January 3, 2019

Alicn Medical (Shenzhen), Inc
Meisong Fang
Manager
4/F, B Building, Shenfubao Modern Optical Factory
Kengzi Street, Pingshan District
Shenzhen, 518122
CHINA

Re: K180435
Trade/Device Name: 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: November 26, 2018
Received: November 26, 2018

Dear Meisong Fang:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/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 -S5

for

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
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)*
K180435

Device Name
Arm Blood Pressure Monitor

Indications for Use *(Describe)*
The Arm 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 upper arm. It can be used at medical facilities or at home. The intended upper arm circumference is 22-32cm.Suitable for adults who over the age of 12.

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

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

The assigned 510(k) number is: _K180435___

1.0 Information of Submitter and Correspondent

Submitter's information:

Alicn Medical (Shenzhen), Inc.
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Submission correspondent's information:

Shenzhen Reanny Medical Devices Management Consulting Co., Ltd
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Contact Person: Reanny Wang; E-mail: cefdacfda@163.com

2.0 Device Information

Type of 510(k) submission:	Traditional
Trade Name:	Arm blood pressure monitor
Model:	AES-U171, AES-U181 and AES-U131
Classification name:	System, Measurement, Blood-Pressure, Non-Invasive
Review Panel:	Cardiovascular
Product Code:	DXN
Device Class:	II
Regulation Number:	21 CFR 870.1130

3.0 Predicate Device Information

Sponsor:	Shenzhen Urion Technology Co., Ltd.
Device:	Upper Arm Electronic Blood Pressure Monitor, U80AH
510(K) Number:	K160019

4.0 Device Description

The arm blood pressure monitor model AES-U171, AES-U181, AES-U131 are sphygmomanometers with electronic manometer intended to be used for the indirect (non-invasive) measurement of diastolic, systolic blood pressure and pulse rate using a standard oscillometric method for adults who over the age of 12 (not for neonatal) . The inflatable cuff is wrapped around the upper arm of an individual. The systolic and diastolic blood pressures are transmitted via air pressure and determined by the transducer integrated on the monitor with the oscillometric method. The systolic and diastolic blood pressure values and pulse rate per minute are displayed on the LCD panel.

The monitors AES-U171, AES-U181 and AES-U131 have the same measurement principle, specification, structure, intended use and similar software, the main differences are appearance, and AES-U171 have print function.

5.0 Intended Use

The Arm 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 upper arm. It can be used at medical facilities or at home. The intended upper arm circumference is 22-32cm.Suitable for adults who over the age of 12.

6.0 Performance Summary

Clinical Test Summary

Testing to insure clinical accuracy of the device in accordance with ISO 81060-2 as documented in Clinical Test report. Eighty-six patients (43 males and 43 females) were invited for the study. Standard auscultation method was used as the reference blood pressure monitor measuring in the left arm. Blood pressure measurements were repeated

alternatively with the device and auscultation in the same arm according to the sequence in ISO 81060-2.

Non-Clinical Test Summary

The Subject Device has performed several non-clinical tests to show that all requirement specifications and standard requirements are met. The tests include the follows:

☐ IEC 60601-1:2005+Am1:2012

☐ IEC 60601-1-2:2007

☐ IEC 60601-1-11:2015

☐ IEC 80601-2-30:2009

7.0 Comparison to predicate device and conclusion

The subject device is substantially equivalent to predicate devices, K160019, U80AH. The substantial equivalence chart is provided as follows:

Elements of Comparison	Predicate Device (K160019)	Subject Device			Judgment
Models	**U80AH**	**AES-U171**	**AES-U181**	**AES-U131**	**--**
Company	Shenzhen Urion Technology Co., Ltd.	Alicn Medical (Shenzhen), Inc.			--
Device Name	Upper Arm Electronic Blood Pressure Monitor	Arm Blood Pressure Monitor			--
Product code	DXN	DXN			SE
Regulation #	21CFR870.1130	21CFR870.1130			SE
Intended use	The U80 Series Upper Arm Electronic 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 upper arm. It can be used at medical facilities or at home. The intended upper arm circumference is 22-36cm.Suitable for adults who over the age of 12.	The Arm 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 upper arm. It can be used at medical facilities or at home. The intended upper arm circumference is 22-32cm.Suitable for adults who over the age of 12.			SE, only upper arm circumference is difference, refer to Remark 3

Elements of Comparison	Predicate Device (K160019)	Subject Device			Judgment
Models	**U80AH**	**AES-U171**	**AES-U181**	**AES-U131**	**--**
Measurement type	Upper arm	Upper arm			SE
Patient population	Adults person over 12	Adults person over 12			SE
Measurement Item	SYS, DYS, Pulse rate	SYS, DYS, Pulse rate			SE
Principle	Oscillometric	Oscillometric			SE
BP measurement range	0-290mmHg	0-290mmHg (0-39kPa)			SE
BP accuracy	±3mmHg (±0.4kPa)	±3mmHg (±0.4kPa)			SE
PR measurement range	40-199 bpm	40-199 pulses/min			SE
PR measurement accuracy	±5% of reading	±5% of reading			SE
Power supply	DC6.0V, 4×AA alkaline batteries or AC adapter	DC7.4V /850mAh internal polymer li-ion battery	DC6.0V, 4×AAA batteries		SE, refer to remark 1
Waterproof	IP22	IP21			SE, refer to remark 2
Degree of protection against electric shock	Type BF applied part	Type BF applied part			SE
Cuff size suitable for arm size	About 22cm between 36cm	cuff: 22cm~32cm			SE, refer to Remark 3
Automatic power off	In 3 minutes	Automatically turn off after 60 seconds			Difference, Refer to Remark 4

Elements of Comparison	Predicate Device (K160019)	Subject Device			Judgment
Models	**U80AH**	**AES-U171**	**AES-U181**	**AES-U131**	**--**
Operation environment	5 ℃ -40°C, 15%-80%RH, 70-106kPa	5℃-40°C, 15%-80%RH, 70-106kPa			SE
Storage environment	-20℃-55℃, 10% -85% RH, avoid crash, sun burn or rain during transportation	-20℃-55℃, 15% -85% RH, 70-106kPa			SE, Refer to Remark 5

Remark 1 :

The power supply of subject device AES-U171 is DC7.4V /850mAh internal polymer li-ion battery, and the predicate device U80AH is DC6.0V, 4×AA alkaline batteries. The subject devices are compliance with IEC 60601-1, IEC 60601-1-2 and IEC 60601-1-11 standards. So the difference will not raise any safety or effectiveness issue.

Remark 2 :

The Arm blood pressure monitor is portable medical equipment in non-transit-operable use, according to IEC 60601-1-11 standard requirement, the enclosure ingress of water and particulate matter requirement should be IP21 at least. The subject devices are compliance with IEC 60601-1-11 standard requirement. So the difference will not raise any safety or effectiveness issue.

Remark 3:

The intended arm circumferences (22-32 cm) of the proposed and predicate device are different. This difference is very slight, and the cuff size is appropriate to the claimed intended arm circumference per IEC 80601-2-30.Therefore, this point is considered as substantially equivalent.

Remark 4:

The time of automatic power off is difference with predicate device, the time of subject devices is less than predicate device, but they are both compliance with the IEC 80601-2-30 standard, so the difference will not raise any safety or effectiveness issue.

Remark 5:

The Relative Humidity of storage environment of subject devices is difference with predicate device, and they are both compliance with IEC60601-1-11 standard, it will not raise any safety or effectiveness issue.

8.0 Conclusions

Arm blood pressure monitor, Model AES-U171, AES-U181 and AES-U131 have the same intended use and similar characteristics as the predicate device. Moreover, the subject device demonstrates product safety by successful completion of testing to the IEC 60601-1 standard and electromagnetic standard IEC 60601-1-2. The performance test demonstrates the monitors meet the IEC 80601-2-30 and clinical test meets the ISO 81060-2. These conclude that any differences in their characteristics do not raise any safety and effectiveness issues.

Form the above information we conclude the subject device, AES-U171, AES-U181 and AES-U131are substantially equivalent to the predicate devices, U80AH.

9.0 Summary prepared date

February 7, 2018