DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

February 12, 2016

Microlife Intellectual Property Gmbh
% Susan Goldstein-Falk
Official Correspondent For Microlife Intellectual Property Gmbh
Mdi Consultants, Inc.
55 Northern Blvd.,
Suite 200
Great Neck, New York 11021

Re: K153077
Trade/Device Name: Microlife Upper Arm Automatic Digital Blood Pressure Monitor, Model BP3MW1-4B
Regulation Number: 21 CFR 870.1130
Regulation Name: Noninvasive Blood Pressure Measurement System
Regulatory Class: Class II
Product Code: DXN
Dated: January 11, 2016
Received: January 13, 2016

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.

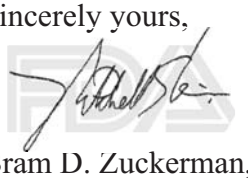
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply

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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



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)*
K153077

Device Name
Microlife Upper Arm Automatic Digital Blood Pressure Monitor, Model BP3MW1-4B

Indications for Use *(Describe)*

The Microlife Upper Arm Automatic Digital Blood Pressure Monitor, Model BP3MW1-4B is a device intended to measure the systolic and diastolic blood pressure, pulse rate of an adult individual by using a non-invasive oscillometric technique in one inflatable cuff is wrapped around the single upper arm.

The device detects the appearance of irregular heartbeat during measurement, and gives a warning signal with the reading once the irregular heartbeat is detected.

This device can accurately measure blood pressure in pregnant patients including those with known or suspected preeclampsia.

The memory data can be transferred to the PC (personal computer) running the Microlife Blood Pressure Analyzer (BPA) software by connecting the monitor via cable. The device can also be used in connection with smart mobile devices running the APP and via Bluetooth.

The blood pressure monitor is a fully automatic digital blood pressure measuring device for use by adults on the upper arm at home.

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.

510(k) SUMMARY

The assigned 5l0(k) number is: **K153077**

1. Submitter's Identification:

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

Date Summary Prepared: February 12, 2016

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 BP3MW1-4B

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):

a. Microlife Upper Arm Automatic Digital Blood Pressure Monitor, Model BP3MW1-4X(R), K140572, Microlife Intellectual Property GmbH.

b. Microlife Upper Arm Automatic Digital Blood Pressure Monitor, Model BP3NF1-2B, K151869, Microlife Intellectual Property GmbH.

4. Device Description:

Microlife Upper Arm Automatic Digital Blood Pressure Monitor, Model BP3MW1-4B is designed to measure systolic and diastolic blood pressure, pulse rate of an individual by using a non-invasive technique in which one inflatable cuff is wrapped around the single upper arm. 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, which is a well - known technique in the market called the “oscillometric method”. This device can accurately measure blood pressure in pregnant patients including those with known or suspected preeclampsia.

The device detects the appearance of irregular heartbeat during measurement, and the symbol “  “is displayed after the measurement. In addition, the memory data can be transferred to the PC (personal computer) running the Microlife Blood Pressure Analyzer (BPA) software by connecting the monitor via cable. The device can also be used in connection with smart mobile devices running the APP and via Bluetooth.

The patient’s level of blood pressure is determined in the circulatory center of the brain and adjusts to a variety of situations through feedback from the nervous system. To adjust blood pressure, the strength and frequency of the heart (pulse), as well as the width of circulatory blood vessels is altered. Blood vessel width is affected by fine muscles in he blood vessel walls.

The patient’s level of arterial blood pressure changes periodically during heart activity. During the "blood ejection" (Systole), the value is highest (systolic blood pressure value). At the end of the heart’s "rest period" (Diastole), pressure is lowest (diastolic blood pressure value).Blood pressure values must lie within certain normal ranges in order to prevent particular diseases.

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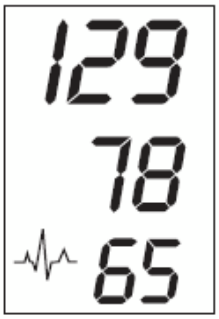
The following standards for assessing high blood pressure (in adults) have been established by the National Institutes of Health JNC7, 2003.

Category	**Systolic** (mmHg)	**Diastolic** (mmHg)
Normal	<120	and <80
Pre-Hypertension	120-139	or 80-89
Hypertension		
Stage 1 Hypertension	140-159	or 90-99
Stage 2 Hypertension	≥160	or ≥100

The appearance of this symbol indicates that certain pulse irregularities were detected during the measurement. In this case, the result may deviate from your normal basal blood pressure – repeat the measurement. In most cases, this is no cause for concern. However, if the symbol appears on a regular basis (e.g., several times a week with measurements taken daily), we advise you to tell your doctor.



The blood pressure monitor is a fully automatic digital blood pressure measuring device for use by adults on the upper arm at home.

5. Indications for Use:

The Microlife Upper Arm Automatic Digital Blood Pressure Monitor, Model BP3MW1-4B is a device intended to measure the systolic and diastolic blood pressure, pulse rate of an adult individual by using a non-invasive oscillometric technique in one inflatable cuff is wrapped around the single upper arm.

The device detects the appearance of irregular heartbeat during measurement, and gives a warning signal with the reading once the irregular heartbeat is detected.

This device can accurately measure blood pressure in pregnant patients including those with known or suspected preeclampsia.

The memory data can be transferred to the PC (personal computer) running the Microlife Blood Pressure Analyzer (BPA) software by connecting the monitor via cable. The device can also be used in connection with smart mobile devices running the APP and via Bluetooth.

The blood pressure monitor is a fully automatic digital blood pressure measuring device for use by adults on the upper arm at home.

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

The modified device model BP3MW1-4B uses the same oscillometric method as the predicate BP3MW1-4X(R) with the same algorithm to determine the systolic and diastolic blood pressure, pulse rate. Upper arm 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 differ by Bluetooth function. The subject device BP3MW1-4B has been added the function of transferring the memory data to the smart phone via

Bluetooth. However, this function is only a way to transfer the data and will not affect the clinical accuracy.

Although the cuff used with the subject BP3MW1-4B is changed to WRS cuff, it is the same with the one cleared in BP3AP1-3E, which was proved in K111652. The other differences also do not affect the accuracy and normal use of this device based on the clinical declaration of identity and clinical testing comparing different functions.

The modified device model BP3MW1-4B uses the same oscillometric method as the predicate device BP3NF1-2B. They have the same function of transferring the memory data via Bluetooth. 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 demonstrating safety and effectiveness of the Microlife Upper Arm Automatic Digital Blood Pressure Monitor, Model BP3MW1-4B 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 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:

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（MISC 002）

2) IEC 60601-1-2 Medical electrical equipment Part 1-2: General requirements for safety and essential performance – Collateral standard: Electromagnetic compatibility 3:2007-03（MISC 001）

3) ISO 14971 Medical devices – Application of risk management to medical devices. 2007（VOL 12, 002）

4) AAMI/ANSI/ISO 10993-1-1 Biological evaluation of medical devices – Part 1: Evaluation and testing. 2010（Biocompatibility Test Report）

5) AAMI/ANSI/ISO 10993-5 Biological evaluation of medical devices – Part 5:

Tests for In Vitro Cytotoxicity, 2009（Biocompatibility Test Report）

6) AAMI/ANSI/ISO 10993-10 Biological evaluation of medical devices – Part （Biocompatibility Test Report）

7) Tests for Irritation and skin sensitization, 2010（Biocompatibility Test Report）

8) 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

9) IEC 60601-1-11 Medical Electrical Equipment - Part 1-11: General Requirements For Basic Safety And Essential Performance - Collateral Standard: Requirements For Medical Electrical Equipment And Medical Electrical Systems Used In The Home Healthcare Environment

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 BP3MW1-4B tested met all relevant requirements of the aforementioned tests.

8. Discussion of Clinical Tests Performed:

Clinical validation concerning the compliance of ANSI/AAMI ISO 81060-2:
The subject device Model BP3MW1-4B is from the technical point of view, identical to the predicate blood pressure monitor BP3MW1-4X(R). Moreover, the measurement algorithm and its program codes of BP3MW1-4X(R) remain unchanged. The fundamental scientific technology of the modified BP3MW1-4B device is the same as the predicate device BP3MW1-4X(R). Therefore the performance of the BP3MW1-4B in terms of blood pressure measurement would be identical with performance of the predicate device BP3MW1-4X(R). Repeat clinical testing in accordance with the standard ANSI/AAMI IEC81060-2 for the subject device BP3MW1-4B is therefore not necessary as clinical testing results were not affected by the changes to the subject modified device.

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 as safe, effective, and performs as well as the predicate device.