DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

June 30, 2015

Jiaxing Zhongfa Medical Products Co., Ltd.
% Mr. Ray Wang
Official Correspondent
Beijing Believe Tech Service Co., Ltd.
1-202, Build 3, Beijing New World, No.5 Chaoyang Rd.,
Chaoyang District
Beijing, 100024 CN

Re: K151246
Trade/Device Name: Aneroid Sphygmomanometer, Models ZF-113, ZF-114, and ZF-115
Regulation Number: 21 CFR 870.1120
Regulation Name: Blood Pressure Cuff
Regulatory Class: Class II
Product Code: DXQ
Dated: May 6, 2015
Received: May 11, 2015

Dear Mr. Ray Wang,

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.

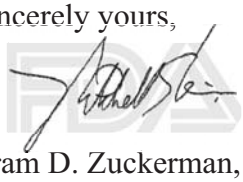
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K151246

Device Name
Aneroid Sphygmomanometer, Models ZF-113, ZF-114, and ZF-115

Indications for Use *(Describe)*

The Aneroid Sphygmomanometer is a non-automated, mechanical blood pressure monitor that is used for the indirect measurement (non-invasive) and display of arterial blood pressure. It can be used by professionals as well as trained individual users over age 18 at hospitals or at home to monitor both systolic and diastolic pressure.

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 510(k) Summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of SMDA 1990 and Title 21, CFR Section 807.92.

The assigned 510(k) Number: _____

1. Date of Preparation:2015/5/6

2. Sponsor Identification

Jiaxing ZhongFa Medical Products Co.,Ltd.
No.38 Building 1, Zhong Fa Group, Zhuang Shi Village, Feng Qiao Town,
Nanhu District, Jiaxing City, Zhejiang Province, China 314008

Establishment Registration Number: Pending

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3. Designated Submission Correspondent

Mr. Ray Wang

Beijing Believe Tech. Service Co., Ltd

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Email: Ray.Wang@believe-med.com

4. Identification of Proposed Device

Trade Name: Aneroid Sphygmomanometer
Common Name: Aneroid Sphygmomanometer
Model(s): ZF113, ZF114, ZF115

Regulatory Information

Classification Name: Blood Pressure Cuff
Classification: 2
Product Code: DXQ
Regulation Number: 870.1120
Review Panel: Cardiovascular

Intended Use Statement:
The Aneroid Sphygmomanometer is a non-automated, mechanical blood pressure monitor that is used for the indirect measurement (non-invasive) and display of arterial blood pressure. It can be used by professionals as well as trained individual users over age 18 at hospitals or at home to monitor both systolic and diastolic pressure.

Device Description
The Aneroid Sphygmomanometer with stethoscope is a non-invasive blood pressure measurement system for monitoring blood pressure levels. This non-automated sphygmomanometer uses an occluding cuff, an sphygmomanometer to measure pressure and a stethoscope for detecting Korotkoff sounds.

The Aneroid Syphygmomanometer contains:

a. Blood Pressure Cuff
b. Stethoscope, which is use to detect the Korotkoff sounds;
c. Rotary Pin, 300 mmHg gauge, which is use to indicate the measurement result;
d. Air pump bulb, which is use to inflate the blood pressure cuff;
e. User Manual, which is use to instruct the user;

The Aneroid Sphygmomanometer with Stethoscope enables the user to monitor the pressure of flowing blood that is exerted against the arteries at highest (systolic or contraction) and lowest (diastolic or relaxation) pressure.

The proposed device has three models, ZF-113/ZF-114/ZF-115, in this submission, the three models has same intended use, same design and measuring principle, same accessories and same measuring range. The only difference between the models is appearance of gauge.

5. Identification of Predicate Device(s)

Predicate Device
K092245
Aneroid Sphygmomanometer with Stethoscope, Model LD-100
HONSUN(NANTONG) CO., LTD.

6. 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:

- ISO 10993-5: 2009 Biological Evaluation Of Medical Devices -- Part 5: Tests For In Vitro Cytotoxicity;
- ISO 10993-10: 2010 Biological Evaluation Of Medical Devices - Part 10: Tests For Irritation And Skin Sensitization;
- EN ISO 81060-1:2012 Non-Invasive Sphygmomanometers – Part 1: Requirements and Test Methods for Non-Automated Measurement Type;
- Bench Testing for the performance of Accuracy;

7. Clinical Test Conclusion

No clinical study is included in this submission.

8. Substantially Equivalent (SE) Comparison

Table 1 General Comparison

ITEM	Proposed Device	Predicate Device	Remark
Intended Use	The Aneroid Sphygmomanometer is a non-automated, mechanical blood pressure monitor that is used for the indirect measurement (non-invasive) and display of arterial blood pressure. It can be used by professionals as well as trained individual users over age 18 at hospitals or at home to monitor both systolic and diastolic pressure.	The Aneroid Sphygmomanometer is a non-automated, mechanical blood pressure monitor that is used for the indirect measurement (non-invasive) and display of arterial blood pressure. It can be used by professionals as well as trained individual users over age 18 at hospitals or at home to monitor both systolic and diastolic pressure. The device is for use in OTC.	SE
Operating Principle	The Aneroid Sphygmomanometer with Stethoscope is a non-invasive blood pressure measurement system for monitoring blood pressure levels. This non-automated sphygmomanometer uses an occluding cuff, an aneroid sphygmomanometer to measure pressure and a stethoscope for detecting Korotkoff sounds.	The Aneroid Sphygmomanometer with Stethoscope is a non-invasive blood pressure measurement system for monitoring blood pressure levels. This non-automated sphygmomanometer uses an occluding cuff, an aneroid sphygmomanometer to measure pressure and a stethoscope for detecting Korotkoff sounds.	SE
Basic Design	The principle of sphygmomanometer is base on hooke's law, the flexible sensitive component (mirco-pressure file box) will be flexible deformation under the influence of pressure and use the mechanical group (gear set) to amplify the pressure value and indicate the value in the gauge.	The principle of sphygmomanometer is base on hooke's law, the flexible sensitive component (mirco-pressure file box) will be flexible deformation under the influence of pressure and use the mechanical group (gear set) to amplify the pressure value and indicate the value in the gauge.	SE
Measuring Method	Aneroid / Auscultatory	Aneroid / Auscultatory	SE
Inflation system:	Manual inflation with air pump bulb	Manual inflation with air pump bulb	SE
Deflation system:	Manual deflation	Manual deflation	SE
Components	Blood Pressure Cuff (Audit)/ Stethoscope/Rotary Pin, 300 mmHg gauge/ Air pump bulb	Adjustable D-ring Cuff (Audit Size)/ Stethoscope/ Non-stop rotary pin, 300 mmHg gauge	SE
Measuring range:	Pressure: 0 - 300 mmHg	Pressure: 0 - 300 mmHg	SE
Accuracy:	Pressure: ±3 mmHg	Pressure: ±3 mmHg	SE

Table 2 Biocompatibility Comparison

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

9. Substantially Equivalent (SE) Conclusion

Based on the comparison and analysis above, the proposed devices are determined to be Substantially Equivalent (SE) to the predicate devices.