October 6, 2018

Shenzhen Kingyield Technology Co., Ltd.
Dacheng Gong
General Manager
Section C2, Fuhai Industrial Zone, Fuyong Town,
Baoan District
Shenzhen, 518000 Cn

Re: K182018
Trade/Device Name: Bluetooth Blood Pressure Monitor, BPW1
Regulation Number: 21 CFR 870.1130
Regulation Name: Noninvasive Blood Pressure Measurement System
Regulatory Class: Class II
Product Code: DXN
Dated: September 5, 2018
Received: September 6, 2018

Dear Dacheng Gong:

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,

Shawn W. Forrest -A

Digitally signed by Shawn W. Forrest -A
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, 0.9.2342.19200300.100.1.1=1300403341, cn=Shawn W. Forrest -A
Date: 2018.10.06 22:21:28 -04'00'

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)*
K182018

Device Name
Bluetooth Blood Pressure Monitor, BPW1

Indications for Use *(Describe)*
This blood pressure monitor is intended to be used to measure blood pressure (systolic and diastolic) and heart rate from the wrist by using the oscillometric method. The device detects the appearance of irregular heartbeats during measurement and gives a symbol with reading. The device is intended for using in only adult population, not applied to the other populations such as neonatal baby. It can't be used while the wrist (arm) has bleeding or wound to avoid the blood flowing from the wound in pressurizing. The wrist circumference is limited to 13.5cm - 21.5cm.

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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510(k) Summary

Date the summary was prepared: September/05/2018

I. Administrative Information

1.1 Submitter/Owner

Name: Shenzhen Kingyield Technology Co., Ltd.

Address: Section C2, Fuhai Industrial Zone, Fuyong Town, Baoan District, Shenzhen, Guangdong 518103, China

Facility registration number: 3007420856

1.2 Contact person

Authorized Contact Person: Dacheng Gong

Position: General Manager

Address: Section C2, Fuhai Industrial Zone, Fuyong Town, Baoan District, Shenzhen, 518103, China

Tel: 86 755 2737 1997

Fax: 86 755 2733 1856

Email: kingyield@kingyield.com

II. MODIFIED DEVICE

Device type by its common name: Bluetooth Blood Pressure Monitor, BPW1

Regulation Number: 21CFR 870.1130

Regulation Name: Noninvasive Blood Pressure Measurement System

Regulatory Class: II

Panel: Cardiovascular

Product Code: DXN

III. PREDICATE/UNMODIFIED DEVICE

Device Name: BP210 Wrist Blood Pressure Monitor

Common/Usual Name: Wrist Blood Pressure Monitor BP210

510(k) Number: K112042

510(k) submitter/holder: Shenzhen Kingyield Technology Co., Ltd.

IV. MODIFIED DEVICE DESCRIPTION

Bluetooth Blood Pressure Monitor, BPW1 is a fully automatic non-invasive blood pressure monitor which measures systolic and diastolic blood pressure and heart rate of adult population using the oscillometric method, including irregular heartbeats (IHB) from the wrist.

The device is powered by a rechargeable Lithium battery.

The device has an START/STOP button for starting the measurement and stopping the measurement at any time when measuring. The MEM button is for displaying the last measurement.

The device can also connect the mobile platform with an MMA (mobile medical application) as its accessory which can start/stop the device through Bluetooth 4.0.

An irregular heartbeats rhythm is defined as a rhythm that varies by 25% less or more than the average rhythm detected while the monitor is measuring the systolic and diastolic blood pressure.

V. INDICATIONS FOR USE

This blood pressure monitor is intended to be used to measure blood pressure (systolic and diastolic) and heart rate from the wrist by using the oscillometric method. The device detects the appearance of irregular heartbeats during measurement and gives a symbol with reading.

The device is intended for using in only adult population, not applied to the other populations such as neonatal baby.

It can't be used while the wrist (arm) has bleeding or wound to avoid the blood flowing from the wound in pressurizing.

The wrist circumference is limited to 13.5cm - 21.5cm.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH PREDICATE/UNMODIFIED DEVICE

Comparison item	Predicate/unmodified device	Modified device	Explanation of the differences
The trade name	BP210 Wrist Blood Pressure Monitor	Bluetooth blood pressure monitor, BPW1	
510(k) Number	K112042		
Applicant	Shenzhen Kingyield technology Co., Ltd.	Shenzhen Kingyield technology Co., Ltd.	Identical
Recommended classification regulation	21CFR 870.1130, Noninvasive Blood Pressure Measurement System	21CFR 870.1130, Noninvasive Blood Pressure Measurement System	Identical
Regulatory Class	II	II	Identical
Panel	Cardiovascular	Cardiovascular	Identical
Product Code	DXN	DXN	Identical
Intended use	BP210 Wrist Blood Pressure Monitor is intended to be used to measure blood pressure (systolic and diastolic) and heart rate from the wrist by using the oscillometric method. The device is intended for using in only adult	This blood pressure monitor is intended to be used to measure blood pressure (systolic and diastolic) and heart rate from the wrist by using the oscillometric method. The device detects the appearance of irregular heartbeats during measurement and gives a symbol with reading.	Identical though the wording is adjusted

	population, not applied to the other populations such as neonatal baby. It can't be used while the wrist (arm) has bleeding or wound to avoid the blood flowing from the wound in pressurizing. The wrist circumference is limited to 13.5cm - 21.5cm.	The device is intended for using in only adult population, not applied to the other populations such as neonatal baby. It can't be used while the wrist (arm) has bleeding or wound to avoid the blood flowing from the wound in pressurizing. The wrist circumference is limited to 13.5cm - 21.5cm.	
Measuring principle	Oscillometric method	Oscillometric method	Identical
Measuring range	Cuff pressure: 0~299 mmHg Pulse : 40~180 beat/min	Cuff pressure: 0~299 mmHg Pulse : 40~180 beat/min	Identical
Max cuff pressure	300mmHg	300mmHg	Identical
Accuracy	Static Pressure: ± 3mmHg Pulse: ± 5% reading value	Static Pressure: ± 3mmHg Pulse: ± 5% reading value	Identical
Inflation	By air pump	By air pump	Identical
Deflation	Not Apply	Not apply	Identical
Pressure release	By automatic valve	By automatic valve	Identical
Dimensional Specifications	Body：77*62*34 Body with cuff：77*62*84	Body：41*47*17.7 Body with bladder & wristband：270.12*41*17.7	Equivalent The changes are tested according to the requirements of the standards IEC 60601-1, IEC 60601-1-2, IEC 62133, EN 1060-3, IEC 80601-2-30, 60601-1-11, EN 300 328, EN 301 489-1, EN 301 489-17, FCC 47 CFR Part 15, Subpart B & FCC 47 CFR Part 15 Subpart C, IEC 62366-1, IEC 60601-1-6, and ISO81060-2. The changes in dimensional specifications are

			documented; do not affect the intended use or the fundamental scientific technology.
Bladder and Cuff	Cuff containing bladder	Bladder + wristband	Equivalent The changes are tested according to the requirements IS081060-2:2013, ISO 10993-1, ISO 10993-5, and ISO 10993-10. The changes in the specifications are documented; do not affect the intended use or the fundamental scientific technology.
Event marking	By pressing the START/STOP button	By pressing the START/STOP button; By click “START/STOP” on APP	Equivalent The change in the specification is documented, the cybersecurity risk has been considered and the overall residual risk is acceptable. The change does not affect the intended use or the fundamental scientific technology.
	By pressing the MEM button	By pressing the MEM button	Equivalent
Display	Device LCD	Device LCD; LCD on collateral device while connecting	Equivalent The changes of the user interface are documented, do not affect the intended use or the fundamental scientific technology..
Operating Temp. & humidity	Temp.: 10~40°C Humidity: 15~90%RH (noncondensing) Atmospheric: 105kPa~80kPa	Temp.: 10~40°C Humidity: 15~90%RH (noncondensing) Atmospheric: 106kPa~80kPa	Equivalent The environmental conditions changes are tested according to the requirements of the standards IEC 80601-2-30

			and IEC60601-1-11. These changes do not affect the intended use.
Storage Temp. & humidity	Temp.: -20~55°C Humidity: 10~90%RH (noncondensing)	Temp.: -20~55°C Humidity: 0~95%RH (noncondensing)	Equivalent The environmental conditions changes are tested according to the requirements of the standards IEC 80601-2-30 and IEC 60601-1-11. These changes do not affect the intended use.
Communication	USB cable--- The memory data can be transferred to the PC by connecting the device with the PC via USB cable	Bluetooth	Equivalent The changes are tested according to the requirements of the standards IEC 80601-2-30 and 60601-1-11. The changes in the specifications are documented; do not affect the intended use or the fundamental scientific technology.
IHB function	IHB function	IHB function	Identical
Memory function	90*2	30	Equivalent The change in the specification is documented and tested, does not affect the intended use or the fundamental scientific technology.
Automatic power-off	In 2 minutes	No automatic power-off function, adding clock function instead.	Equivalent The change in the specification is documented and tested, does not affect the intended use or the fundamental scientific technology.
Clock function	No clock	Yes	Equivalent The change in the

			specification is documented and tested, does not affect the intended use or the fundamental scientific technology.
Material	PC and ABS for the case and plastic foil for the labels of the device. Biocompatible materials are used for the applied parts (Cuff containing bladder).	Zinc alloy for the case of the device and ABS for Button. Biocompatible materials are used for the applied parts (Bladder + wristband).	Equivalent The change in the specification is documented and tested, does not affect the intended use or the fundamental scientific technology.
Energy source	AAA alkaline battery x 2 pcs	Li-ion Rechargeable battery with 250 charging cycles	Equivalent The change in the specification is documented and tested, does not affect the intended use or the fundamental scientific technology.
Sterilization	Not applicable	Not applicable	Identical
Expiration date	Not applicable	The rechargeable battery installed in the device will self-discharge	Equivalent Instruction Manual is revised to add “The device's battery should be recharged periodically, even during storage since the rechargeable battery installed in the device will self-discharge, leading to an unacceptably low voltage, thus damaging the battery.” The change in the specification is documented, does not affect the intended use or the fundamental scientific technology.
Accessories	Instruction manual	Instruction manual which is revised according to the changes made	Equivalent The change in the specification is documented, does not affect the intended use or the fundamental scientific technology.

	---	Soft rule	Equivalent The adding of the soft rule that increases the measuring accuracy of the device is documented
	BP-management software on Personal Computer	A mobile medical app on Android	Equivalent The change in the specification is documented, the cybersecurity risk has been considered and the overall residual risk is acceptable. The change does not affect the intended use or the fundamental scientific technology.

VII. PERFORMANCE DATA

VII.I Performance Testing – Bench

Testing information demonstrating safety and effectiveness of the device in the intended environment of use is supported by testing that was conducted.

The following testing was conducted to prove safety and effectiveness as well as substantial equivalence to the predicate devices.

The following National and International Standards were utilized for testing the subject device.

a. **EMC Test**:

- IEC 60601-1-2：2014

General Requirements for Basic Safety and Essential Performance - Collateral Standard: Electromagnetic Disturbances - Requirements and Tests

b. **Safety Test**:

-IEC 60601-1:2005+A1:2012, Medical electrical equipment - Part 1: General requirements for basic safety and essential performance

-IEC 60601-1-11:2015, Medical electrical equipment-Part 1-11: General Requirement for basic safety and essential performance– Collateral Standard: Requirements for medical electrical systems used in the home healthcare Environment

-IEC 62133:2012, Secondary cells and batteries containing alkaline or other non-acid electrolytes – Safety requirements for portable sealed secondary cells, and for batteries made from them, for use in portable applications

c. **Reliability Test**:
-IEC 80601-2-30:2009+A1:2013 Medical electrical equipment-Part 2-30: Particular requirements for the basic safety and essential performance of automated noninvasive sphygmomanometers, 2013

-EN 1060-3: 1995+A2:2009 Non-invasive sphygmomanometers Part 3: Supplementary requirements for electro-mechanical blood pressure measuring systems

d. **Radio Frequency Wireless Test:**
-EN 300 328 V2.1.1, Wideband transmission systems; Data transmission equipment operating in the 2,4 GHz ISM band and using wide band modulation techniques;
Harmonised Standard covering the essential requirements of article 3.2 of Directive 2014/53/EU

-Draft EN 301 489-1 V2.2.0, ElectroMagnetic Compatibility (EMC) standard for radio equipment and services; Part 1: Common technical requirements; Harmonised Standard covering the essential requirements of article 3.1(b) of Directive 2014/53/EU and the essential requirements of article 6 of Directive 2014/30/EU

-Draft EN 301 489-17 V3.2.0, ElectroMagnetic Compatibility (EMC) standard for radio equipment and services; Part 17: Specific conditions for Broadband Data Transmission Systems; Harmonised Standard covering the essential requirements of article 3.1(b) of Directive 2014/53/EU

e. **FCC Test:**
-FCC 47 CFR Part 15, Subpart B
-FCC 47 CFR Part 15, Subpart C
-FCC 47 CFR Part 1.1307
-FCC 47 CFR Part 2.1093

f. **Biocompatibility Test:**
-ISO 10993-1:2009, Biological evaluation of medical devices- Part 1: Evaluation and testing within a risk management process
-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

None of the testing demonstrated any design characteristics that violated the requirements of the Reviewer Guidance or resulted in any safety hazards. It was our conclusion that Bluetooth Blood Pressure Monitor, BPW1 tested met all relevant requirements of the aforementioned tests. The evaluation of these results present no new issues related to safety or effectiveness of the device. The testing was conducted to prove safety and effectiveness as well as substantial equivalence to the predicate devices.

The test methods used are the same as those submitted in the original submission.

VII-II Performance Testing – Animal N/A

VII-III Performance Testing – Clinical

Clinical Validation:

- ISO81060-2:2013 Non-invasive sphygmomanometers —Part 2: Clinical validation of automated measurement type

The device has achieved the requirements of ISO18060-2:2013.

VII-IV Cybersecurity Risk Management

- FDA Content of Premarket Submissions for Management of Cybersecurity in Medical Devices (2014)
- FDA Post Market Management of Cybersecurity in Medical Devices (2016)

The overall residual risk posed by the medical device is acceptable using the criteria defined in the risk management plan.

VIII. SUBSTANTIAL EQUIVALENCE CONCLUSION

The modified device has been found to be substantially equivalent to the predicate/unmodified device. Differences between the modified device and the predicate/unmodified device do not raise new questions of safety or effectiveness.