May 29, 2020

Xiamen Ants Bro Technology Co., Ltd.
% Cassie Lee
Manager
Guangzhou GLOMED Biological Technology Co., Ltd.
2231, Building 1, Rui Feng Center, Kaichuang Road
Huangpu District
Guangzhou, 510000 Cn

Re: K190982
Trade/Device Name: Automatic Digital 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 1, 2019
Received: April 15, 2019

Dear Cassie Lee:

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,

LT 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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K190982

Device Name
Automatic Digital Blood Pressure Monitor

Indications for Use *(Describe)*
Automatic Digital Blood Pressure Monitor is intended to measure the systolic and diastolic blood pressure as well as the pulse rate of adult person via non-invasive oscillometric technique in which an inflatable cuff is wrapped around the wrist or the upper arm. It can be used at medical facilities or at home. The intended wrist circumference is 12.5~20 cm and the intended arm circumference has several models: 23~33 cm, 25~35 cm, 22~42 cm, 33~43 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.

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Sponsor:	Xiamen Ants Bro Technology Co., Ltd.
Subject Device:	Automatic Digital Blood Pressure Monitor, Models: BA4110/AS-35A, BA6310/AS-35E, BA4900/AS-35W, AS-35K, AS-35I, AS-35H, AS-35X, AS-35J, AS-35L, AS-35F, AS-55G, AS-55A, AS-55M, AS-55F

510(k) Summary

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

1. Submitter's Information

510(k) Owner's Name: Xiamen Ants Bro Technology Co., Ltd.

Establishment Registration Number: Applying

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Contact Person: Jane Xu (Manger)

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Application Correspondent:

Contact Person: Cassie Lee

Guangzhou GLOMED Biological Technology Co., Ltd.

Address: 2231, Building 1, Rui Feng Center, Kaichuang Road, Huangpu District, Guangzhou, Guangdong, China

Tel: +86 20 8266 2446

Email: regulatory@glomed-info.com

Sponsor:	Xiamen Ants Bro Technology Co., Ltd.
Subject Device:	Automatic Digital Blood Pressure Monitor, Models: BA4110/AS-35A, BA6310/AS-35E, BA4900/AS-35W, AS-35K, AS-35I, AS-35H, AS-35X, AS-35J, AS-35L, AS-35F, AS-55G, AS-55A, AS-55M, AS-55F

2. Subject Device Information

Type of 510(k): Traditional

Common Name:Non-invasive blood pressure measurement systems

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

Trade Name:Automatic Digital Blood Pressure Monitor

Model Name: BA4110/AS-35A, BA6310/AS-35E, BA4900/AS-35W, AS-35K, AS-35I, AS-35H, AS-35X, AS-35J, AS-35L, AS-35F, AS-55G, AS-55A, AS-55M, AS-55F

Review Panel: Cardiovascular

Product Code: DXN

Regulation Number: 870.1130

Regulatory Class: 2

3. Predicate Device Information

Sponsor	Shenzhen Combei Technology Co.,Ltd.	Dongguan Ageless Health Industrial Co., Ltd.
Device Name and Model	Digital Blood Pressure Monitor Wrist Style Models: BP800W, BP603W, BP880W, BP885W, BPCB0A-2F, BP850W, BP300W, BP810W, BP602W, BP608W, BP606W, BP660W, BP830W, BP866W	AGE Automatic Upper Arm Blood Pressure Monitor Model: BA-801X, BA-802X, BA-803X, BA-805X, BA-806X, BA-811X, BA-812X, BA-813X, BA-821X, BA-822X, BA-823X, BA-826X (X can be A, B, C, D, E, F)
510(k) Number	K171833	K153552
Product Code	DXN	DXN
Regulation	870.1130	870.1130

Number		
Regulation Class	II	II

4. Device Description

Automatic Digital Blood Pressure Monitor is a non-invasive blood pressure measurement system intended to measure the diastolic and systolic blood pressures and pulse rate of an adult individual via non-invasive Oscillometric technique in which an inflatable cuff is wrapped around the wrist or the upper arm.It can be used at medical facilities or at home.

The Automatic Digital Blood Pressure Monitor main units have the operating elements of ON/OFF knob, SET key which can be user-friendly controlled.

Arm type Blood Pressure Monitor is equipped with inflatable cuff, while The wrist type Blood Pressure Monitor`s cuff is attached to the device body itself.

5. Intended Use / Indications for Use

Automatic Digital Blood Pressure Monitor is intended to measure the systolic and diastolic blood pressure as well as the pulse rate of adult person via non-invasive oscillometric technique in which an inflatable cuff is wrapped around the wrist or the upper arm.It can be used at medical facilities or at home. The intended wrist circumference is 12.5~20 cm and the intended arm circumference has several models: 23~33 cm, 25~35 cm, 22~42 cm, 33~43 cm.

6. Test Summary

Automatic Digital Blood Pressure Monitor has been evaluated the safety and performance by lab bench testing as following:

- Electrical safety test according to IEC 60601-1 and IEC 80601-2-30 standards
- Electromagnetic compatibility test according to IEC 60601-1-2 standard

- Biocompatibility test according to ISO 10993-5 and ISO 10993-10 standards
- Usability test according to IEC62366 standard
- Software verification and validation test according to the requirements of the FDA “Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices”

7. Summary of the clinical study

ISO 81060-2:2013 Non-invasive sphygmomanometers - Part 2: Clinical validation of automated measurement type;

In this clinical investigation, Arm sphygmomanometer had ninety patients (23-33cm: 49 males and 41 females, 25-35cm: 38 males and 52 females, 22-42cm: 48 males and 42 females, and 33-43cm: 38 males and 52 females) and Wrist sphygmomanometer also had ninety patients (43 males and 47 females) participated in the clinical study. Same simultaneous method was adopted during the clinical testing. The manual Mercury Sphygmomanometer was used as a reference device. All the subjects were volunteer to take part in the clinical study, all the subjects completed the clinical study without any adverse event or side-effect.

The results showed the accuracy of the blood pressure monitor is within acceptable scope specified in ISO 81060-2.

8. Comparison to predicate device and conclusion

The technological characteristics, features, specifications, materials, mode of operation, and intended use of Automatic Digital Blood Pressure Monitor is substantially equivalent to the predicate devices quoted above.

The differences between the subject device and predicate devices do not raise new issues of safety or effectiveness.

Elements of Comparison	**Subject Device**	**Predicate Device1**	**Predicate Device2**	**Verdict**

Elements of Comparison	**Subject Device**	**Predicate Device1**	**Predicate Device2**	**Verdict**
Company	Xiamen Ants Bro Technology Co., Ltd.	Shenzhen Combei Technology Co.,Ltd.	Dongguan Ageless Health Industrial Co., Ltd.	--
Trade Name	Automatic Digital Blood Pressure Monitor	Digital Blood Pressure Monitor Wrist Style	AGE Automatic Upper Arm Blood Pressure Monitor	--
Classification Name	Non-invasive blood pressure measurement system	Non-invasive blood pressure measurement system	Non-invasive blood pressure measurement system	SE
510(k) Number	Applying	K171833	K153552	--
Product Code	DXN	DXN	DXN	SE
Intended Use / Indications for Use	Automatic Digital Blood Pressure Monitor is intended to measure the diastolic, systolic blood pressures and pulse rate of an adult individual in hospitals, hospital-type facilities and home environments by using a non-invasive oscillometric technique in which an inflatable cuff is wrapped around the wrist or the upper arm. The intended wrist circumference is 12.5~20 cm and the intended arm circumference with four sizes: 23~33 cm, 25~35 cm, 22~42 cm, 33~43 cm	The subject device intended to measure the diastolic, systolic blood pressures and pulse rate of an adult individual in hospitals, hospital-type facilities and home environments by using a non-invasive oscillometric technique in which an inflatable cuff (size: 12.5~21.5cm(4.9~8.5in) is wrapped around the single	AGE Automatic Upper Arm 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	SE Note 1

Elements of Comparison	Subject Device	Predicate Device1	Predicate Device2	Verdict
		wrist. The Subject device is not intended to be diagnostic device.	wrapped around the upper arm. The cuff circumference is six sizes.	
Display	LCD Digital Display	LCD Digital Display	LCD Digital Display	SE
Measurement Site	Wrist Upper Arm	Wrist	Upper Arm	SE
Cuff Circumference	Wrist type:12.5~20 cm Arm type: 23~33 cm, 25~35 cm, 22~42 cm, 33~43 cm	12.5~21.5cm	size A: 17cm--22cm size B: 22cm--30cm size C: 24cm--34cm size D: 22cm--42cm size E: 30cm--42cm size F: 42cm--50cm	SE Note 1
Inflation and Deflation	Program-controlled and automatic	Program-controlled and automatic	Program-controlled and automatic	SE
Measuring Method	Non-invasive Oscillometric	Non-invasive Oscillometric	Non-invasive Oscillometric	SE
Measuring scope	Pressure: 30mmHg~280 mmHg; Pulse: 40 bpm~199 bpm	Pressure: 30mmHg~280 mmHg Pulse: 40 bpm ~200 bpm	Pressure: 0mmHg~280 mmHg Pulse: 40 bpm ~200 bpm	SE
Measuring accuracy	Pressure: ±3mmHgPulse: ±5%	Pressure: ± 3mmHg Pulse: ±5%	Pressure: ± 3mmHg Pulse: ±5%	SE
Patient Population	Adult	Adult	Adult	SE
Display	LCD Digital Display	LCD Digital Display	LCD Digital Display	SE
Power Supply	Wrist type:	2x 1.5V “AAA”	4x 1.5V “AA”	SE

Elements of Comparison	**Subject Device**	**Predicate Device1**	**Predicate Device2**	**Verdict**
	2x 1.5V “AAA” batteries Arm type: 4x 1.5V “AA” batteries/ 4x 1.5V “AAA” batteries	batteries	batteries	
Operation condition	Temperature: +5 to +40 °C, Humidity: 15 to 85%, Pressure: 70.0k Pa - 106.0k Pa	Temperature: +5 to +40 °C, Humidity: 15 to 85%,	Temperature: +5 to +40 °C, Humidity: 10 to 90%, Pressure: 86.0k Pa - 106.0k Pa	SE
Transport/storage environment	Temperature:-25°C - +70°C, Humidity:10%～95%, Pressure: 70.0k Pa - 106.0k Pa	Temperature:-10°C - +55°C, Humidity:10%～95%,	Temperature:-20°C - +65°C, Humidity:10%～95%, Pressure: 86.0k Pa - 106.0k Pa	SE
Safety	IEC 60601-1 IEC 60601-1-11 IEC 80601-2-30	IEC 60601-1 IEC 60601-1-11 IEC 80601-2-30	IEC 60601-1	SE
EMC	IEC 60601-1-2	IEC 60601-1-2	IEC 60601-1-2	SE
Dimensions (L * D * H, unit: mm)	BA4110 (AS-35A): 125 X 95 X 60 BA6310 (AS-35E): 140X105X65 A4900 (AS-35W): 133 X 75 X 33 AS-35H: 150 X 110 X 70 AS-35I: 140 X 105 X 62 AS-35K: 135 X 115 X 83	--	--	SE Note 2

Elements of Comparison	Subject Device	Predicate Device1	Predicate Device2	Verdict
	AS-35X: 150 X 110 X 74 AS-35J: 150X 110X 74 AS-35L: 140 X 113 X 73 AS-35F: 140X 10 X 63 AS-55A: 78X 62 X 65 AS-55G: 90 X 66 X26 AS-55M: 89 X 66 X55 AS-55F: 63 X 66 X69			
Weight (not include battery)	BA4110 (AS-35A): about 300g BA6310 (AS-35E): about 300g A4900 (AS-35W): about 300g AS-35H: about 300g AS-35I: about 250g AS-35K: about 250g AS-35X: about 300g AS-35J: about 328g AS-35L: about 280g AS-35F: about 281g AS-55A: about 95g AS-55G: about 95g AS-55M: about 100g	--	--	SE Note 2

Elements of Comparison	Subject Device	Predicate Device1	Predicate Device2	Verdict
	AS-55F: about 102g			

Comparison in Detail(s):

Note 1:

Although “Intended Use / Indications for Use” and “Cuff Circumference” of the subject device are a little different from the predicate devices, but the different circumference range of subject device can be covered by the combination range of the predicate device K171833 and K153552, they are very similar. So these parameters’ differences will not raise any safety or effectiveness issue.

Note 2:

Although the “Dimensions” and “Weight” of the subject device are a little different from the predicate devices, but all these factors are not the essential parameters of the device which will not affect the effectiveness, and all of them are complied with the safety standards IEC 60601-1, IEC 60601-1-11 and IEC 80601-2-30, which show the safety of subject device, so these parameters’ differences will not raise any safety or effectiveness issue.

Final Conclusion：

The subject device Non-invasive Sphygmomanometer (Automatic Digital Blood Pressure Monitor) (Model: BA4110/AS-35A, BA6310/AS-35E, BA4900/AS-35W, AS-35K, AS-35I, AS-35H, AS-35X, AS-35J, AS-35L, AS-35F, AS-55G, AS-55A, AS-55M, AS-55F) has all features of the predicate device. Thus, the subject device is substantially equivalent to the predicate device.

9. Date of the summary prepared: May 27, 2020