March 16, 2018

Microlife Intellectual Property GmbH
% Susan Goldstein-Falk
MDI Consultants, Inc.
55 Northern Blvd.
Great Neck, New York 11021

Re: K171937
Trade/Device Name: Microlife Upper Arm Automatic Digital 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 7, 2018
Received: February 8, 2018

Dear Susan Goldstein-Falk:

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,

Jessica E. Paulsen -S

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)*
K171937

Device Name
Microlife Upper Arm Automatic Blood Pressure Monitor, Model WatchBP Office Central (Twin200 CBP)

Indications for Use *(Describe)*

The Microlife Upper Arm Automatic Digital Blood Pressure Monitor, Model WatchBP Office Central (TWIN200 CBP) is a device intended to measure the systolic and diastolic blood pressure, pulse rate, Mean Arterial Pressure (MAP), ankle-arm blood pressure and calculates Pulse Pressure (PP) and Ankle Brachial Index (ABI) of an adult individual with arm circumference sizes ranging from 22-42 cm and ankle circumference sizes ranging from 22-32 cm. It uses a non-invasive oscillometric technique using one (single arm) or two (dual arm measurement) inflatable cuffs wrapped around the upper arms and one inflatable cuff wrapped around the ankle (ABI).

The device provides aortic blood pressure parameters, includes central systolic blood pressure (cSBP), central pulse pressure (cPP) and central diastolic pressure (cDBP), non-invasively through the use of a brachial cuff.

The device detects the appearance of atrial fibrillation during measurement and gives a warning signal together with the measured blood pressure value if atrial fibrillation is detected.

The device can be connected to a personal computer (PC) running the WatchBP Analyzer Office software. The measured patient data can be transferred from the blood pressure monitor to the PC by means of a USB cable connection.

The blood pressure monitor is an automated digital professional clinical device for measuring blood pressure in upper arm and ankle in adults.

The device is for hospital use only.

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

The assigned 5l0(k) number is: K171937

1. Submitter's Identification:

Microlife Intellectual Property GmbH, Switzerland
Espenstrasse 139
9443 Widnau / Switzerland

Date Summary Prepared: March 16, 2018

Contact: Mr. Gerhard Frick
Vice President of Technical and Service
Microlife Intellectual Property GmbH, Switzerland
Tel: +41 79 216 0070
E-Mail: gerhard.frick@microlife.ch

2. Name of the Device:

Microlife Upper Arm Automatic Digital Blood Pressure Monitor, Model WatchBP Office Central (TWIN200 CBP)

Regulation Number: 21 CFR Part 870.1130
Regulation Name: Non-Invasive Blood Pressure Measurement System
Regulatory Class: II
Product Code: DXN

3. Information for the 510(k) Cleared Device (Predicate Device):

Primary Predicate:

a. Microlife Upper Arm Automatic Digital Blood Pressure Monitor, Model WatchBP Office ABI (TWIN200 ABI), K112845, Microlife Intellectual Property GmbH.

Reference Predicate:

b. Microlife Automatic Talking Blood Pressure Monitor, Model BP3AP1-3E (BP A130), K111652, Microlife Intellectual Property GmbH.

4. Device Description:

Microlife Upper Arm Automatic Digital Blood Pressure Monitor, Model WatchBP Office Central (TWIN200 CBP) is designed to measure systolic and diastolic blood pressure, pulse rate and calculate Pulse Pressure (PP), Mean Arterial Pressure (MAP),Ankle Brachial Index (ABI), Central Blood Pressure(CBP) and Central Pulse Pressure(CPP) of an adult individual with arm circumference sizes ranging from 22 -42 cm a (rigid cuff for central BP and a soft cuff for brachial BP measurements) and ankle circumference sizes ranging from 22 -32 cm (using a soft cuff) by using a non-invasive technique in which one (or two) inflatable cuff(s) is (are) wrapped around the single (or dual) upper

arm(s) and one inflatable cuff is wrapped around the ankle. Our method to define systolic and diastolic pressure is similar to the auscultatory method but use two resistive pressure sensors rather than a stethoscope and mercury manometer. The sensors convert tiny alterations in cuff pressure to electrical signals, by analyzing those signals to define the systolic and diastolic blood pressure and calculating pulse rate, Pulse Pressure (PP), Mean Arterial Pressure (MAP),Ankle Brachial Index (ABI) Central Blood Pressure(CBP) and Central Pulse Pressure(CPP) which is a well - known technique in the market called the “oscillometric method”.

The device has <<SCREEN>>, <<CENTRAL>> and <<ABI>> measurement modes and has atrial fibrillation detection function, inflation pressure setting function, measurement intervals setting function etc. In addition, the device can be used in connection with your personal computer (PC) running the WatchBP Analyzer Office software. The memory data can be transferred to the PC by connecting the monitor with the PC via cable.

The <<SCREEN>> mode is selected to complete a fully-automated triple measurements on both arms according to recommended ESH/AHA blood pressure measurement protocols for a patient’s first office visit.

The <<CENTRAL>> mode is selected to perform central blood pressure measurements on the preferred arm for prompt and accurate office measurements.

The <<ABI>> mode is selected for Ankle Brachial Index pressure measurement. Select the lateral with the higher blood pressure value according to the measurement result of <<SCREEN>> mode.

The device detects the appearance of atrial fibrillation during measurement and the atrial fibrillation symbol “  ” is displayed on the LCD screen if any atrial fibrillation signal has been detected.

The blood pressure monitor is an automated digital professional clinical device for measuring blood pressure in upper arm and ankle in adults

5. Indications for Use:

The Microlife Upper Arm Automatic Digital Blood Pressure Monitor, Model WatchBP Office Central (TWIN200 CBP) is a device intended to measure the systolic and diastolic blood pressure, pulse rate, Mean Arterial Pressure (MAP), ankle-arm blood pressure and calculates Pulse Pressure (PP) and Ankle Brachial Index (ABI) of an adult individual with arm circumference sizes ranging from 22 - 42 cm and ankle circumference sizes ranging from 22 -32 cm. It uses a non- invasive oscillometric technique using one (single arm) or two (dual arm measurement) inflatable cuffs wrapped around the upper arms and one inflatable cuff wrapped around the ankle (ABI).

The device provides aortic blood pressure parameters, includes central systolic blood pressure (cSBP), central pulse pressure (cPP) and central diastolic pressure (cDBP), non-invasively through the use of a brachial cuff.

The device detects the appearance of atrial fibrillation during measurement and gives a warning signal together with the measured blood pressure value if atrial fibrillation is detected.

The device can be connected to a personal computer (PC) running the WatchBP Analyzer Office software. The measured patient data can be transferred from the blood pressure monitor to the PC by means of a USB cable connection.

The blood pressure monitor is an automated digital professional clinical device for measuring blood pressure in upper arm and ankle in adults.

The device is for hospital use only.

6. Comparison to the 510(k) Cleared Device (Predicate Device):

The subject WatchBP Office Central (TWIN200 CBP) uses the same oscillometric method as the predicate WatchBP Office ABI (TWIN200 ABI) with the same software algorithm to determine the systolic and diastolic blood pressure, pulse rate, pulse pressure (PP), mean arterial pressure (MAP) and Ankle Brachial Index (ABI) 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) and one inflatable cuff is wrapped around the ankle. The cuff is inflated automatically by pump, the deflation rate is controlled by factory set exhaust valve and the deflation pressures are transferred via tubing to a sensor in these two units. They both detect the appearance of atrial fibrillation during measurement and give a warning signal with the reading once the atrial fibrillation is detected.

They differ by the measurement mode name and CBP&CPP (Central blood pressure& Central Pulse Pressure) measurement function. The aortic blood pressure parameters, includes central systolic blood pressure, central pulse pressure and central diastolic pressure which can be estimated accurately by WatchBP Office Central (TWIN200 CBP). The efficacy of the use of the rigid conical cuff was proven clinically. The brachial blood pressure measurement algorithm, AFIB detection and Ankle Brachial Index (ABI) measurement of WatchBP Office Central (TWIN200 CBP) is substantially equivalent with the predicate device (WatchBP Office ABI) and repeated clinical testing for aforementioned parameters is not required. There was no repeated clinical testing required for brachial blood pressure, AFIB detection and Ankle Brachial Index (ABI) to support WatchBP Office Central as the subject device WatchBP Office Central (TWIN200 CBP) can leverage the clinical validation of WatchBP Office ABI (TWIN200 ABI) that was proven in K112845. Repeat clinical testing in accordance with the standard AAMI / ANSI /ISO81060-2 for the subject device WatchBP Office Central (TWIN200 CBP) regarding brachial blood pressure measurement, AFIB detection and ABI detection is therefore not necessary. Please see the clinical evaluation of WatchBP Office Central for details.

Although the upper arm cuff used with the subject WatchBP Office Central (TWIN200 CBP) is changed to WRR conical cuff, the validation study results for the brachial systolic and diastolic blood pressure of WatchBP Office Central (TWIN200 CBP) against auscultation reference measurement confirmed the performance of WatchBP Office Central (TWIN200 CBP) using WRR conical cuff through our published clinical study (Cheng et al) “Measurement Accuracy of a Stand-Alone Oscillometric

Central Blood Pressure Monitor: A Validation Report for Central Microlife WatchBP Office Central".

The mutispandex material used for the cuff (WRR Conical Cuff) is identical to the cuff material of the Microlife BP3AP1-3E as it was cleared in K111652 meets ISO 10993-1 requirements and does not need make biocompatibility test.

Based upon the aforementioned information, the two devices are substantially equivalent.

7. Discussion of Non-Clinical Tests Performed for Determination of Substantial Equivalence are as follows:

Testing information for the Microlife Upper Arm Automatic Digital Blood Pressure Monitor, Model WatchBP Office Central (TWIN200 CBP) in the intended environment of use is supported by testing that was conducted in accordance with the FDA November 1993 Draft "Reviewer Guidance for Premarket Notification Submissions", DCRND, which outlines Electrical, Mechanical and Environmental Performance requirements.

The following testing was conducted to demonstrate substantial equivalence to the predicate devices:

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

1) IEC 60601-1 Medical electrical equipment – Part 1: General requirements for basic safety and essential performance AAMI / ANSI ES60601-1:2005/(R) 2012 And A1:2012, C1:2009/(R) 2012 And A2:2010/(R) 2012

2) IEC 60601-1-2:2007 Medical electrical equipment Part 1-2: General requirements for safety and essential performance – Collateral standard: Electromagnetic Disturbances - Requirements And Tests.

3) ISO 14971: 2007 Medical devices – Application of risk management to medical devices.

4) AAMI / ANSI / ISO 10993-1:2009/(R)2013, Biological evaluation of medical devices – Part 1: Evaluation And Testing Within A Risk Management Process.

5) AAMI / ANSI / ISO 10993-5:2009/(R)2014, Biological evaluation of medical devices – Part 5: Tests for In Vitro Cytotoxicity.

6) AAMI / ANSI / ISO 10993-10:2010/(R)2014, Biological evaluation of medical devices - Part 10: Tests for Irritation and Skin Sensitization

7) AAMI/ANSI/IEC 80601-2-30 Medical electrical equipment – Part 2-30: Particular requirements for the basic safety and essential performance of automated non-invasive sphygmomanometers, 2013

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 Microlife Upper Arm Automatic Digital Blood Pressure Monitor, Model WatchBP Office Central (TWIN200 CBP) tested met all relevant requirements of the aforementioned tests.

8) AAMI/ANSI/ISO 81060-2 Non-Invasive Sphygmomanometers – Part 2: Clinical Validation of Automated Measurement Type (Cardiovascular) Second Edition 2013-05-01.

8. Discussion of Clinical Tests Performed:

Clinical validation concerning the compliance of ANSI/AAMI/ ISO 81060-2: The subject device Model WatchBP Office Central (TWIN200 CBP) is from the technical point of view, identical to the predicate blood pressure monitor WatchBP Office ABI (TWIN200 ABI). Moreover, the measurement algorithm and its program codes of WatchBP Office ABI (TWIN200 ABI) remain unchanged. The fundamental scientific technology of the modified WatchBP Office Central (TWIN200 CBP) device is the same as the predicate device WatchBP Office ABI (TWIN200 ABI). Therefore the performance of the WatchBP Office Central (TWIN200 CBP) in terms of brachial blood pressure measurement, AFIB detection and ABI detection would be essential equivalent with performance of the predicate device WatchBP Office ABI (TWIN200 ABI). So the subject device WatchBP Office Central (TWIN200 CBP) can leverage the clinical validation of WatchBP Office ABI (TWIN200 ABI) which was proved in K112845.

Although the upper arm cuff used with the subject WatchBP Office Central (TWIN200 CBP) is changed to WRR conical cuff, the study result of validation of brachial systolic and diastolic blood pressure of WatchBP Office Central (TWIN200 CBP) against auscultation reference measurement confirmed the performance of WatchBP Office Central (TWIN200 CBP) using WRR conical cuff.

The aortic blood pressure parameters, includes central systolic blood pressure, central pulse pressure and central diastolic pressure can be estimated accurately by WatchBP Office Central (TWIN200 CBP).

9. Software information:

Software validation was conducted in accordance with a moderate level of concern designation in accordance with the FDA November 2005 document “Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices “.In addition, since our device requires the use of off-the-shelf software to operate the PC- link function, we adhered to the FDA September 1999 document “Guidance for Off-The- Shelf Software Use in Medical Devices”.

10. Conclusions:

Conclusions drawn from the non-clinical and clinical tests demonstrate that the subject device is substantially equivalent to the predicate device.