May 30, 2018

Wenzhou Bokang Instruments Co., Ltd
Youhua Xiang
General Manager
No. 1500 Haining Road, Haibin Longwan
Wenzhou, 325024 Zhejiang, China

Re: K173246
Trade/Device Name: Aneroid Sphygmomanometer, M BK2002, BK2002-3001, BK2002a, BK2002a-3001, BK2015, BK2015-3001
Regulation Number: 21 CFR 870.1120
Regulation Name: Blood Pressure Cuff
Regulatory Class: Class II
Product Code: DXQ, LDE
Dated: September 28, 2017
Received: October 6, 2017

Dear Youhua Xiang:

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)*
K173246

Device Name
Aneroid Sphygmomanometer, Models BK2002, BK2002-3001, BK2002a, BK2002a-3001, BK2015, BK2015-3001

Indications for Use *(Describe)*
The device is intended to be used by medical professionals or in the home for the measurement of systolic and diastolic pressure. The device is intended to be manually attached to a patient and manually inflated along with a manual method for detecting Korotkoff sounds.

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

Company Name:	WENZHOU BOKANG INSTRUMENTS CO., LTD
Company Address:	No. 1500 Haining Rd., Haibin Longwan
	Wenzhou, 325024 Zhejiang, China
Telephone:	+86-577-86876969
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Contact Person:	Youhua Xiang
Summary Preparation Date:	2017.9.28
Device Trade Name:	Aneroid Sphygmomanometer, Models BK2002, BK2002-3001,
	MODEL BK2002a, BK2002a-3001, BK2015, BK2015-3001
Classification Name:	Blood pressure cuff, Stethoscope, manual
Regulation Number:	21 CFR 870.1120/ 21 CFR 870.1875
Product Code:	DXQ; LDE
Device Class:	Class 2
Panel:	Cardiovascular

PREDICATE DEVICE:

ANEROID SPHYGMOMANOMETER, MODEL BK2002 (K043286)

INDICATIONS FOR USE

The device is intended to be used by medical professionals or in the home for the measurement of systolic and diastolic pressure. The device is intended to be manually attached to a patient and manually inflated along with a manual method for detecting Korotkoff sounds.

DEVICE DESCRIPTION

Aneroid Sphgmomanometer, Models BK2002, BK2002-3001, BK2002a, BK2002a-3001, BK2015, BK2015-3001, are a manual non-invasive aneroid sphygmomanometer which respectively uses an inflation cuff wrapped around the upper arm. The cuff is inflated and deflated by a manual inflation bulb. Besides a manometer (Aneroid gauge), the accessories of MODEL BK2002, BK2002-3001, BK2015, BK2015-3001 also includes one selected cuff, one inflation bulb, instruction manual and a vinyl

bag. Model BK2002-3001 and BK2015-3001 include additional stethoscope. It is conjunction with Stethoscope when use.

This is modified device differs from the original one (K043286) in terms of added the optional PVC inflation bulb (original bulb is made of nature latex) and in terms of added the optional various size of cuffs which cuffs outside layer is made of Nylon Cloth and inside bladder is made of PVC or nature latex (original bulb is made of nature latex and cuff outside layer is made of Cotton Cloth).

Substantial Equivalence Comparison

It is substantially equivalent to the predicate device (K043286), Aneroid Sphgmomanometer MODEL BK2002, BK2002-3001, MODEL BK2002a, BK2002a-3001, BK2015, BK2015-3001 MODEL with respect to indications for use, device description, and technical characteristics.

All comparison table for applied devices are as following, and the substantial equivalence determination is based on the 510(k) Substantial Equivalence Decision-Making Process Flowchart which includes the comparison and discussion of indications for use, technology, and performance specifications.

The new device column includes the following devices: MODEL BK2002, BK2002-3001, MODEL BK2002a, BK2002a-3001, BK2015, BK2015-3001 MODEL

comparison item	**New device ANEROID SPHYGMOMANOMETER, MODEL BK2002, BK2002-3001, BK2015, BK2015-3001**	**Predicate device ANEROID SPHYGMOMANOMETER, MODEL BK2002 (K043286)**	**Result of Comparasion**
Applicant	WENZHOU BOKANG INSTRUMENTS CO., LTD	WENZHOU BOKANG INSTRUMENTS CO., LTD	SAME
Classification	Class II	Class II	SAME
Regulation	21CFR 870.1120	21CFR 870.1120	SAME

comparison item	New device ANEROID SPHYGMOMANOMETER, MODEL BK2002, BK2002-3001, BK2015, BK2015-3001	Predicate device ANEROID SPHYGMOMANOMETER, MODEL BK2002 (K043286)	Result of Comparasion
number			
Product code	DXQ, LDE	DXQ, LDE	SAME
Indications for use	The device is intended to be used by medical professionals or at home for the measurement of systonic and diastonic pressure by detecting Korotkoff sounds.	The device is intended to be used by medical professionals or at home for the measurement of systonic and diastonic pressure on adult by detecting Korotkoff sounds.	Similar
Over-The-Counter Use	Yes	Yes	SAME
Where used	Home, Hospital, heathcare facility, ambulance etc.	Home, Hospital, heathcare facility, ambulance etc.	SAME
Target population	Children (greater than 2 to 12 years of age) Young Adults (greater than 12 to 21 years of age) Adults (greater than 21	Adult (greater than 21 years of age)	Different

comparison item	New device ANEROID SPHYGMOMANOMETER, MODEL BK2002, BK2002-3001, BK2015, BK2015-3001	Predicate device ANEROID SPHYGMOMANOMETER, MODEL BK2002 (K043286)	Result of Comparasion
	years of age)		
Anatomical sites	Upper Arm (leg for child)	Upper Arm	Different
Measurement Method	Auscultatory Korotkoff sounds Method	Auscultatory Korotkoff sounds Method	SAME
Inflation	Manual by inflation bulb	Manual by inflation bulb	SAME
Deflation	Manual deflation via valve	Manual deflation via valve	SAME
Display	Aneroid Manometer	Aneroid Manometer	SAME
The monitor scale	From 0 to 300 mmHg with a minimum interval of 2 mmHg.	From 0 to 300 mmHg with a minimum interval of 2 mmHg.	SAME
Design	The device comprises tubing attached to a soft inelastic cuff with an integrated inflatable bladder that is wrapped around the patient's limb and secured by hook and loop closure. (BK2002/2002-3001):The	The device comprises tubing attached to a soft inelastic cuff with an integrated inflatable bladder that is wrapped around the patient's limb and secured by hook and loop closure. The device tubing is	Same as_ BK2002/2002-3001 Different from BK2015/2015-3001

comparison item	New device ANEROID SPHYGMOMANOMETER, MODEL BK2002, BK2002-3001, BK2015, BK2015-3001	Predicate device ANEROID SPHYGMOMANOMETER, MODEL BK2002 (K043286)	Result of Comparasion
	device tubing is connected to a non-invasive sphygmomanometer. (BK2015/2015-3001):The bulb and aneroid manometer are connected together.	connected to a non-invasive sphygmomanometer.	
Materials	The manometer: aluminum and stainless steel materials. The tubing, inflation bulb: PVC. Cuff: Nylon cloth or cotton cloth for outside layer. Cuff bladder: PVC or nature latex.	The manometer: aluminum and stainless steel materials. The tubing, inflation bulb: nature latex. Cuff: cotton cloth for outside layer. Cuff bladder: nature latex.	Differernt
Accuracy	Pressure:+/- 3 mmHg of reading	Pressure:+/- 3 mmHg of reading	SAME
Compatibility with environment	It can be used from 50°F to 104°F (10℃ to 40℃) and	It can be used from 50°F to 104°F (10℃ to 40℃) and	SAME

comparison item	New device ANEROID SPHYGMOMANOMETER, MODEL BK2002, BK2002-3001, BK2015, BK2015-3001	Predicate device ANEROID SPHYGMOMANOMETER, MODEL BK2002 (K043286)	Result of Comparasion
	15% ~ 85%RH humidity.	15% ~ 85%RH humidity.	
Cuff Size	20”x 5.5” (510mm*140mm) 21.7″x 6.3″ (550mm*160mm) 24.4″x 6.9″ (620mm*175mm) 28.3″x 8.3″ (720mm*210mm) 13.4″x 4.15″ (340mm*105mm) 10.2″x 3″(260mm*75 mm)	15 9”(l) x 4 9”(w) (480mm x 145 mm)	Different
Cuff Circumference	Fits arm circumferences 8.7” to 17.3” (220mm to 440 mm), The standard cuff should be available for use in measuring a child’s leg blood pressure and for children with larger arms.	Fits arm circumferences 8.7” to 17.3” (220mm to 440 mm)	Different
Cuff bladder Size	8.7”x 4.7”(220mm*120mm) 11.8”x 5.9”(300mm*150mm) 13.4”x	8 8”(l) x 4 8”(w) (225mm x 120 mm)	Different

comparison item	New device ANEROID SPHYGMOMANOMETER, MODEL BK2002, BK2002-3001, BK2015, BK2015-3001	Predicate device ANEROID SPHYGMOMANOMETER, MODEL BK2002 (K043286)	Result of Comparasion
	6.7”(340mm*170mm) 6.9”x 3.3”(175mm*85mm) 7.5”x 2”(190mm*50mm)		
Cuff Color	Blue, Gray, Red, Green, Yellow, Black	Blue, Gray, Red, Green, Yellow, Black	Same
Contents (with accessories)	Aneroid gauge, Arm Cuff, Inflation Bulb, Vinyl storage pouch and Instruction Manual, Stethoscope (BK2002-3001 and BK2015-3001 only)	Aneroid gauge, Arm Cuff, Inflation Bulb, Vinyl storage pouch and Instruction Manual, Stethoscope (option)	Same
Biocompatibility	biocompatible as requirement of ISO 10993-1 ISO 10993-5 ISO 10993-10	biocompatible as requirement of ISO 10993-1 ISO 10993-5 ISO 10993-10	Same
Performance	compatible as requirement of ISO 81060-1	compatible as requirement of AAMI SP9	Similar

Discussion

Comparing with the predicate device, ANEROID SPHYGMOMANOMETER Model BK2002 (K043286), modified ANEROID SPHYGMOMANOMETER Model BK2002, BK2001-3001, BK2015 and BK2015-3001 have same product name, classification and product code, product physical design and operation, same Aneroid gauge, packaging

materials, performance parameter ranges, physical properties, mechanical properties, biocompatibility. The differences between those two devices are as following,

- The AAMI SP9 standard which predicate device complied with is invalid to FDA recognized standard, and current recognized standard is ISO 81060-1:2010. All verification and validation activities, such as comparison test between modified device and original one was performed and the results demonstrated that predetermined acceptance criteria were met the requirement of standards.

- The Nylon cuff, PVC bulb and PVC bladder have been used with another predicate device (K111141, Bokang Digital Blood Pressure Monitor, Model BK6001 which use same bulb and cuff bladder). All the materials which contacts with body skin are no changed as predicate device, and meet the FDA requirement of Biocompatibility.

- The extended sizes of the cuffs are provided optionally in order to accommodate target population besides adults, such as infants, children and young adults. Based on the performance testing in this submission, the slight difference between these blood pressure cuffs does not raise any safety or effectiveness issue. All performance specification was verified to comply with the ISO81060-1 standard. (Please see section 18 of this submission)

Non-Clinical Testing
Non-clinical testing included biocompatibility and bench testing. The tests listed in the ISO10993 and ISO81060-1, were included. Results of testing were acceptable.

C**linical Study**
No clinical study is included in this submission.

CONCLUSION
ANEROID SPHYGMOMANOMETER, MODEL BK2002 have the same intended use and similar technological characteristics as the above predicate devices. Moreover, information contained in this submission supplied demonstrates that any differences in their characteristics do not raise any new questions of safety or effectiveness. Thus, ANEROID SPHYGMOMANOMETER, MODEL BK2002, BK2002-3001, MODEL BK2002a, BK2002a-3001, BK2015, BK2015-3001 MODEL are substantially equivalent to the predicate devices.