April 10, 2023

Famidoc Technology Company Limited
Amos Zou
Management Representative
No. 212 Yilong Road, Hexi Industrial Zone
Jinxia, Changan Town
Dongguan, Guangdong 523853
China

Re: K222887
Trade/Device Name: Arm Blood Pressure Monitor/Automatic Wireless Smart Blood Pressure Monitor
Regulation Number: 21 CFR 870.1130
Regulation Name: Noninvasive Blood Pressure Measurement System
Regulatory Class: Class II
Product Code: DXN
Dated: April 6, 2023
Received: April 7, 2023

Dear Amos Zou:

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 (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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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,

Aneesh S. Deoras -S

for

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)*
K222887

Device Name
Arm Blood Pressure Monitor/Automatic Wireless Smart Blood Pressure Monitor

Indications for Use *(Describe)*
Arm Blood Pressure Monitor/Automatic Wireless Smart Blood Pressure is intended to measure the blood pressure and pulse rate of adults and children at least 12 years of age, at household or medical center. with the cuff around the left upper arm according to the instruction in the user's guide manual(Cuff size 220 ~ 420 mm).

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

This summary of 510(K) safety and effective information is being submitted in accordance with the requirement SMDA and 21 CFR 807.92.

1. Submitter of 510(K):

Date of Prepared:	17/1/2023
Submitter's Name:	Famidoc Technology Company Limited
Address:	No.212 Yilong Road, Hexi Industrial Zone, Jinxia, Changan Town Dongguan Guangdong 523853 CN
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TEL:	+(86) -769-8927-2488
FAX:	+(86) -769-8927-2498
E-mail:	qa@famidoc.com

2.Proposed Device and code:

Device Trade Name:	Arm Blood Pressure Monitor/Automatic Wireless Smart Blood Pressure monitor (Model:FDBP-A7B、FDBP-A7BL、FDBP-A7BT、FDBP-A7BLT、FDBP-A8B、FDBP-A8BL、FDBP-A8BT、FDBP-A8BLT、FDBP-A9B、FDBP-A9BL、FDBP-A9BT、FDBP-A9BLT、FDBP-A10B、FDBP-A10BL、FDBP-A10BT、FDBP-A10BLT）
Regulation Medical Specialty	Noninvasive blood pressure measurement system.
Product Code:	DXN
Regulation number	21 CRF 870.1130
Device Class	2

3. Predicate Device:

510(K)	Trade or Proprietary or Model Name	Manufacturer
K210770	Fully Automatic Electronic Blood Pressure Monitor	Andon Health Co,.Ltd.

4. Description of Proposed Device:

Arm Blood Pressure Monitor/Automatic Wireless Smart Blood Pressure Monitor(Model:FDBP-A7B、FDBP-A7BL、FDBP-A7BT、FDBP-A7BLT、FDBP-A8B、FDBP-A8BL、FDBP-A8BT、FDBP-A8BLT、FDBP-A9B、FDBP-A9BL、FDBP-A9BT、

FDBP-A9BLT、FDBP-A10B、FDBP-A10BL、FDBP-A10BT、FDBP-A10BLT）includes utilize modular design method, It consists of nine main modules:

 power-on self-test module, system initialization module,sampling data processing and pressure, pulse rate calculation module, display processing module, power detection processing module, data storage module, key scanning processing module, sampling processing module, ,wireless function module, and each module communicates through a message queue.

 The blood pressure monitor controls the pneumatic flow control module through single-chipped microcomputer to pressurize the cuff module in order to exceed the lower pressure of patients, the blood being pushed against the artery walls;

 Pneumatic Flow Control Module being directed to release the pressure, while the pressure detection module collect pulse pressure signal and amplify filter;

 amplified filtersignal being read by single-chipped microcomputer for pressure and pulse signal,through unique algorithm to obtain the systolic and diastolic pressure with pulse;

 Single-chipped microcomputer will control the inflation/deflation module to release the pressure after receive measurements;

 in the meanwhile, display the measurements results then stored the values with memory module.

5. Intended for Use

Arm Blood Pressure Monitor/Automatic Wireless Smart Blood Pressure is intended to measure the blood pressure and pulse rate of adults and children at least 12 years of age, at household or medical center. with the cuff around the left upper arm according to the instruction in the user's guide manual(Cuff size 220 ~ 420 mm).

6. Technical and Performance

The following table compares the device to the predicate device with basic technological characteristics.

7.Comparison of Technological Characteristics with Predicate Device

Elements of Comparison	**Subject Devices**				**Predicate Device**	**Comparison Result**
Device Name	Arm Blood Pressure Monitor/Automatic Wireless Smart Blood Pressure Monitor				Fully Automatic Electronic Blood Pressure Monitor	/
Device Model	FDBP-A7BL	FDBP-A7BT	FDBP-A10BL	FDBP-A10BT	KD-5810, KD5810B, KD-5811, KD-5920TL, KD-552	/
510 (k) Number	K222887	K222887	K222887	K222887	K210770	/
Product Code	DXN	DXN	DXN	DXN	DXN	SE
Regulation No.	870.1130	870.1130	870.1130	870.1130	870.1130	SE
Classification	II	II	II	II	II	SE
Intended Use and indications for Use						
Intended Use	Arm Blood Pressure Monitor/Automatic Wireless Smart Blood Pressure is intended to measure the blood pressure and pulse rate of adults and children at least 12 years of age, at household or medical center. with the cuff around the left upper arm according to the instruction in the user's guide manual(Cuff size 220 ~ 420 mm).	Arm Blood Pressure Monitor/Automatic Wireless Smart Blood Pressure is intended to measure the blood pressure and pulse rate of adults and children at least 12 years of age, at household or medical center. with the cuff around the left upper arm according to the instruction in the user's guide manual(Cuff size 220 ~ 420 mm).	Arm Blood Pressure Monitor/Automatic Wireless Smart Blood Pressure is intended to measure the blood pressure and pulse rate of adults and children at least 12 years of age, at household or medical center. with the cuff around the left upper arm according to the instruction in the user's guide manual(Cuff size 220 ~ 420 mm).	Arm Blood Pressure Monitor/Automatic Wireless Smart Blood Pressure is intended to measure the blood pressure and pulse rate of adults and children at least 12 years of age, at household or medical center. with the cuff around the left upper arm according to the instruction in the user's guide manual(Cuff size 220 ~ 420 mm).	Fully Automatic Electronic Blood Pressure Monitor is for use by medical professionals or at home and is a non-invasive blood pressure measurement system intended to measure the diastolic and systolic blood pressures and pulse rate of an adult individual by using a non-invasive technique in which an inflatable cuff is wrapped around the	SE

					upper arm. The cuff circumference is limited to 22cm-48cm.	
Performance Specification						
Measuring Method	Oscillometric Method	Oscillometric Method	Oscillometric Method	Oscillometric Method	Oscillometric Method	SE
Measuring Range	Systolic: 60-250mmHg Diastolic: 30-195mmHg Pulse: 40-199beats/min	Systolic: 60-250mmHg Diastolic: 30-195mmHg Pulse: 40-199beats/min	Systolic: 60-250mmHg Diastolic: 30-195mmHg Pulse: 40-199beats/min	Systolic: 60-250mmHg Diastolic: 30-195mmHg Pulse: 40-199beats/min	Systolic: 60-260mmHg Diastolic: 40-199mmHg Pulse rate: 40-180 beats/min	Similar Note 1
Pressure resolution	1 mmHg or 0.1 kPa	1 mmHg or 0.1 kPa	1 mmHg or 0.1 kPa	1 mmHg or 0.1 kPa	1 mmHg or 0.1 kPa	SE
Accuracy	Pressure: ±3 mmHg (±0.4kPa) Pulse:±5%	Pressure: ±3 mmHg (±0.4kPa) Pulse:±5%	Pressure: ±3 mmHg (±0.4kPa) Pulse:±5%	Pressure: ±3 mmHg (±0.4kPa) Pulse:±5%	Pressure: ±3mmHg Pulse rate: Less than 60: ±3bpm More than 60 (incl.) : ±5%	Similar Note 2
Patient Population	Adult	Adult	Adult	Adult	Adult	SE
Measurement Site of Body	Upper Arm	Upper Arm	Upper Arm	Upper Arm	Upper Arm	SE
Inflation and Deflation	Automatic	Automatic	Automatic	Automatic	Automatic	SE
Memory Size	2x60 sets record	2x60 sets record	2x60 sets record	2x60 sets record	4×60 times with time and date stamp	Similar Note 3
Indicators	Blood Pressure (Systolic and Diastolic), Pulse, Date, Time, WHO BP Classification Indicating Bar, Low Battery Icon, Heart Icon, Memory	Blood Pressure (Systolic and Diastolic), Pulse, Date, Time, WHO BP Classification Indicating Bar, Low Battery Icon, Heart Icon, Memory	Blood Pressure (Systolic and Diastolic), Pulse, Date, Time, WHO BP Classification Indicating Bar, Low Battery Icon, Heart Icon, Memory	Blood Pressure (Systolic and Diastolic), Pulse, Date, Time, WHO BP Classification Indicating Bar, Low Battery Icon, Heart Icon, Memory	Blood Pressure (Systolic and Diastolic), Pulse, Date, Time, WHO BP Classification Indicating Bar, Low Battery Icon, Heart Icon, Memory	SE

	Record Number,Bluetooth symbol	Record Number,Bluetooth symbol	Record Number,Bluetooth symbol	Record Number,Bluetooth symbol	Record Number,Bluetooth symbol	
Cuff Circumference	220mm ～420mm	220mm ～420mm	220mm ～420mm	220mm ～420mm	22cm-30cm, 30cm-42cm(Optional), 42cm-48cm(Optional), 22cm-42cm (Optional)	Similar Note 4
Power Battery	3.7V lithium battery or USB 5V adapter	4xAAA 1.5V alkaline batteries or USB 5V adapter	3.7V lithium battery or USB 5V adapter	4xAAA 1.5V alkaline batteries or USB 5V adapter	4xAA 1.5V alkaline batteries or DC 6V adapter	Similar Note 5
Display	LED Digital Display	LED Digital Display	LCD Digital Display	LCD Digital Display	LCD Digital Display	Similar Note 6
OPERATING&STORANE CONDITIONS						
Operating Environment	Temperature: 5℃~40℃ Humidity: 15% RH~90% RH, No condensation Atmospheric pressure: 70kPa~106kPa	Temperature: 5℃~40℃ Humidity: 15% RH~90% RH, No condensation Atmospheric pressure: 70kPa~106kPa	Temperature: 5℃~40℃ Humidity: 15% RH~90% RH, No condensation Atmospheric pressure: 70kPa~106kPa	Temperature: 5℃~40℃ Humidity: 15% RH~90% RH, No condensation Atmospheric pressure: 70kPa~106kPa	Temperature: 10℃~40℃ Humidity: ≤85%RH Atmospheric pressure: 80kPa~105kPa	Similar Note 7
Storage Environment	Temperature: -25℃~55℃ Humidity: 15% RH~95% RH, No condensation Atmospheric pressure: 70kPa~106kPa	Temperature: -25℃~55℃ Humidity: 15% RH~95% RH, No condensation Atmospheric pressure: 70kPa~106kPa	Temperature: -25℃~55℃ Humidity: 15% RH~95% RH, No condensation Atmospheric pressure: 70kPa~106kPa	Temperature: -25℃~55℃ Humidity: 15% RH~95% RH, No condensation Atmospheric pressure: 70kPa~106kPa	Temperature: -20℃~50℃ Humidity: ≤85%RH Atmospheric pressure: 80kPa~105kPa	Similar Note 8
COMPLIANCE STANDARDS						
Electrical Safety	IEC 60601-1	IEC 60601-1	IEC 60601-1	IEC 60601-1	IEC 60601-1	SE
EMC	IEC 60601-1-2	IEC 60601-1-2	IEC 60601-1-2	IEC 60601-1-2	IEC 60601-1-2	SE
Home Use	IEC 60601-1-11	IEC 60601-1-11	IEC 60601-1-11	IEC 60601-1-11	IEC 60601-1-11	SE
Performance	IEC 80601-2-30	IEC 80601-2-30	IEC 80601-2-30	IEC 80601-2-30	IEC 80601-2-30	SE
Biocompatibility	All the patient	All the patient	All the patient	All the patient	All the patient	SE

	contracting materials are evaluated by the biocompatibility standard ISO 10993 -5, -10.	contracting materials are evaluated by the biocompatibility standard ISO 10993 -5, -10.	contracting materials are evaluated by the biocompatibility standard ISO 10993 -5, -10.	contracting materials are evaluated by the biocompatibility standard ISO 10993 -5, -10.	contracting materials are evaluated by the biocompatibility standard ISO 10993 -5, -10.	
Performance	ANSI/AAMI/ISO 81060-2	ANSI/AAMI/ISO 81060-2	ANSI/AAMI/ISO 81060-2	ANSI/AAMI/ISO 81060-2	ANSI/AAMI/ISO 81060-2	SE

Note 1 and 2

The Measuring Range and Accuracy of proposed device and predicate device are different.But the difference is very slight,it will not affect the main function and the intended use of the device. and Measuring Range and Accuracy of proposed device they are both compliance with IEC 60601-1 and IEC 80601-2-30 Standard Therefore, this difference will not result in any safety and effectiveness issue of the proposed device.

Note 3

The Memory Size of proposed device and predicate device are different,is clearly indicated in user manual and outer carton. Therefore, this difference will not result in any safety and effectiveness issue of the proposed device.

Note 4

The Cuff Circumference of proposed device and predicate device is compliance with IEC 80601-2-30 Standard,this difference will not result in any safety and effectiveness issue of the proposed device.

Note 5 and Note 6

The Power Battery and Display of proposed device and predicate device are compliance with IEC 60601-1 and IEC 80601-2-30 Standard,these difference will not result in any safety and effectiveness issue of the proposed device.

Note 7 and Note 8

The Temperature, Relative Humidity and Atmospheric pressure of Operation and storage environment of subject devices is difference with predicate

device,and they are both compliance with IEC 60601-1-11 standard,it will not raise any safety or effectiveness issue.

8.Subject Devices Different Table

model	**FDBP-A7BL**	**FDBP-A8BL**	**FDBP-A7B**	**FDBP-A8B**
Power source	Rechargeable 3.7V lithium battery/USB 5V	Rechargeable 3.7V lithium battery/USB 5V	4*AAA battery /USB 5V	4*AAA battery /USB 5V
Number of keys	Three	Three	Three	Three
Display module	LED（No backlight）	LED（No backlight）	LED（No backlight）	LED（No backlight）
Intended Use and indications for Use	See chapter 7	Same	Same	Same
Performance Specification	See chapter 7	Same	Same	Same
OPERATING&STORANE CONDITIONS	See chapter 7	Same	Same	Same
Measuring Method	See chapter 7	Same	Same	Same
COMPLIANCE STANDARDS	See chapter 7	Same	Same	Same

FDBP-Axyy

"x"= 7, 8, 9, 10"yy"=L, B, BL, T, LT,BT, BLT or blank.

"x" 7, 9 are identical except the display, "x" 8, 10 are identical except the display.

"x" 7, 8 use the LED display, "x" 9, 10 use the LCD display.

“yy" had "L" mean the device use the lithium battery to offer the power. If not, mean use the 4*AAA batteries and the internal circuit no charging circuit.

"yy" had "B" mean the device had Bluetooth and Wifi function. If not, mean no this function.

"yy" had "T" mean no setting button, only memory and start/stop button. If not, mean had an extra settingsbutton.

*All models can use USB cable to provide 5Vdc power. If it is a lithium battery device, the power provided by the USB cable can only charge the lithium battery, and the device will not work properly during the charging process. If it is a 4*AAA battery device, the power supply provided by the USB cable will power the device, and the device can work normally.

Model	**FDBP-A7BT**	**FDBP-A8BT**	**FDBP-A8BLT**	**FDBP-A7BLT**
Power source	4*AAA battery /USB 5V	4*AAA battery /USB 5V	Rechargeable 3.7V lithium battery/USB 5V	Rechargeable 3.7V lithium battery/USB 5V
Number of keys	Two	Two	Two	Two

Display module	LED（No backlight）	LED（No backlight）	LED（No backlight）	LED（No backlight）
Intended Use and indications for Use	See chapter 7	Same	Same	Same
Performance Specification	See chapter 7	Same	Same	Same
OPERATING&STORANE CONDITIONS	See chapter 7	Same	Same	Same
Measuring Method	See chapter 7	Same	Same	Same
COMPLIANCE STANDARDS	See chapter 7	Same	Same	Same

FDBP-Axyy

"x"= 7, 8, 9, 10"yy"=L, B, BL, T, LT,BT, BLT or blank.

"x" 7, 9 are identical except the display, "x" 8, 10 are identical except the display.

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“yy" had "L" mean the device use the lithium battery to offer the power. If not, mean use the 4*AAA batteries and the internal circuit no charging circuit.

"yy" had "B" mean the device had Bluetooth and Wifi function. If not, mean no this function.

"yy" had "T" mean no setting button, only memory and start/stop button. If not, mean had an extra settingsbutton.

*All models can use USB cable to provide 5Vdc power. If it is a lithium battery device, the power provided by the USB cable can only charge the lithium battery, and the device will not work properly during the charging process. If it is a 4*AAA battery device, the power supply provided by the USB cable will power the device, and the device can work normally.

Model	**FDBP-A10BL**	**FDBP-A9BL**	**FDBP-A9B**	**FDBP-A10B**
Power source	Rechargeable 3.7V lithium battery/USB 5V	Rechargeable 3.7V lithium battery/USB 5V	4*AAA battery /USB 5V	4*AAA battery /USB 5V
Number of keys	Three	Three	Three	Three
Display module	LCD（backlight）	LCD（backlight）	LCD（backlight）	LCD（backlight）
Intended Use and indications for Use	See chapter 7	Same	Same	Same

Performance Specification	See chapter 7	Same	Same	Same
OPERATING&STORANE CONDITIONS	See chapter 7	Same	Same	Same
Measuring Method	See chapter 7	Same	Same	Same
COMPLIANCE STANDARDS	See chapter 7	Same	Same	Same

FDBP-Axyy

"x"= 7, 8, 9, 10"yy"=L, B, BL, T, LT,BT, BLT or blank.

"x" 7, 9 are identical except the display, "x" 8, 10 are identical except the display.

"x" 7, 8 use the LED display, "x" 9, 10 use the LCD display.

“yy" had "L" mean the device use the lithium battery to offer the power. If not, mean use the 4*AAA batteries and the internal circuit no charging circuit.

"yy" had "B" mean the device had Bluetooth and Wifi function. If not, mean no this function.

"yy" had "T" mean no setting button, only memory and start/stop button. If not, mean had an extra settingsbutton.

*All models can use USB cable to provide 5Vdc power. If it is a lithium battery device, the power provided by the USB cable can only charge the lithium battery, and the device will not work properly during the charging process. If it is a 4*AAA battery device, the power supply provided by the USB cable will power the device, and the device can work normally.

Model	**FDBP-A10BT**	**FDBP-A98T**	**FDBP-A9BLT**	**FDBP-A10BLT**
Power source	4*AAA battery /USB 5V	4*AAA battery /USB 5V	Rechargeable 3.7V lithium battery/USB 5V	Rechargeable 3.7V lithium battery/USB 5V
Number of keys	Two	Two	Two	Two
Display module	LCD（backlight）	LCD（backlight）	LCD（backlight）	LCD（backlight）
Intended Use and indications for Use	See chapter 7	Same	Same	Same
Performance Specification	See chapter 7	Same	Same	Same
OPERATING&STORANE CONDITIONS	See chapter 7	Same	Same	Same

Measuring Method	See chapter 7	Same	Same	Same
COMPLIANCE STANDARDS	See chapter 7	Same	Same	Same

FDBP-Axyy

"x"= 7, 8, 9, 10"yy"=L, B, BL, T, LT,BT, BLT or blank.

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"yy" had "B" mean the device had Bluetooth and Wifi function. If not, mean no this function.

"yy" had "T" mean no setting button, only memory and start/stop button. If not, mean had an extra settingsbutton.

*All models can use USB cable to provide 5Vdc power. If it is a lithium battery device, the power provided by the USB cable can only charge the lithium battery, and the device will not work properly during the charging process. If it is a 4*AAA battery device, the power supply provided by the USB cable will power the device, and the device can work normally.

9. Performance
Testing:
Performance data includes “Non-Clinical Data” and “Clinical Data”, brief description of which are shown as below.

9.1 Non-Clinical Data:
The following performance data were provided in support of the substantial equivalence determination.

9.2 Biocompatibility testing
The biocompatibility evaluation for the FDBP A series Upper arm Blood Pressure Monitor and the NIBP CUFF were conducted in accordance with the International Standard ISO 10993-1 “Biological Evaluation of Medical Devices − Part 1: Evaluation and Testing Within a Risk Management Process,” as recognized by FDA. The worst case of the whole system is considered tissue contacting for duration of less than 24 hours. And the testing included the following tests:
 Cytotoxicity
 Skin Sensitization
 Skin Irritation

9.3 Electrical safety and electromagnetic compatibility (EMC)
Electrical safety and EMC testing were conducted on the FDBP A series Upper arm Blood Pressure Monitor, consisting of all the modules and accessories in the system. The system complies with the IEC 60601-1: 2012 Medical electrical equipment Part 1: General requirements for basic safety and essential performance for safety and the IEC 60601-1-2: 2014 Medical electrical equipment –Part 1-2: General requirements for basic safety and essential performance – Collateral Standard:Electromagnetic disturbances – Requirements and tests standard for EMC.

9.4 Bench Testing
Bench testing was conducted on the FDBP A series Upper arm Blood Pressure Monitor,consisting of all the accessories in the system. The system complies with the IEC 60601-1-11: 2015 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: 2018 Medical electrical equipment — Part 2-30: Particular requirements for basic safety and essential performance of automated non-invasive sphygmomanometers standards for performance effectiveness.

9.5 Software Verification and Validation Testing
Software verification and validation testing were conducted and documentation was provided as recommended by FDA’s Guidance for Industry and FDA Staff, “Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices.” The software for this device was considered as a “Moderate” level of concern.

9.6 Usability Testing
Usability testing according to following FDA Guidance 1757, Applying Human Factors and Usability Engineering to Optimize Medical Device Design, was conducted.

9.7 Clinical data:
Clinical testing is conducted per ISO 81060-2: 2018 Non-invasive sphygmomanometers - Part 2: Clinical investigation of intermittent automated measurement type.

Based on the same product principle, and the clinical validation data on the FDBP-A7BL can cover all the models included in this submission.

In this clinical study, 85 patients(43 males and 42 females) participated in the clinical study. Same arm sequentialmethod was adopted during the clinical study. The manual MercurySphygmomanometer was used as a reference sphygmomanometer. All the subjectswere volunteer to take part in the clinical study, all the subjects completed theclinical study without any AE or side-effect. The results showed the accuracy of thesubject device is within acceptable scope specified in ISO 81060-2.

9.8 Summary

Based on the non-clinical and clinical performance as documented in the device development, the subject devices were found to have a safety and effectiveness profile that is similar to the predicate device.

10. Conclusions:

The proposed device has the same intended use and similar characteristics as the predicate device, AGE Automatic Upper Arm Blood Pressure Monitor with Models KD-5810, KD5810B, KD-5811, KD-5920TL and KD-552(K210770) Meanwhile, performance testing, bench testing, and safety report documentation supplied in this submission demonstrates that any differences in their technological characteristics do not raise any new questions of safety or effectiveness. Based on performance testing, the proposed device is Substantially Equivalent (SE) to the predicate device