November 20, 2017

Ningbo Albert Novosino Co.,Ltd.
% Ms. Doris Dong
Manager
Shanghai CV Technology Co., Ltd.
Room 903 of Dongbao Building
No. 19 Dongbao Road, Songjiang Area
Shanghai, 201316 Cn

Re: K173044
Trade/Device Name: Reusable Blood Pressure Cuff, Disposable Blood Pressure Cuff
Regulation Number: 21 CFR 870.1120
Regulation Name: Blood Pressure Cuff
Regulatory Class: Class II
Product Code: DXQ
Dated: September 20, 2017
Received: September 28, 2017

Dear Ms. Doris Dong:

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. 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); good

manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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,

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)*
K173044

Device Name
REUSABLE BLOOD PRESSURE CUFF; DISPOSABLE BLOOD PRESSURE CUFF

Indications for Use *(Describe)*
The REUSABLE BLOOD PRESSURE CUFF is an accessory used in conjunction with noninvasive blood pressure measurement systems. The cuff is non-sterile and may be reused. It is available in infant, pediatric and adult sizes.
The DISPOSABLE BLOOD PRESSURE CUFF is an accessory used in conjunction with noninvasive blood pressure measurement systems. The cuff is non-sterile and for single-patient use. It is available in neonatal, pediatric and adult sizes.

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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Section 5
510(k) Summary
[As required by 21 CFR 807.92]

1. Submission Sponsor

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3. Date Prepared

Sept 20, 2017

4. Device Identification

Trade/Proprietary Name:
REUSABLE BLOOD PRESSURE CUFF; DISPOSABLE BLOOD PRESSURE CUFF
Common Name/Classification Name: Blood Pressure Cuff
Product Code: DXQ
Regulation Number: 21 CFR 870.1120
Regulation Class: Class II
Review Panel: Cardiovascular

5. Predicate Devices

The proposed devices are substantially equivalent to the following predicate devices:

Applicant	Device name	510(k) Number	Product code
Shenzhen Vistar Medical Supplies Co., Ltd.	Disposable Blood Pressure Cuff	K152465	DXQ

Shenzhen Vistar Medical Supplies Co., Ltd.	Reusable Blood Pressure Cuff	K152468	DXQ

6. Device Description

The proposed device is an accessory used in conjunction with noninvasive blood pressure measurement systems. It is available in neonatal, infant, pediatric and adult sizes.

The proposed device includes disposable blood pressure cuff and reusable blood pressure, both disposable and reusable blood pressure cuff has same structure, which contains Cuff with bladder and Air Hose. Air hose has single tube and double tube.

The disposable blood pressure cuff is single use device, and which is made of non-woven fabrics &PVC (Cuff) and PVC (Air Hose), thereinto, the non-woven fabrics & PVC (Cuff) is the material used to contacting with the patient.

The disposable blood pressure cuff has 26 models with different size for different population with different arm size, and the 13 models of 26 are use single tube of air hose and other 13 models are use double tube of air hose, which is used for different noninvasive blood pressure measurement system.

The reusable blood pressure cuff is reusable device, and which is made of 210D Nylon TPU (Cuff) and PVC (Air Hose), thereinto, the 210D Nylon TPU (Cuff) is the material used to contacting with the patient.

The reusable blood pressure cuff has 16 models with different size for different population with different arm size, and the 8 models of 16 are use single tube of air hose and other 8 models are use double tube of air hose, which is used for different noninvasive blood pressure measurement system.

7. Indication for Use Statement

• REUSABLE BLOOD PRESSURE CUFF

Is an accessory used in conjunction with noninvasive blood pressure measurement systems. The cuff is non-sterile and may be reused. It is available in infant, pediatric and adult sizes.

• DISPOSABLE BLOOD PRESSURE CUFF

Is an accessory used in conjunction with noninvasive blood pressure measurement systems. The cuff is non-sterile and for single-patient use. It is available in neonatal, pediatric and adult sizes.

8. Comparison of Technological Characteristics

The following table compares the proposed devices to the predicate device with respect to

intended use, technological characteristics and principles of operation, providing more detailed information regarding the basis for the determination of substantial equivalence.

Table 5A – General Comparison(DISPOSABLE BLOOD PRESSURE CUFFS)

ITEM	Proposed Device	Predicate Device	Remark
Trade name	DISPOSABLE BLOOD PRESSURE CUFF	DISPOSABLE BLOOD PRESSURE CUFF	
510(K) Submitter	Ningbo Albert Novosino Co.,Ltd.	Shenzhen Vistar Medical Supplies Co., Ltd.	
510(K) Number	K173044	K152465	
Classification Regulation	21CRF 870.1120	21CRF 870.1120	SE
Classification and Code	Class II, DXQ	Class II, DXQ	SE
Common name	Non-invasive Blood Pressure Cuff	Non-invasive Blood Pressure Cuff	SE
Intended Use	The disposable blood pressure cuff is an accessory used in conjunction with noninvasive blood pressure measurement systems. The cuff is non-sterile and for single-patient use. It is available in neonatal, pediatric and adult sizes.	The disposable blood pressure cuff is an accessory used in conjunction with noninvasive blood pressure measurement systems. The cuff is non-sterile and for single-patient use. It is available in neonatal, pediatric and adult sizes.	SE
Patient Populations	Adults/Pediatrics	Adults/Pediatrics	SE
Tube Configuration	One or two tube	One or two tube	SE
Principles of Operation	Bladder is wrapped around the patient's limb and secured by hook and loop closure Air hose is connected to the noninvasive blood pressure measurement systems	Bladder is wrapped around the patient's limb and secured by hook and loop closure Air hose is connected to the noninvasive blood pressure measurement systems	SE
Size	Conform to AHA bladder sizes Recommendations Neonatal 1 (3-6 cm) Neonatal 2 (4-8cm) Neonatal 3 (6-11 cm) Neonatal 4 (7-13 cm)	Conform to AHA bladder sizes Recommendations Neonatal 1 (3-6 cm) Neonatal 2 (4-8 cm) Neonatal 3 (6-11 cm) Neonatal 4 (7-13 cm)	Analysis 1

	Neonatal 5 (8-15cm) Infant (8-14 cm) Child (13-20 cm) Small Adult (18-26 cm) Adult (26-35 cm) Adult Long (29-38 cm) Large Adult (32-42 cm) Large Adult Long (35-44 cm) Thigh (42 – 50 cm)	Neonatal 5 (8-15 cm) Infant (9-14.8 cm) Child (13.8-21.5 cm) Small Adult (20.5-28.5 cm) Adult (27.5-36.5 cm) Adult Long (27.5-36.5 cm) Large Adult(35.5-46 cm) Large Adult (35.5 – 46 cm) Thigh (45 – 56.5 cm)	
Single Use	Y	Y	SE
Sterile	No	No	SE
Pressure Range	0-300 mmHg	0-300 mmHg	SE
Max.Pressure	400mmHg	400mmHg	SE
Tubing Size(mm)	OD = 8.0; ID=4.0; L=200;	OD = 8.0; ID=4.0; L=200;	SE
Max. Leakage	< 4mm Hg/ min.	< 4mm Hg/ min.	SE
Material	non-woven fabrics & PVC (Cuff) and PVC (Air Hose)	non-woven fabrics & PVC (Cuff) and PVC (Air Hose)	SE

Table 5B – General Comparison(REUSABLE BLOOD PRESSURE CUFFS)

ITEM	Proposed Device	Predicate Device	Remark
Trade name	REUSABLE BLOOD PRESSURE CUFF	REUSABLE BLOOD PRESSURE CUFF	
510(K) Submitter	Ningbo Albert Novosino Co.,Ltd.	Shenzhen Vistar Medical Supplies Co., Ltd.	
510(K) Number	K173044	K152468	
Classification Regulation	21CRF 870.1120	21CRF 870.1120	SE
Classification and Code	Class II, DXQ	Class II, DXQ	SE
Common name	Non-invasive Blood Pressure Cuff	Non-invasive Blood Pressure Cuff	SE
Intended Use	The reusable blood pressure cuff is an accessory used in conjunction with noninvasive blood pressure measurement systems. The cuff is non-sterile and may be reused. It is available	The reusable blood pressure cuff is an accessory used in conjunction with noninvasive blood pressure measurement systems. The cuff is non-sterile and may be reused. It is available	SE

	in infant, pediatric and adult sizes.	in infant, pediatric and adult sizes.	
Patient Populations	Adults/Pediatrics	Adults/Pediatrics	SE
Tube Configuration	One or two tube	One or two tube	SE
Principles of Operation	Bladder is wrapped around the patient's limb and secured by hook and loop closure Air hose is connected to the noninvasive blood pressure measurement systems	Bladder is wrapped around the patient's limb and secured by hook and loop closure Air hose is connected to the noninvasive blood pressure measurement systems	SE
Size	Conform to AHA bladder sizes Recommendations Infant (8-14 cm) Child (13-20 cm) Small Adult (18-26 cm) Adult (26-35 cm) Adult Long (29-38 cm) Large Adult (32-42 cm) Large Adult Long (35-44 cm) Thigh (42 – 50 cm)	Conform to AHA bladder sizes Recommendations Infant (8-13 cm) Child (12-19 cm) Small Adult (17-25 cm) Adult (23-33 cm) Adult Long (23-33 cm) Large Adult(31-40 cm) Large Adult Long (31 – 40 cm) Thigh (38 – 50 cm)	Analysis 1
Single Use	Y	Y	SE
Sterile	No	No	SE
Pressure Range	0-300 mmHg	0-300 mmHg	SE
Max.Pressure	400mmHg	400mmHg	SE
Tubing Size(mm)	OD = 8.0; ID=4.0; L=200;	OD = 8.0; ID=4.0; L=200;	SE
Max. Leakage	< 4mm Hg/ min.	< 4mm Hg/ min.	SE
Material	210D Nylon TPU (Cuff) and PVC (Air Hose)	210D Nylon TPU (Cuff) and PVC (Air Hose)	SE

Analysis 1:
The proposed device has different cuff sizes compared with the predicate device for different patient arm circumference. The proposed devices are compliant with the ISO 81060-1 for the performance and Biocompatibility test and ISO 10993-1 for safety. We consider that these differences do not affect the substantial equivalence, safety or effectiveness when compared with the predicate device.

Table 5C – Biocompatibility Comparison

ITEM	Proposed Device	Predicate Device	Remark
Cytotoxicity	Under the conditions of the study, not	Comply with ISO 10993-5	SE

	cyteotoxicity effect		
Irritation	Under the conditions of the study, not an irritant	Comply with ISO 10993-10	SE
Sensitization	Under conditions of the study, not a sensitizer.		SE

Conclusion:
The proposed devices share the same indications for use, device operation, overall technical and functional capabilities, meet the same standards and requirements and therefore, are substantially equivalent to the predicate device(s).

9. Non-Clinical Test Conclusion

Non clinical tests were conducted to verify that the proposed device met all design specifications as was Substantially Equivalent (SE) to the predicate device. The test results demonstrated that the proposed device complies with the following standards:
• AAMI / ANSI / ISO 10993-5:2009/(R) 2014, Biological Evaluation Of Medical Devices -- Part 5: Tests For In Vitro Cytotoxicity.
• ISO 10993-10 Third Edition 2010-08-01, Biological Evaluation Of Medical Devices - Part 10: Tests For Irritation And Skin Sensitization.
• ISO 81060-1:2007 Non-Invasive Sphygmomanometers - Part 1: Requirements And Test Methods For Non-Automated Measurement Type

10. Clinical Test Conclusion

No clinical study is included in this submission.

11. Statement of Substantial Equivalence

It has been shown in this 510(k) submission that the difference between the proposed devices and the predicate devices do not raise any questions regarding safety and effectiveness. Performance testing and compliance with voluntary standards, demonstrate that the proposed are substantially equivalent to the relevant aspects of the predicate devices in terms of design, components, materials, principals of operation, biocompatibility, performance characteristics, and intended use. Therefore the proposed devices are determined to be substantially equivalent to the referenced predicate Devices.