May 19, 2023

Microlife Intellectual Property GmbH
% Vaibhav Rajal
Official Correspondent for Microlife Intellectual Property GmbH
mdi Consultants, Inc.
55 Northern Blvd., Suite 200
Great Neck, New York 11021

Re: K222979
Trade/Device Name: Microlife Upper Arm Automatic Digital Blood Pressure Monitor, Model BP3KV1-5W
Regulation Number: 21 CFR 870.1130
Regulation Name: Noninvasive Blood Pressure Measurement System
Regulatory Class: Class II
Product Code: DXN
Dated: September 26, 2022
Received: September 28, 2022

Dear Vaibhav Rajal:

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,

for Kenneth J. Cavanaugh -S

Robert Kazmierski
Acting Assistant Director
DHT2A: Division of Cardiac
Electrophysiology, Diagnostics
and Monitoring Devices
OHT2: 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K222979

Device Name
Microlife Upper Arm Automatic Digital Blood Pressure Monitor, Model BP3KV1-5W

Indications for Use *(Describe)*
The Upper Arm Blood Pressure Monitor, Model BP3KV1-5W is a device intended to measure the systolic and diastolic blood pressure and pulse rate of an adult individual by using a non-invasive oscillometric technique in which an inflatable cuff is wrapped around the upper arm for a circumference range from 22 to 52cm.

The device is suitable for use by adults, including adults with conditions of diabetes, pregnancy, or pre-eclampsia.

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 a smart phone via Bluetooth or with a personal computer (PC) via USB. The measurement data can be transferred to a smart phone running the Microlife Connected Health+ mobile software (App) or a PC running the Microlife BP Analyzer+ (BPA+) software.

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.

Microlife Intellectual Property GmbH

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510(k) SUMMARY

The assigned 510(k) number is K222979

1. **Submitter's Identification:**

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

Date Summary Prepared: May 18, 2023

Contact: Mrs. Ariel Wang
Global Regulatory Affairs & Quality management Director
Microlife Intellectual Property GmbH, Switzerland
Tel: 886-2-87971288 # 366
E-Mail: ariel.wang@microlife.com.tw

2. **Name of the Device:**

Microlife Upper Arm Automatic Digital Blood Pressure Monitor, Model BP3KV1-5W

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 BP3MW1-4B, K153077, Microlife Intellectual Property GmbH.

Reference Predicate:

b. Microlife Upper Arm Automatic Digital Blood Pressure Monitor, Model BP3GX1-5X (BP A3 PC), K183469, Microlife Intellectual Property GmbH.

4. **Device Description:**

Microlife Upper Arm Automatic Digital Blood Pressure Monitor, Model BP3KV1-5W is designed to measure systolic and diastolic blood pressure, pulse rate of an 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 using a semiconductor sensor rather than a stethoscope and mercury manometer. The sensor converts 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 device can 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 use by adults on the upper arm at home.

5. **Indications for Use:**

The Upper Arm Blood Pressure Monitor, Model BP3KV1-5W is a device intended to measure the systolic and diastolic blood pressure and pulse rate of an adult individual by using a non-invasive oscillometric technique in which an inflatable cuff is wrapped around the upper arm for a circumference range from 22 to 52cm.

The device is suitable for use by adults, including adults with conditions of diabetes, pregnancy, or preeclampsia.

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 a smart phone via Bluetooth or with a personal computer (PC) via USB. The measurement data can be transferred to a smart phone running the Microlife Connected Health+ mobile software (App) or a PC running the Microlife BP Analyzer+ (BPA+) software.

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

Based on information from the comparison chart:

The differences and changes are the microprocessor and firmware versions. The measurement algorithm and mechanism of operation, as well as the safety & essential performance of the devices remain identical before and after the changes.

The subject (Modified) device BP3KV1-5W uses the same oscillometric method as the predicate device BP3GX1-5X/3MW1-4B with the same fundamental scientific technology to determine the systolic and diastolic blood pressure and pulse rate. Cuff is inflated automatically by pump and the pressures are transferred via tubing to a sensor in these units.

The subject (Modified) device BP3KV1-5W and the predicate device BP3MW1-4B have traffic light function, IHD function, MAM function, Bluetooth function and DMT technology and the predicate device BP3GX1-5X have traffic light function, IHD function, MAM function and DMT technology.

The differences between these devices are:

1) **Physical Dimension**
   The physical dimension of the subject device BP3KV1-5W is 157.5 x 105 x 61.5mm, while predicate device BP3GX1-5X is 85 x 143 x 58mm and predicate device BP3MW1-4B is 110 x 120 x 85mm. The difference is caused because of their different appearance, but the difference does not raise any new safety and effectiveness questions. This has been tested and confirmed according to IEC 60601-1-2 EMC Test Report, IEC 60601-1, AAMIANSI ES60601-1 Safety Test Report and IEC 80601-2-30 Test Report.

2) Display

The display of the Predicate device BP3MW1-4B is with touch pad; however, the display of the subject device BP3KV1-5W and the predicate device BP3GX1-5X is without touch pad. The functionality of the icons among the predicate devices (BP3MW1-4B and BP3GX1-5X) and subject device (BP3KV1-5W) are same, except that the subject device (BP3KV1-5W) has three additional icons representing the functions of Cuff fit check, My check and My BP.

3) Microprocessor

The microprocessor of the subject device BP3KV1-5W is R5F11NMEAFB, whereas the microprocessor of the predicate device BP3GX1-5X is R5F2LA8CANFP and predicate device BP3MW1-4B is C38D59GF. The microprocessors have different connection pin specifications, but the computing architectures are the same, but the computing architectures are the same. This difference does not affect performance and accuracy which was evaluated in the performance testing.

4) Sensor

The microprocessor of the subject device BP3KV1-5W is semiconductor sensor, whereas the microprocessor of the predicate device BP3GX1-5X and predicate device BP3MW1-4Bare capacitive sensor. Their calculation algorithms are the same. But the type of sensor is different. It does not affect performance and accuracy which was evaluated in the performance testing.

5) Cuff Fit Check Function

The subject device BP3KV1-5W has the cuff fit check function, whereas the predicate device BP3GX1-5X/3MW1-4B does not have the function. The cuff fit check function is to check pulse strength during measurement, and indicates if pulse strength is OK. If pulse is too weak, nothing is indicated. This function is just a reference for properly wearing the cuff and does not affect the accuracy and efficacy of the use according to the clinical and essential performance testing, so it does not affect the safety or effectiveness.

6) 28 Days Average Function

The subject device BP3KV1-5W has the 28 days average function, whereas the predicate device BP3GX1-5X/3MW1-4B does not have the function. The 28days average function is an indication of the blood pressure level of the most recent 4 weeks. This stands for the average of measurement values from the last 28 days, so this doesn’t affect the clinical test.

7) MyCheck Function

The subject device BP3KV1-5W has the MyCheck function, whereas the predicate device BP3GX1-5X/3MW1-4B does not have the function. The MyCheck function displays a qualitative comparison of the most recent measurement versus the 4-week measurement average (stored in memory), to provide an immediate, simplified indication whether the current measurement is similar, above or below the 4-week average, without additional operations.

8) MyBP Function

The subject device BP3KV1-5W has the MyBP function, whereas the predicate device BP3GX1-5X/3MW1-4B does not have the function. The MyBP function shows an averaged value, which includes only readings taken in the morning or evening of the most recent 3 to 7 days for computation, per clinical guideline suggestion. The value is displayed only when sufficient number of readings meeting the criteria (below) have been obtained, to provide a more clinically relevant average. If data in the memory are insufficient, it is not displayed. This function is based on the measured data, so this doesn't affect the clinical test.

Based upon the aforementioned information, the three 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 BP3KV1-5W 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 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 10993-10:2010/(R)2014,, Biological evaluation of medical devices – Part 10: Tests for Irritation and Skin Sensitization
6. 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, 2018
7. AAMI/ANSI/ISO 10993-5:2009/(R)2014, Biological evaluation of medical devices – Part 5: Tests for In Vitro Cytotoxicity
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

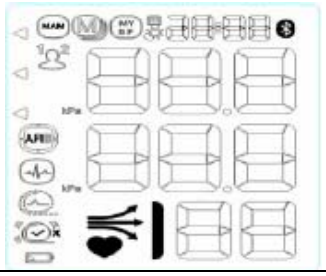
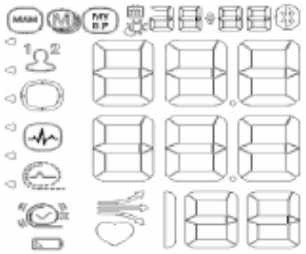
Electrical Equipment And Medical Electrical Systems Used In The Home Healthcare Environment

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 BP3KV1-5W tested met all relevant requirements of the aforementioned tests

8. <u>Discussion of Clinical Tests Performed:</u>

The proposed subject Microlife Upper Arm Automatic Digital Blood Pressure Monitor, Model BP3KV1-5W device uses the same deflation valve and sensor as BP3KT1-3N (European Device). Below is a comparison between the proposed BP3KV1-5W device and the BP3KT1-3N European Device:

Item	BP3KT1-3N European device	Proposed Subject BP3KV1-5W device	Similar or Different
Indications for Use	This oscillometric blood pressure monitor is intended for measuring non-invasive blood pressure in people aged 12 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. The device can detect an irregular pulse suggestive of Atrial Fibrillation (AF). Please note that the device is not intended to diagnose AF. A diagnosis of AF can only be confirmed by ECG. The patient is advised to see a physician. Note: Content above from the CE Mark version IFU. This device is indicated for cuffs covering the upper arm circumference range from 17 to 52cm (refer to "Accessories").	The Upper Arm Blood Pressure Monitor, Model BP3KV1-5W is a device intended to measure the systolic and diastolic blood pressure and pulse rate of an adult individual by using a non-invasive oscillometric technique in which an inflatable cuff is wrapped around the upper arm for a circumference range from 22 to 52cm. The device is suitable for use by adults, including adults with conditions of diabetes, pregnancy, or pre-eclampsia. 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 a smart phone via Bluetooth or with a personal computer (PC) via USB. The measurement data can be transferred to a smart phone running the Microlife Connected Health+ mobile software (App) or a PC running the Microlife BP Analyzer+ (BPA+) software	Different
Device Technology	Oscillometric method	Oscillometric method	√
Measuring Location	Upper Arm	Upper Arm	√

Appearance (ID Design)			Different
Physical Dimension	138 x 94.5 x 62.5 mm	157.5mm x 105mm x 61.5mm	Different
Microprocessor	HY16F198B 1. Hycon IC 2. Main clock frequency: 16 MHz 3. Sub clock frequency:32.768 kHz 4. System voltage level: 3.3 V 5. Pressure sensor type: Semiconductor Sensor 6. The amount of MCU pins: 100 pins(package type)	R5F11NMEAFB 1. Renesas MCU core 2. Main clock frequency: 16 MHz 3. Sub clock frequency: 32.768 kHz 4. System voltage level: 3.3 V 5. Pressure sensor type: Semiconductor Sensor 6. The amount of MCU pins: 80 pins	Different
Sensor	Semiconductor sensor	Semiconductor sensor	√
Deflation Valve	Electromechanical solenoid valve	Electromechanical solenoid valve	√
Algorithm	1. Blood pressure algorithm: Upper arm for deflation measurement 2. Signal filter: FIR filter 3. Algorithm: Oscillometric measurement 4. Irregular heart beat detection: Yes	1. Blood pressure algorithm: Upper arm for deflation measurement 2. Signal filter: FIR filter 3. Algorithm: Oscillometric measurement 4. Irregular heart beat detection: Yes	√
Display	Digital liquid crystal display (Without Touch pad) 	Digital liquid crystal display (Without Touch pad) 	Different
Pressure and Pulse Rate Accuracy	Pressure within ± 3 mmHg or 2% of reading >200mmHg Pulse ± 5 % of the reading	Pressure within ± 3 mmHg or 2% of reading >200mmHg Pulse ± 5 % of the reading	√
Measuring Range	SYS: 60-255 mmHg DIA: 40-200 mmHg Pulse: 40 to 199 beats per minute	SYS: 60-255 mmHg DIA: 40-200 mmHg Pulse: 40 to 199 beats per minute	√
Pressure Resolution	1mm Hg	1mm Hg	√
Cuff Display Range	O to 299mm Hg	O to 299mm Hg	√
Power Source	4 AA batteries, Or AC adapter 6 V DC 600 mA	4 AA batteries, Or AC adapter 6 V DC 600 mA	√
Low Battery Voltage Detection	YES	YES	√
Atrial Fibrillation Detection Function	YES	NO	Different

User	1	2	Different
Last Measurement Recall	1X99 sets	2X99 sets	Different
Beeper Indication	NO	YES	Different
Irregular Heartbeat Detection Function	YES	YES	√
Traffic Light Function	YES	YES	√
MAM Function	YES	YES	√
PC-link function	NO	YES	Different
Blood Pressure Analyzer Software	NO	YES	Different
Cuff Fit Check Function	YES	YES	√
MyCheck Function	NO	YES	Different
MyBP Function	NO	YES	Different
Display Backlight	NO	YES	Different
AC/DC Adaptor Compatible	YES	YES	√
28 Day Memory Day Average	NO	YES	Different
All Memory Average	YES	No	Different
Bluetooth Function	NO	Yes. Using Bluetooth(4.2) to connect with the smart mobile devices running the APP	Different
Operation Range	+10℃to +40℃ at RH 15% to 90%	+10℃to +40℃ at RH 15% to 90%	√
Storage Range	-20℃to +55℃ at RH 15% to 90%	-20℃to +55℃ at RH 15% to 90%	√
Life Time	At least 10000 times of operation	At least 10000 times of operation	√
Cuff Material	Nylon cuff fabric	Nylon cuff fabric	√
Accessories	Standard: M-L size (wide range) cuff for circumference 22-42cm Carrying Punch Special (Optional) 1. S size cuff for arm circumference 17-22cm 2. M size cuff for arm circumference 22-32cm 3. L size cuff for arm circumference 32-42cm 4. L-XL size cuff for arm circumference 32-52cm 5. Adapter (out 6V DC/600 mA)	Standard: Wide range cuff for circumference 22-42cm USB (A to mini B) cable Carrying Punch Special (Optional) 1. L-XL size cuff for arm circumference 32-52cm 2. Adapter (out 6V DC/600 mA)	Different

That said, we are supporting our clinical testing with using the clinical study validation conducted on the BP3KT1-3N (European Device).

The AIM of the clinical study conducted using the BP3KT1-3N was validation of the Microlife BP B3 AFIB upper arm blood pressure monitor in adults and adolescents according to the ANSI/AAMI/ISO 81060-2:2019 test standard. This is a prospective, open-label, non-randomized, single-center validation study following ANSI/AAMI/ISO 81060-2:2019 test standard.

Conclusion: The Microlife device has passed the criteria of the ANSI/AAMI/ISO 81060-2:2019 test standard.

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”.

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 devices.