



April 18, 2018

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

Re: K172880

Trade/Device Name: Microlife Upper Arm Automatic Digital Blood Pressure Monitor, Model
BP3GX1-5X (BP A3 PC)

Regulation Number: 21 CFR 870.1130

Regulation Name: Noninvasive Blood Pressure Measurement System

Regulatory Class: Class II

Product Code: DXN

Dated: March 14, 2018

Received: March 16, 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,



for

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)
K172880

Device Name

Microlife Upper Arm Automatic Digital Blood Pressure Monitor, Model BP3GX1-5X (BP A3 PC)

Indications for Use (Describe)

The Microlife Upper Arm Automatic Digital Blood Pressure Monitor, Model BP3GX1-5X (BP A3 PC) is a device intended to measure the systolic and diastolic blood pressure and pulse rate of an adult individual of 12 years and older, with arm circumference sizes ranging from 22 -52 cm by using a non-invasive oscillometric technique in an inflatable cuff being wrapped around the upper arm.

The device is also validated for patients with diabetes mellitus in the age 56 years and older.

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

The device can be used in connection with your personal computer (PC) running the Microlife Blood Pressure Analyzer (BPA) software. The memory data can be transferred to the PC by connecting the monitor via cable with PC.

The blood pressure monitor is a fully automatic digital blood pressure measuring device for use by adults (also applicable for diabetic patients) on the upper arm at home or in your doctor's/nurse's office.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRASStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) SUMMARY

The assigned 510(k) number is: K172880

1. Submitter's Identification:

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

Date Summary Prepared: March 14, 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 BP3GX1-5X (BP A3 PC)

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):

Microlife Upper Arm Automatic Digital Blood Pressure Monitor, Model BP3GT1-6X, K131346, Microlife Intellectual Property GmbH.

4. Device Description:

Microlife Upper Arm Automatic Digital Blood Pressure Monitor, Model BP3GX1-5X (BP A3 PC) is designed to measure systolic and diastolic blood pressure, pulse rate of an adult individual with arm circumference sizes ranging from 22 -52 cm 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".

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 is also validated for patients with diabetes mellitus.

The blood pressure monitor is a fully automatic digital blood pressure measuring device for use by adults (also applicable to the diabetic patients) on the upper arm at home or in your doctor’s/nurse’s office.

5. **Indications for Use:**

The Microlife Upper Arm Automatic Digital Blood Pressure Monitor, Model BP3GX1-5X (BP A3 PC) is a device intended to measure the systolic and diastolic blood pressure and pulse rate of an adult individual of 12 years and older, with arm circumference sizes ranging from 22 -52 cm by using a non-invasive oscillometric technique in an inflatable cuff being wrapped around the upper arm.

The device is also validated for patients with diabetes mellitus in the age 56 years and older.

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

The device can be used in connection with your personal computer (PC) running the Microlife Blood Pressure Analyzer (BPA) software. The memory data can be transferred to the PC by connecting the monitor via cable with PC.

The blood pressure monitor is a fully automatic digital blood pressure measuring device for use by adults (also applicable for diabetic patients) on the upper arm at home or in your doctor’s/nurse’s office.

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

The subject BP3GX1-5X (BP A3 PC) uses the same oscillometric method as the predicate BP3GT1-6X 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.

The subject BP3GX1-5X (BP A3 PC) and the predicate BP3GT1-6X both have MAM function, IHD function, traffic light function, PC-link function. They use the same fundamental scientific technology. They only differ by the user population. The subject device BP3GX1-5X (BP A3 PC) is validated in adult patients including those with diabetes mellitus. The clinical performance according to ANSI/AAMI IEC81060-2 of BP3GX1-5X (BP A3 PC) for the diabetic adults was

evaluated in a clinical trial. According to the standard ANSI/AAMI IEC81060-2, the subject device BP3GX1-5X(BP A3 PC) can leverage the clinical validation of BP3GT1-6X which was proved in K131346. Moreover, our risk management file and reliability test report (MISC 004) proved the accuracy and normal use are not affected. Therefore, repeated clinical testing for the normal adults in accordance with the standard ANSI/AAMI/IEC 81060-2 for BP3GX1- 5X (BP A3 PC) is not warranted.

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 BP3GX1-5X (BP A3 PC) 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
- 2) IEC 60601-1-2:2014 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 o 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

- 8) IEC 60601-1-11:2015 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
- 9) AAMI/ANSI/ISO 81060-2:2013 Non-Invasive Sphygmomanometers- Part 2: Clinical Validation of Automated Measurement Type.

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 BP3GX1-5X (BP A3 PC) tested met all relevant requirements of the aforementioned tests.

Based on our performance testing the subject device Microlife Upper Arm Automatic Digital Blood Pressure Monitor, Model BP3GX1-5X (BP A3 PC) is substantially equivalent to the predicate device, Microlife Upper Arm Automatic Digital Blood Pressure Monitor, Model BP3GT1-6X.

8. **Discussion of Clinical Tests Performed**

Clinical Validation Concerning the Compliance of ANSI/AAMI/ ISO 81060-2:

The subject device Model BP3GX1-5X (BP A3 PC) is from the technical point of view, identical to the predicate blood pressure monitor BP3GT1-6X. Moreover, the measurement algorithm and its program codes of BP3GT1-6X remain unchanged. The fundamental scientific technology of the modified BP3GX1-5X (BP A3 PC) device is the same as the predicate device BP3GT1-6X. Therefore the performance of the BP3GX1-5X (BP A3 PC) in terms of blood pressure measurement for the normal adults would be similar to performance of the predicate device BP3GT1-6X. Repeated clinical testing for the normal adults in accordance with the standard ANSI/AAMI/ ISO 81060-2 for the subject device BP3GX1-5X (BP A3 PC) is therefore not necessary as clinical testing results were not affected by the changes to the subject modified device.

The subject device BP3GX1-5X (BP A3 PC) is validated also for patients with diabetes mellitus. The clinical performance according to ANSI/AAMI IEC 81060-2 of BP3GX1-5X (BP A3 PC) for the diabetic adults was evaluated in a clinical trial (please see VOL 10, 002).

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 devices.