June 24, 2019

Rudolf Riester GmbH
% Diana Hong
General Manager
Mid-Link Consulting Co., Ltd
P.O. Box 120-119
Shanghai, 200120 Cn

Re: K190927
Trade/Device Name: Oscillometric Blood Pressure Monitor
Regulation Number: 21 CFR 870.1130
Regulation Name: Noninvasive Blood Pressure Measurement System
Regulatory Class: Class II
Product Code: DXN
Dated: February 21, 2019
Received: April 9, 2019

Dear Diana Hong:

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/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Stephen Browning
Assistant Director
Division of Cardiac Electrophysiology, Diagnostics
and Monitoring Devices
Office of Cardiovascular Devices
Office of Product Evaluation and Quality
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)*
K190927

Device Name
Oscillometric Blood Pressure Monitor

Indications for Use *(Describe)*
This oscillometric blood pressure monitor is intended to measure the systolic and diastolic blood pressure, pulse rate and mean arterial pressure (MAP) in people aged 3 years or older. This device is intended to be operated by trained personnels only. Examples of trained operators include professional clinical and healthcare personnels.

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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Tab 7 510(k) Summary

This 510(k) Summary is being submitted in accordance with requirements of Title 21, CFR Section 807.92.

The assigned 510(k) Number: K190927

1. Date of Preparation: 06/24/2019

2. Sponsor Identification

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3. Designated Submission Correspondent

Ms. Diana Hong (Primary Contact Person)
Mr. Chengyu Wang (Alternative Contact Person)

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4. Identification of Proposed Device

Trade Name: Oscillometric Blood Pressure Monitor;
Common Name: Blood Pressure Monitor;
Models: RBP-100

Regulatory Information
Classification Name: Noninvasive blood pressure measurement system
Classification: II
Product Code: DXN;
Regulation Number: 21 CFR 870.1130;
Review Panel: Cardiovascular;

Indication for Use Statement:
This oscillometric blood pressure monitor is intended to measure the systolic and diastolic blood pressure, pulse rate and mean arterial pressure (MAP) in people aged 3 years or older. This device is intended to be operated by trained personnels only. Examples of trained operators include professional clinical and healthcare personnels.

Device Description:
The proposed device, oscillometric blood pressure monitor, is a battery driven automatic non-invasive blood pressure monitor. It can automatically complete the inflation, deflation and measurement, which can measure systolic and diastolic blood pressure, pulse rate and mean arterial pressure of the person aged 3 years or older at upper arm within its claimed range and accuracy via the oscillometric technique.

The proposed oscillometric blood pressure monitor is available in one model, RBP 100.

Three sizes of cuffs are provided with proposed device, which are S size, M size and L-XL size (S size: 14~22cm; M size: 22~32cm; L-XL size: 32~52cm).

The proposed device is intended to be used in medical facilities.

5. Identification of Predicate Device

510(k) Number: K101275
Product Name: Upper Arm Automatic Digital Blood Pressure Monitor
Manufacturer: Microlife Intellectual Property GmbH

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:

IEC 60601-1:2005+CORR.1:2006+CORR.2:2007+AM1:2012, Medical electrical equipment – Part 1: General requirements for basic safety, and essential performance.

IEC 60601-1-2:2014, Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic Compatibility

IEC 80601-2-30:2009, Medical electrical equipment - Part 2-30: Particular requirements for the basic safety and essential performance of automated noninvasive sphygmomanometers

7. Clinical Test Conclusion

The blood pressure model for proposed device is identical to the device WatchBP cleared in K101275. Therefore, a new clinical study was not conducted on the proposed device and a study performed on WatchBP per ISO 81060-2:2013 is provided to demonstrate the accuracy of the professional oscillometric blood pressure monitor in adults and children, the clinical study result is summarized in following.

Three 85 subjects (aged 54±19 years), 33 subjects (aged 53±17 years) and 41 children (7.7±2.8 years) were respectively recruited to fulfil the age, sex, BP and cuff distribution criteria of the ISO standard using the same-arm sequential BP measurement method. Three cuffs were tested in this clinical study to cover all proposed cuff models (small for arm circumference 14–22 cm, medium for 22–32cm and large cuff for 32–52cm). The test results can meet the requirements of acceptance criteria and ISO 81060. Therefore, the clinical accuracy of proposed device used on adult and children can be demonstrated.

8. Substantially Equivalent

Table 1 Substantially Equivalent Comparison

ITEM	**Proposed Device**	**Predicate Device, K101275**
Product Code	DXN	DXN
Regulation No.	21 CFR 870.1130	21 CFR 870.1130
Class	II	II
Indication for Use	This oscillometric blood pressure monitor is intended for measuring non-invasive blood pressure in people aged 3 years or older. It is clinically validated in patients with hypertension, hypotension, diabetes, pregnancy, pre-eclampsia, atherosclerosis, end-stage renal disease, obesity and the elderly. This device is intended to be operated by trained personnels only. Examples of trained operators include professional clinical and healthcare personnels.	The Microlife Upper Arm Automatic Digital Blood Pressure Monitor, Model WatchBP Office AFIB (TWIN200 AFS) is a device intended to measure the systolic and diastolic blood pressure, pulse rate, pulse pressure (PP) and mean arterial pressure (MAP) of an adult individual by using a non-invasive oscillometric technique in one (or two) inflatable cuff(s) is (are) wrapped around the single (or dual) upper arm(s). The device detects the appearance of atrial fibrillation during measurement and gives a warning signal with the reading once the atrial fibrillation is detected.
Measurement Type	Upper arm	Upper arm
Patient Population	People aged 3 years or older	Adult
Measurement Item	Systolic Pressure, Diastolic Pressure, Pulse Rate, MAP	Systolic Pressure, Diastolic Pressure, Pulse Rate, MAP
Principle	Oscillometric	Oscillometric
Arm circumference	S size: 14~22cm; M size: 22~32cm; L-XL size: 32~52cm	M size: 22~32cm; L size: 32~42cm
Blood Pressure Range	60 - 255 mmHg – systolic blood pressure 30 - 200 mmHg – diastolic blood pressure	30 ~ 280 mmHg

Blood Pressure Accuracy	3 mmHg	3 mmHg
Pulse Rate Range	40 ~ 200 bpm	40 ~ 200 bpm
Dimensions	170mm×135mm×41mm	200mm×125mm×90mm
Weight	510g (including batteries)	1100g (including batteries)
Patient Contact Material	Cuff – Nylon	Cuff – Nylon
Electrical Safety	Comply with IEC 60601-1	Comply with IEC 60601-1
EMC	Comply with IEC 60601-1-2	Comply with IEC 60601-1-2
Particular Performance	Comply with IEC 80601-2-30:2009 and ISO 81060-2:2013	Comply with IEC 80601-2-30:2009 and ISO 81060-2:2013
Software Level Concern	Moderate	Moderate

The differences between proposed device and predicate include target population, arm circumference and blood pressure range. Target population and arm circumference of proposed device has been validated by clinical trials. The range of proposed device is completely covered by that of predicate. These differences do not raise any question regarding its safety and effectiveness.

9. Substantially Equivalent (SE) Conclusion

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