CH-S603. The system complies with the AAMI ANSI ES60601-1, IEC 60601-1-11 for electrical safety, the IEC 60601-1-2 standard for EMC, IEC 80601-2-30 and ISO 81060-2 for performance.

- **Software Verification and Validation Testing**
  Software verification and validation was performed for the subject device in accordance with Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices - Guidance for Industry and FDA Staff, May 2005.

  Software Description:
  The software for this device was considered as a “moderate” level of concern, since a failure or latent flaw in the software could result in Minor Injury, either to a patient or to a user of the device. The software of the system, on the whole, is accountable for the system scheduler of the device, including Pressure and pulse signal acquisition, calculation and display, the button presses of end user, display the result of the measurement, measurement data storage and average calculation, memory data query, prompt of error message, low battery voltage detection and prompt, measurement Unit conversion.

9. Discussion of Clinical Accuracy Testing Performed

The clinical accuracy test report and data analysis followed the requirements of the ISO 81060-2 Third edition 2018-11 Amendment 1 2020-01.

The clinical accuracy testing evaluated 85 of subjects, division of all subjects:

Subjects' requirement		**Number specified in ISO 81060-2 Third edition 2018-11 Amendment 1 2020-01**	**Actual number**	
Total		A minimum of 85 people	85	
Male		At least 26 people	34	
Female		At least 26 people	51	
Age ≥ 18		100%	100%	
Arm circumference range	18 ≤ x < 24	≥20%	19	22.35%
	24 ≤ x < 30	≥20%	21	24.71%
	30 ≤ x < 36	≥20%	25	29.41%
	36 ≤ x ≤ 42	≥20%	20	23.53%
	18 ≤ x ≤ 21	≥10%	10	11.76%
	39 ≤ x ≤ 42	≥10%	11	12.94%
Systolic BP	Systolic BP ≤ 100mmHg	≥5%	51	7.50%
	Systolic BP ≥ 160mmHg	≥5%	40	5.88%

	Systolic BP ≥140mmHg	≥20%	177	26.03%
Diastolic BP	Diastolic BP ≤ 60mmHg	≥5%	41	6.03%
	Diastolic BP ≥ 100mmHg	≥5%	46	6.76%
	Diastolic BP ≥ 85mmHg	≥20%	160	23.53%

The test data showed the clinical accuracy of the subject device complied with the requirements of ISO 81060-2 Third edition 2018-11 Amendment 1 2020-01.

Reference equipment used for measurements:

Name	Aneroid sphygmomanometer
Model	CM-BPM-D
Manufacturer	Shanghai Caremate Medical Device Co. Ltd
Measuring Method	Aneroid/auscultation method
K number	K211084

10. Conclusions

The Automatic Blood Pressure Monitor has the same intended use and similar characteristics as the cleared predicate device A&D Medical TM-2657 Family of Digital Blood Pressure. Moreover, bench testing contained in this submission supplied demonstrate that the differences existed between Automatic Blood Pressure Monitor and predicate device A&D Medical TM-2657 Family of Digital Blood Pressure do not raise any new questions of safety or effectiveness.

The non-clinical tests support the safety of the device and the hardware and software verification and validation demonstrate that the Automatic Blood Pressure Monitor performs as intended in the specified use conditions are same with predicate device. The clinical performance tests demonstrate that the Automatic Blood Pressure Monitor performs comparably to the predicate device that is currently marketed for the same intended use. Thus, the Automatic Blood Pressure Monitor is Substantially Equivalent (SE) to the predicate device A&D Medical TM-2657 Family of Digital Blood Pressure, Model: TM-2657P (K151953).