February 26, 2018

Visiomed Group SA
% Dacheng Gong
General Manager
Shenzhen Kingyield Technology Co., Ltd.
Section C2, Fuhai Industrial Zone
Fuyong Town, Baoan District
Shenzhen, 518000 China

Re: K171668
Trade/Device Name: BW-BA1 Bluetooth Blood Pressure Monitor
Regulation Number: 21 CFR 870.1130
Regulation Name: Noninvasive Blood Pressure Measurement System
Regulatory Class: Class II
Product Code: DXN
Dated: January 18, 2018
Received: January 23, 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. 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)*
K171668

Device Name
BW-BA1 Bluetooth blood pressure monitor

Indications for Use *(Describe)*
BW-BA1 Bluetooth Blood Pressure Monitor is intended to be used to measure systolic and diastolic blood pressure and heart rate from the upper arm with arm circumference ranging from 8.7 inches to 16.5 inches (approx.22 cm to 42 cm) using the oscillometric method. The device detects the appearance of irregular heartbeats during measurement and gives a "IHB" warning signal with readings. The intended patient population of the device is only adult population aged 18 or older at home, not applied to the other populations such as neonatal baby.

It cannot be used while the arm has bleeding or wound to avoid the blood flowing from the wound in pressurizing. The device cannot be used by pregnant patients or patients suffering from pre-eclampsia.

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

I. Administrative Information

1.1 Submitter/Owner

Visiomed Group SA
Address: 112 Av. Kleber Paris Paris, FRANCE 75116
Establishment Registration Number: 3012440774

1.2 Contact person

Authorized Contact Person: Dacheng Gong who works for the manufacturer Shenzhen Kingyield Technology Co., Ltd who manufactures BW-BA1 for Visiomed Group SA
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. PROPOSED DEVICE

Device type by its common name: BW-BA1 Bluetooth Blood pressure monitor
Regulation Number: 21CFR 870.1130
Regulation Name: Noninvasive Blood Pressure Measurement System
Regulatory Class: II
Panel: Cardiovascular
Product Code: DXN

III. PREDICATE DEVICE

Device Name: Withings Blood Pressure Monitor, Upper Arm Type BP-801
Common/Usual Name: Blood Pressure Monitor, Upper Arm Type BP-801
510(k) Number: K133125
510(k) submitter/holder: Withings (VA HORNG Electronic Co., Ltd.)

IV. DEVICE DESCRIPTION

BW-BA1 Bluetooth Blood Pressure Monitor 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 during inflating @ 3~8mmHg/second from about 30mmHg by inflating a cuff on the upper arm. The device detects the appearance of irregular heartbeats during measurement and gives a warning signal with readings. An irregular heartbeat rhythm is defined as rhythm that is 25% less or 25% more than the average rhythm detected while the monitor is measuring the systolic and diastolic blood

pressure.

BW-BA1 Bluetooth Blood Pressure Monitor without any display component achieves its function by integrating the device with a collateral device iPhone, iPad with a specific mobile app to constitute a complete blood pressure measurement system. And the new device connects the mobile platform with the mobile app through Bluetooth 4.0.

The operational principle is based on oscillometric and pressure sensor technology, it can calculate the systolic and diastolic blood pressure, and the measurement results can be classified by the function of blood pressure classification indicator according to the classification rule developed by WHO.

The BW-BA1 is powered by a rechargeable Lithium battery.

The device has an ON/START button for starting the measuring and stopping the measuring at any time when measuring.

V. INDICATIONS FOR USE

BW-BA1 Bluetooth Blood Pressure Monitor is intended to be used to measure systolic and diastolic blood pressure and heart rate from the upper arm with arm circumference ranging from 8.7 inches to 16.5 inches (approx.22 cm to 42 cm) using the oscillometric method. The device detects the appearance of irregular heartbeats during measurement and gives a "IHB" warning signal with readings. The intended patient population of the device is only adult population aged 18 or older at home, not applied to the other populations such as neonatal baby.

It cannot be used while the arm has bleeding or wound to avoid the blood flowing from the wound in pressurizing. The device cannot be used by pregnant patients or patients suffering from pre-eclampsia.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

Comparison item	Proposed device	Predicate device
Applicant	Shenzhen Kingyield technology Co., Ltd.	Withings (VA HORNG Electronic Co., Ltd.)
Model	BW-BA1 Bluetooth blood pressure monitor	Withings Blood Pressure Monitor, Upper Arm Type BP-801
510k number		k133125
Collateral device	Same The collateral device is iPhone, iPad, but USB connection is deleted.	The Withings BP-801 is a blood pressure monitor achieves its function by integrate the device with an iPhone 4S. As it does not include a LCD or other display components, it is necessary for the new device to connect to an

		iPhone 4S containing a support software to constitute a complete blood pressure measurement system. And the new device connects iPhone 4S through Bluetooth or USB cable.
Intended use	Same	Intended to measure the systolic and diastolic blood pressures and pulse rate of an adult individual, over age 18, at home by using a noninvasive technique in which an inflatable cuff is wrapped around the upper arm. The cuff circumference is limited to be 9 to 17 inches (22cm-42cm) for Upper Arm type.
Measuring method	Same	Oscillometric
IHB	Rhythm that is 25% less or 25% more than the average rhythm detected while the monitor is measuring the systolic and diastolic blood pressure	No IHB function
Measuring range	Cuff pressure: 0~299 mmHg Pulse: 40~180 beat/min	Cuff pressure: 0~285 mmHg Pulse : 40~180 beat/min
Accuracy	Pressure: ± 3mmHg Pulse: ± 5% reading value	Pressure: <200 mmHg ± 3mmHg or 200mmHg±2% Pulse: ±5% of reading value
Inflation	Electric pump inflation	By air pump
Deflation	N/A	Automatic linear pressure deflation valve
Pressure release	Pressure release valve	Automatic solenoid venting valve
Pressure sensor	Same	Semiconductor pressure sensor
Accessories	Same	Storage case, instruction manual
Operating Temp. & humidity	Temp.: 10~40°C Humidity: 15~90%RH (noncondensing) Atmospheric: 105kPa~80kPa	Temp.: 10~40°C Humidity: 15~90%RH, Atmospheric 86kPa~106kPa, Altitude: 2000m
Storage Temp. & humidity	Temp.: -20~55°C Humidity: 10~90%RH (noncondensing)	-25 to 70°C,10 to 95%RH, Atmospheric 86kPa-106kPa, altitude: 2000m
Display	Same	Can display the measurement

		result on the iPhone 4S
Battery	Li-ion Rechargeable battery with 250 charging cycles	AAA alkaline battery x 4 pcs

VII. PERFORMANCE DATA

VII.I Performance Testing – Bench

Testing information demonstrating safety and effectiveness of BW-BA1 Bluetooth Blood Pressure Monitor 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 60601-1-11:2010, 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, Electromagnetic compatibility and Radio spectrum Matters (ERM); Wideband transmission systems; Data transmission equipment operating in the 2.4 GHz

ISM band and using wide band modulation techniques; Harmonized EN covering the essential requirements of article 3.2 of the R&TTE Directive

-EN 301 489-1, Electromagnetic compatibility and Radio spectrum Matters (ERM); Electromagnetic Compatibility (EMC) standard for radio equipment and services; Part 1: Common technical requirements
-EN 301 489-17, Electromagnetic compatibility and Radio spectrum Matters (ERM); Electro Magnetic Compatibility (EMC) standard for radio equipment; Part 17: Specific conditions for Broadband Data Transmission Systems

d. **FCC Test:**
FCC 47 CFR Part 15, Subpart B & FCC 47 CFR Part 15, Subpart C

e. **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, Third Edition Biological evaluation of medical devices-Part 10: Tests for irritation and skin sensitization

f. **Software Verification and Validation**:
- Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices Document issued on: May 11, 2005

g. **Usability Engineering**:
-IEC 62366-1:2015 Medical devices – Part 1: Application of usability engineering to medical devices
-IEC 60601-1-6: 2010 +A1:2013 Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability

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 BW-BA1 Bluetooth Blood Pressure Monitor tested met all relevant requirements of the aforementioned tests.

VII-II Performance Testing – Animal N/A

VII-III Performance Testing – Clinical

Clinical validation concerning the compliance of ISO 81060-2 has been performed that the device BW-BA1 is the same as the predicate except IHB adding for our device. And the fundamental scientific technology of the device is identical with the predicate and IHB adding does not raise new questions of safety and effectiveness. Therefore the performance of the device in terms of blood pressure measurement would be identical with performance of the

predicate.

VIII. SUBSTANTIAL EQUIVALENCE CONCLUSION

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