November 27, 2019

Famidoc Technology Company Limited
Leon Cao
General Manager
No. 212 Yilong Road, Hexi Industrial Zone
Jinxia, Changan Town
Dongguan, Guangdong 523853
CHINA

Re: K191673
Trade/Device Name: FDBP A Series Upper Arm Blood Pressure Monitor
Regulation Number: 21 CFR 870.1130
Regulation Name: Noninvasive Blood Pressure Measurement System
Regulatory Class: Class II
Product Code: DXN
Dated: October 28, 2019
Received: November 6, 2019

Dear Leon Cao:

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,

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K191673

Device Name
FDBP A Series Upper Arm Blood Pressure Monitor

Indications for Use *(Describe)*
FDBP A series Upper Arm Blood Pressure Monitor 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. (Not suitable for neonate, pregnancy or pre-eclampsia). with the cuff around the left upper arm according to the instruction in the user's guide manual.

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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Department of Health and Human Services
Centre of Device and Radiological Health
Office of Device Evaluation
Traditional 510(k) section

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:	11/27/2019
Submitter's Name:	Famidoc Technology Company Limited
Address:	No.212 Yilong Road, Hexi Industrial Zone, Jinxia, Changan Town Dongguan Guangdong 523853 CN
Contact person:	Mr. Leon Cao
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E-mail:	leon@famidoc.com

2. Proposed Device and code:

Device Trade Name:	FDBP A series Upper Arm Blood Pressure Monitor (Model:FDBP-A8,FDBP-A11,FDBP-A12,FDBP-A14）
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
K172895	AGE Automatic Upper Arm Blood Pressure Monitor with Models BA-815, BA-816, BA-818 and BA-819	Ageless Health Industrial Co., Ltd.

4. Description of Proposed Device:

FDBP A series Upper Arm Blood Pressure Monitor (Model:FDBP-A8,FDBP-A11,FDBP-A12,FDBP-A14)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, voice broadcast processing 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

FDBP A series Upper Arm Blood Pressure Monitor 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. (Not suitable for neonate, pregnancy or pre-eclampsia). with the cuff around the left upper arm according to the instruction in the user's guide manual.

6. Technical and Performance

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

Elements of Comparison	Subject Devices				Predicate Device	Verdoct
Device Name	Upper Arm Blood Pressure Monitor				AGE Automatic Upper Arm Blood Pressure	/
Device Model	FDBP-A8	FDBP-A12	FDBP-A14	FDBP-A11	BA-815, BA-816, BA-818, BA-819	/
510 (k) Number	N/A	N/A	N/A	N/A	K172895	/
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	FDBP A series Upper Arm Blood Pressure Monitor is intended to measure the blood pressure and pulse rate of adult at household or medical center. (Not suitable for neonate, pregnancy or pre-eclampsia). with the cuff around the left upper arm according to the instruction in the user's guide manual.	FDBP A series Upper Arm Blood Pressure Monitor is intended to measure the blood pressure and pulse rate of adult at household or medical center. (Not suitable for neonate, pregnancy or pre-eclampsia). with the cuff around the left upper arm according to the instruction in the user's guide manual.	FDBP A series Upper Arm Blood Pressure Monitor is intended to measure the blood pressure and pulse rate of adult at household or medical center. (Not suitable for neonate, pregnancy or pre-eclampsia). with the cuff around the left upper arm according to the instruction in the user's guide manual.	FDBP A series Upper Arm Blood Pressure Monitor is intended to measure the blood pressure and pulse rate of adult at household or medical center. (Not suitable for neonate, pregnancy or pre-eclampsia). with the cuff around the left upper arm according to the instruction in the user's guide manual.	AGE Automatic Upper Arm Blood Pressure Monitor is intended for use by medical professionals or at home to monitor and display diastolic, systolic blood pressure and pulse rate on adult each time, with the cuff around the left upper arm according to the instruction in the user's guide manual.	SE
Performance Specification						
Measuring Method	Oscillometric Method	Oscillometric Method	Oscillometric Method	Oscillometric Method	Oscillometric Method	SE
Measuring Range	Pressure: 0~280 mmHg Pulse: 40~200 beats/minute SYS(systolic pressure): 60-255mmHg DIA (diastolic pressure): 40-200mmHg	Pressure: 0~280 mmHg Pulse: 40~200 beats/minute SYS(systolic pressure): 60-255mmHg DIA (diastolic pressure): 40-200mmHg	Pressure: 0~280 mmHg Pulse: 40~200 beats/minute SYS(systolic pressure): 60-255mmHg DIA (diastolic pressure): 40-200mmHg	Pressure: 0~280 mmHg Pulse: 40~200 beats/minute SYS(systolic pressure): 60-255mmHg DIA (diastolic pressure): 40-200mmHg	Pressure: 0~280 mmHg Pulse: 40~199 beats/minute SYS(systolic pressure): 60-255mmHg DIA (diastolic pressure): 40-200mmHg	SE
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: ±3 mmHg Pulse:±5%	SE

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	2x90 sets record	Similar Note 1
Indicators	Blood Pressure (Systolic and Diastolic), Pulse, Date, Time, WHO BP Classification Indicating Bar, Low Battery Icon, Heart Icon, Memory Record Number	Blood Pressure (Systolic and Diastolic), Pulse, Date, Time, WHO BP Classification Indicating Bar, Low Battery Icon, Heart Icon, Memory Record Number	Blood Pressure (Systolic and Diastolic), Pulse, Date, Time, WHO BP Classification Indicating Bar, Low Battery Icon, Heart Icon, Memory Record Number	Blood Pressure (Systolic and Diastolic), Pulse, Date, Time, WHO BP Classification Indicating Bar, Low Battery Icon, Heart Icon, Memory Record Number	Blood Pressure (Systolic and Diastolic), Pulse, Date, Time, WHO BP Classification Indicating Bar, Low Battery Icon, Heart Icon, Memory Record Number	SE

Cuff Circumference	220mm ～320mm	220mm ～320mm	220mm ～320mm	220mm ～320mm	For BA-815: 22-34 cm; For BA-816: 28-42 cm; For BA-818 and BA-819, there are 6 size: size A: 17cm--22cm (SMALL ADULT CUFF) size B: 22cm--30cm (ADULT CUFF-1) size C: 24cm--34cm (ADULT CUFF-2) size D: 22cm--42cm (L-LARGE ADULT CUFF) size E: 30cm--42cm (LARGE ADULT CUFF) size F: 42cm--50cm (EXTRA LARGE ADULT CUFF)	SE
Power Battery	DC 6V (4xAA 1.5V alkline batteries or DC Adaputer)	DC 6V (4xAA 1.5V alkline batteries or DC Adaputer)	DC 6V (4xAAA 1.5V alkline batteries or DC Adaputer)	DC 6V (4xAAA 1.5V alkline batteries or DC Adaputer)	DC 6V (4xAA 1.5V alkline batteries)	Similar Note 2
Display	LCD Digital Display	LCD Digital Display	LCD Digital Display	LED Digital Display	LCD Digital Display	Similar Note 3
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: 5°C ~ 40°C Humidity: 15~90%RH Atmospheric Pressure: 86 kPa~106 kPa	Similar Note 4

Storage Environment	Temperature: -25℃-55℃ Humidity: 15%RH-95%RH, No condensation Atmospheric pressure 700hPa~1060hPa	Temperature: -25℃-55℃ Humidity: 15%RH-95%RH, No condensation Atmospheric pressure 700hPa~1060hPa	Temperature: -25℃-55℃ Humidity: 15%RH-95%RH, No condensation Atmospheric pressure 700hPa~1060hPa	Temperature: -25℃-55℃ Humidity: 15%RH-95%RH, No condensation Atmospheric pressure 700hPa~1060hPa	Temperature: -20°C ~ +65°C Humidity: 10~95%RH Atmospheric Pressure: 86 kPa~106 kPa	Similar Note 5
COMPLIANCE STANDARDS						
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
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 contracting materials are evaluated by the biocompatibility standard ISO 10993 -5, -10.	All the patient contracting materials are evaluated by the biocompatibility standard ISO 10993 -5, -10.	All the patient contracting materials are evaluated by the biocompatibility standard ISO 10993 -5, -10.	All the patient contracting materials are evaluated by the biocompatibility standard ISO 10993 -5, -10.	All the patient contracting materials are evaluated by the biocompatibility standard ISO 10993 -5, -10.	SE

Note 1 and 2

The Memory Size,Power Battery 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 Memory Size,Power Battery of proposed device 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 3

The Display 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 they are both compliance with IEC 60601-1 and IEC 60601-1-2 Standard. Therefore, this difference will not result in any safety and effectiveness issue of the proposed device.

Note 4 and 5:

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.

Conclusion:

The subject device AGE Automatic Upper Arm Blood Pressure Monitor has all features of the predicate device. The differences between them do not affect the safety and effectiveness. Thus, the subject device is substantially equivalent to the predicate device.

7. Performance Testing:

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

7.1 Non-Clinical Data:

The following performance data were provided in support of the substantial equivalence determination.

7.2 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

7.3 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.

7.4 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, ISO 80601-2-30: 2009 Medical electrical equipment — Part 2-56: Particular requirements for basic safety and essential performance of automated non-invasive sphygmomanometers standards for performance effectiveness.

7.5 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.

7.6 Usability Testing

Usability testing according to following FDA Guidance 1757, Applying Human Factors and Usability

Engineering to Optimize Medical Device Design, was conducted.

7.7 Clinical data:

Clinical testing is conducted per ISO 81060-2: 2013 Non-invasive sphygmomanometers - Part 2: Clinical

validation of automated measurement type.

7.7 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.

8. 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 BA-815, BA-816, BA-818 and BA-819(K172895) 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.