June 28, 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: K230075
Trade/Device Name: Microlife Upper Arm Automatic Digital Blood Pressure Monitor, Model BP3KVl-5K
Regulation Number: 21 CFR 870.1130
Regulation Name: Noninvasive Blood Pressure Measurement System
Regulatory Class: Class II
Product Code: DXN
Dated: May 22, 2023
Received: May 23, 2023

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,

Robert T. Kazmierski -S

for

LCDR 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K230075

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

Indications for Use *(Describe)*
The Upper Arm Blood Pressure Monitor, Model BP3KV1-5K 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 17 to 52cm.

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.

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VOL 4, 001

510(k) SUMMARY

The assigned 510(k) number is:_____.

1. Submitter's Identification:

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

Date Summary Prepared: September 26, 2022

Contact: Miss. 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 BP3KV1-5K

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 BP3MW1-4Y, K172498, Microlife Intellectual Property GmbH.

Reference Predicate:

b. Microlife Upper Arm Automatic Digital Blood Pressure Monitor, Model BP3MS1-4A (BP A200 Comfort), K153450, Microlife Intellectual Property GmbH.

4. Device Description:

Microlife Upper Arm Automatic Digital Blood Pressure Monitor, Model BP3KV1-5K is designed to measure systolic and diastolic blood pressure, pulse rate of an individual with arm circumference sizes ranging from 17-52 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 BP3KV1-5K 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 17 to 52cm.

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 sensor, cuff size, and the non-clinical functions will be discussed as below. 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 BP3KV1-5K uses the same oscillometric method as the predicate device BP3MW1-4Y and BP3MS1-4A 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 BP3KV1-5K and the predicate device BP3MW1-4Y and BP3MS1-4A have traffic light function, MAM function, IHD function, PC-link Function, and IMT technology.

The differences between these devices are:

1).Physical Dimension

The physical dimension of the subject device BP3KV1-5K is 157.5 x 105 x 61.5 mm, while predicate device BP3MW1-4Y and BP3MS1-4A is 110 x 120 x 85 mm and 152 x92 x 42mm. 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). Sensor

The sensor of the subject device BP3KV1-5K is semiconductor sensor whereas the microprocessor of the predicate device BP3MW1-4Y and BP3MS1-4A is capacitive pressure sensor. Within the performance scope and specification of non-invasive blood pressure measurement system (product code DXN), the performance characteristics of the sensor types are deemed equivalent. The comparing test on the two aspects: laboratory performance test and clinical test demonstrates that the subject device and the predicate device both meet the relevant performance specification requirements and have equivalent essential performance despite the difference in the sensor type used.

3). Version of Blood Pressure Analyzer Software

The version of Blood Pressure Analyzer Software of the subject device BP3KV1-5K is BPA+ , whereas the version of Blood Pressure Analyzer Software of the predicate device BP3MW1-4Y and BP3MS1-4A is BPA. The function of the software is to transfer, storage, display of blood pressure data from compatible Microlife blood pressure monitors to PC (via USB connection). The difference between BPA+ and BPA is only User Interface Aesthetic Design and Software Update Check. This USB data transfer function is independent of the device blood pressure measurement function, and does not affect the measurement function or results.

4).Cuff Fit Check Function

The subject device BP3KV1-5K has the cuff fit check function, whereas the predicate device BP3MW1-4Y and BP3MS1-4A does not have the function. The cuff fit check function checks whether the pulse strength meets a threshold suggestive of sufficiently snug cuff fit during measurement, and indicates Cuff Fit OK if the criteria is met. If the pulse does not meet the threshold, the Cuff Fit OK is not indicated. The cuff fit check function is meant to provide the user with a reference about the status of the cuff fit and to encourage the user to repeat measurement in case the cuff fit is not optimal; the cuff fit check function is independent of the device blood pressure measurement function, and does not affect the measurement function or results.

5).28 Days Average Function

The subject device BP3KV1-5K has the 28 days average function, whereas the predicate device BP3MW1-4Y and BP3MS1-4A does not have the function. The 28days average function provides the user an indication of the blood pressure level of the most recent 4 weeks. It is the average of measurement values from the last 28 days stored in the device memory, and it does not affect the device essential performance.

6).AM/PM Average

The predicate device BP3MW1-4Y has the AM/PM average function, whereas the subject device BP3KV1-5K and BP3MS1-4A does not have the function. The AM/PM average function is an indication of the blood pressure level of all BP measurements taken in the mornings & evenings. This stands for the average of measurement values taken in the mornings & evenings, so this doesn't affect the device essential performance.

7).MyCheck Function

The subject device BP3KV1-5K has the MyCheck function, whereas the predicate device BP3MW1-4Y and BP3MS1-4A does not have the function. The MyCheck function displays a qualitative comparison of the most recent measurement versus the 28-day measurement average (stored in memory), to provide an immediate, simplified indication whether the current measurement is similar, above or below the 28-day average, without additional operations by the user (e.g. switch to memory mode). This function is based on the measured data in the memory and independent of the blood pressure measurement function, and doesn't affect the device essential performance.

8).MyBP Function

The subject device BP3KV1-5K has the MyBP function, whereas the predicate device BP3MW1-4Y and BP3MS1-4A does not have the function. The MyBP function provides the user with an averaged blood pressure value, which includes only readings taken in the morning or evening of the most recent 3 to 7 days for computation, per clinical guideline suggestions (of taking multiple readings in the morning and evening). The MyBP average value is displayed only when sufficient number of readings meeting the criteria 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 device essential performance.

9).Bluetooth function

The subject device BP3KV1-5K and the predicate device BP3MW1-4Y has the Bluetooth function, whereas the predicate device BP3MS1-4A does not have the function. This function is only a way to transfer the data and will not affect the clinical accuracy. They have the same fundamental scientific technology, so this doesn't affect the device essential performance.

10).Cuff Size

The compatible cuff sizes of the subject device BP3KV1-5K and the predicate device BP3MS1-4A is 22–52 cm, whereas the cuff size of the predicate device BP3MW1-4Y is 22–42 cm. 22–52 cm soft cuff was verified in device BP3MS1-4A K153450 and confirm it does not affect performance and accuracy.

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 BP3KV1-5K 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 of 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, 2018.

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

8. Discussion of Clinical Tests Performed:

The subject modified device blood pressure monitor model BP3KV1-5K is from a technical point of view, identical to the predicate blood pressure monitor model BP3MW1-4Y and BP3MS1-4A.

The differences between two models are in (Please see VOL 5,001 for more details):

- Model name
- Industrial and mechanical design
- Sensor
- User interface
- Non-clinical features: Cuff fit check (cuff fit indication), MyCheck comparison, My BP average, AM/PM average, 28days average, Bluetooth, BP traffic light (level classification).

The difference between the subject device and the predicate device listed above do not affect the measurement accuracy, safety, and essential performance of the device, and both devices share common blood pressure measurement technological architecture and algorithm.

The cuff size used with the subject BP3KV1-5K is 17 to 52cm. It is the same with the 510(k) cleared in BP3MS1-4A, which was cleared under K153450. Although the cuff size used with the subject BP3MW1-4Y is 22 to 42cm, the cuff size range is more limited and can be covered by K153450.

Therefore, the clinical validation of the predicate device BP3MW1-4Y and BP3MS1-4A, in adult population per ANSI/AAMI/ISO81060-2 standard, approved in 510(K) K172498 and K153450, is applicable to the subject device BP3KV1-5K. Therefore,

repeated clinical testing in accordance with the standard ANSI/MMI/IEC 81060-2 for BP3KV1-5K is not necessary.

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