July 23, 2026

Microlife Corporation
% Vaibhav Arvind Rajal
Senior Regulatory Affairs Consultant
Mdi Consultants, Inc.
Contact Address

Re: K261082
Trade/Device Name: Microlife Wrist Blood Pressure Monitor (Model BPHJG5-G)
Regulation Number: 21 CFR 870.1130
Regulation Name: Noninvasive Blood Pressure Measurement System
Regulatory Class: Class II
Product Code: DXN
Dated: June 30, 2026
Received: June 30, 2026

Dear Vaibhav Arvind 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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Management System Regulation (QMSR) (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

STEPHEN C. BROWNING -S

CDR 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)*
K261082

Device Name
Microlife Wrist Blood Pressure Monitor (Model BPHJG5-G)

Indications for Use *(Describe)*
The Microlife Wrist Blood Pressure Monitor Model, BPHJG5-G 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 wrist for a circumference range from 13.5 to 21.5cm.

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

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 510(k) number is: K261082.

1. Submitter's Identification:

Microlife Corporation
9F, 431, RuiGuang Road, NeiHu,
Taipei 11492, Taiwan, China

Date Summary Prepared: July 10, 2026

Contact: Mr. Jimmy Deng
Global Regulatory Affairs & Quality Management Director
Microlife Corporation
Tel: 886-2-87971288 # 376
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2. Name of the Device:

Microlife Wrist Blood Pressure Monitor (Model BPHJG5-G)

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 Wrist Watch Blood Pressure Monitor, Model BP3GK1-4B, K211288, Microlife Intellectual Property GmbH.

4. Device Description:

Microlife Wrist Blood Pressure Monitor Model, Model BPHJG5-G is designed to measure systolic and diastolic blood pressure and pulse rate of an individual by using a non-invasive technique in which an inflatable cuff is wrapped around the wrist. Our method to define systolic and diastolic pressure is similar to the auscultatory method but uses 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”.

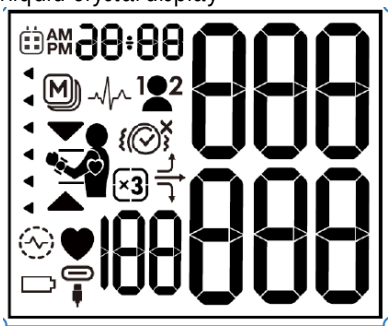
5. Indications for Use:

The Microlife Wrist Blood Pressure Monitor Model, BPHJG5-G 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 wrist for a circumference range from 13.5 to 21.5cm.

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

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

Item	1. Predicate device (Primary): Microlife Wrist Watch BPM BP3GK1-4B, Microlife Intellectual Property GmbH, K211288	Subject device: Microlife Wrist Blood Pressure Monitor BPHJG5-G, Microlife Intellectual Property GmbH	Similar or Different
Indications for Use	The Wrist Watch Blood Pressure Monitor, Model BP3GK1-4B 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 wrist for a circumference range from 13.5 to 21.5cm. 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 running the APP. The memory data can be transferred to the smart phone via Bluetooth.	The Microlife Wrist Blood Pressure Monitor Model, BPHJG5-G 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 wrist for a circumference range from 13.5 to 21.5cm. The device detects the appearance of irregular heartbeat during measurement and gives a warning signal with the reading once the irregular heartbeat is detected.	Different
Device Technology	Oscillometric method	Oscillometric method	√
Measuring Location	Wrist	Wrist	√
Appearance (ID design)			Different
Physical Dimension	81x65x21 mm 3.19x2.56x0.83inch	89x74x22 mm 3.50x2.91x0.87inch	Different
Microprocessor	HY16F198B 1. HYCOM MCU core 2. Main clock frequency: 8 MHz 3. Sub clock frequency: 32.768kHz 4. System voltage level: 3.3V 5. Pressure sensor type: Semiconductor sensor 6. The amount of MCU pins: 100 pins	HY16F198B 1. HYCOM MCU core 2. Main clock frequency: 8 MHz 3. Sub clock frequency: 32.768kHz 4. System voltage level: 3.3V 5. Pressure sensor type: Semiconductor sensor 6. The amount of MCU pins: 100 pins	√

Item	1. Predicate device (Primary): Microlife Wrist Watch BPM BP3GK1-4B, Microlife Intellectual Property GmbH, K211288	Subject device: Microlife Wrist Blood Pressure Monitor BPHJG5-G, Microlife Intellectual Property GmbH	Similar or Different
Sensor	Semiconductor sensor	Semiconductor sensor	√
F/W reversion of Algorithm	Yi2 1. Blood pressure algorithm: Wrist for inflation measurement 2. Signal filter: FIR filter 3. Algorithm: Oscillometric measurement 4. Irregular heart beat detection: IHD	Yi6 1. Blood pressure algorithm: Wrist for inflation measurement 2. Signal filter: FIR filter 3. Algorithm: Oscillometric measurement 4. Irregular heart beat detection: IHD	Different
Signal Detection Technology	Detect electrical while inflating (Called "IMT" technology)	Detect electrical while inflating (Called "IMT" technology)	√
Display	Digital liquid crystal display 	Digital liquid crystal display 	Different
Pressure and Pulse Rate Accuracy	Pressure within ± 3 mmHg or 2% of reading >200mmHg Pulse ± 5% of the reading	Pressure within ± 3 mmHg Pulse ± 5% of the reading	√
Measuring Range	SYS: 60-255 mmHg DIA: 40-200 mmHg Pulse: 40 to 199 per minute	SYS: 60-255 mmHg DIA: 40-200 mmHg Pulse: 40 to 199 per minute	√
Pressure Resolution	1mmHg	1mmHg	√
Cuff Display Range	0 to 299mmHg	0 to 299mmHg	√
Power Source	2 Batteries, Size AAA 1.5V	2 Batteries, Size AAA 1.5V, Or AC adapter DC 5V, 1.0 A	Different
Low Battery Voltage Detection	Yes	Yes	√
User	2	2	√
Last Measurement Recall	2*100 sets	2*99 sets	Different
Beeper Indication	Yes	NO	Different
Irregular Heartbeat Detection Function	Yes	Yes	√
Traffic Light Function	Yes	Yes	√
MAM function	Yes	Yes	√

Item	1. Predicate device (Primary): Microlife Wrist Watch BPM BP3GK1-4B, Microlife Intellectual Property GmbH, K211288	Subject device: Microlife Wrist Blood Pressure Monitor BPHJG5-G, Microlife Intellectual Property GmbH	Similar or Different
Wrist Position Check function	Yes	Yes	√
Cuff fit check function	Yes	Yes	√
MyCheck function	Yes	Yes	√
MyBP function	Yes	NO	Different
AC/DC Adaptor Compatible	NO	Yes	Different
AM/PM Average stored Function	Yes	No	Different
28-Day Memory Average	No	Yes	Different
Bluetooth function	Yes Using Bluetooth(4.2)	NO	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	Flannelette cuff cloth PVC bladder	Nylon cuff cloth PVC bladder	Different
Quick exhaust valve	Electromechanical solenoid valve	Electromechanical solenoid valve	√
Accessories	**Necessary:** Cuff for wrist circumference 13.5-21.5cm AAA batteries Instruction manual Gift box	**Necessary:** Cuff for wrist circumference 13.5-21.5cm AAA batteries Instruction manual Gift box Storage case **Special(optional):** Adapter(out 5V 1A 5W)	Different

Based on information from the comparison chart:

The differences and changes are power source, 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 BPHJG5-G uses the same oscillometric method as the predicate device BP3GK1-4B 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 BPHJG5-G and the predicate device BP3GK1-4B have traffic light function, MAM function, IHD function, IMT technology, Cuff fit check function, 2 users function and MyCheck function.

The differences between these devices are:

1) Indications for Use

The subject device BPHJG5-G and predicate device BP3GK1-4B both are 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 wrist for a circumference range from 13.5 to 21.5cm. The differences between subject device and predicate device both are the Bluetooth function. The predicate device BP3GK1-4B can be used in connection with a smart phone running the APP and the memory data can be transferred to the smart phone via Bluetooth. However, this function is only a way to transfer the data and does not affect effectiveness and safety.

2) Physical Dimension

The physical dimension of the subject device BPHJG5-G is 89 x 74 x 22 mm, while predicate device BP3GK1-4B is 81 x 65 x 21 mm. 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.

3) Display

The subject device BPHJG5-G and predicate device BP3GK1-4B both have digital liquid crystal display. The only difference is the UI. But, it does not affect the effectiveness according to the essential performance testing.

4) F/W reversion of Algorithm

The algorithm of subject device BPHJG5-G is yi6, while predicate device BP3GK1-4B is yi2. The only difference is the algorithm version, because the BPHJG5-G incorporates an additional adapter-based power supply function. However, their calculation algorithm is the same. It does not affect performance and accuracy which was evaluated in the performance testing.

5) Last Measurement Recall

The subject device BPHJG5-G and predicate device BP3GK1-4B have Different number of stored measurement values. This does not affect effectiveness and safety.

6) My BP function

The subject device BPHJG5-G does not have the MyBP function, whereas the predicate device BP3GK1-4B 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.

7) AM/PM Average Stored Function

The subject device BPHJG5-G does not have the AM/PM average stored function, whereas the predicate device BP3GK1-4B has the function. The AM/PM average stored function is to give an average result based on AM or PM measurements are taken. This function is based on the measured data, so this doesn't affect the clinical test.

8) 28-Day Memory Average

The subject device BPHJG5-G has the 28-Day Memory Average function, whereas the predicate device BP3GK1-4B does not have the function. The AM/PM average stored function refers to calculating the average of all measured values within a 28-day period. This function is based on the measured data, so this doesn't affect the clinical test.

9) Bluetooth function

The subject device BPHJG5-G does not have the Bluetooth function, whereas the predicate device BP3GK1-4B has the function. This function is only a way to transfer the data and is based on the measured data, so it does not affect effectiveness and safety according to the performance testing and safety testing.

10) Beeper Indication

The subject device BPHJG5-G does not have the Beeper Indication, whereas the predicate device BP3GK1-4B has the function. This function provides audio alerts during operation. For example, a beep will sound at the start and end of a measurement to notify the user. Therefore, it does not affect effectiveness and safety according to the performance testing and safety testing.

11) Power Source

The power supply of the subject device BPHJG5-G is compatible with not only AAA batteries but also AC/DC Adaptor whereas the predicate device BP3GK1-4B is only compatible with AAA batteries. But the difference does not raise any new safety and effectiveness questions. This does not affect the device essential performance. 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.

12) Cuff material

The subject device BPHJG5-G uses nylon cloth for cuff material, whereas the predicate device BP3GK1-4B uses flannelette cloth. As the bladder is the same, the Different cloth material does not affect effectiveness and safety. A biological evaluation was conducted for the blood pressure cuff in compliance with ISO 10993-1

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

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

Testing information demonstrating the safety and effectiveness of the Microlife Wrist Blood Pressure Monitor Model, Model BPHJG5-G 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 device:

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

1) ANSI AAMI ES60601-1:2005/(R)2012 & A1:2012, C1:2009/(R)2012 &A2:2010/(R)2012 (Cons. Text) [Incl. AMD2:2021]Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005, MOD) [Including Amendment 2(2021)]

2) IEC 60601-1-2 Edition 4.1 2020-09 CONSOLIDATED VERSION Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests

3) ISO 14971: 2019 Medical devices – Application of risk management of medical devices.

4) ISO 10993-1 Fifth edition 2018-08
Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process

5) ISO 10993-5 Third edition 2009-06-01
Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity

6) AAMI/ANSI/IEC 80601-2-30:2018 Medical electrical equipment – Part 2-30: Particular requirements for the basic safety and essential performance of automated non-invasive sphygmomanometers

7) ISO 10993-10 Fourth edition 2021-11
Biological evaluation of medical devices - Part 10: Tests for skin sensitization

8) IEC 60601-1-11:2020 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 Wrist Blood Pressure Monitor Model, Model BPHJG5-G tested met all relevant requirements of the aforementioned tests.

8. Discussion of Clinical Tests Performed:

The Microlife W2 Slim automated blood pressure monitors fulfilled the ISO 81060-

2:2018 (including AMD 1:2020 & AMD 2:2024) protocols, and can be recommended for self-measurement in the general population. The study were tested on 85 were analyzed [mean age: 63.4 ± 18.0 (SD) years, 34 men, 51 women, wrist circumference 17.5 ± 2.2 cm, range: 13.5–21.5 cm]. For validation criterion 1, the mean difference ± SD between the test device and reference BP readings (N = 255) was 1.23 ± 7.2/−0.27 ± 6.22 mmHg (systolic/diastolic; threshold ≤5 ± 8 mmHg). For criterion 2, the SD of the average BP differences between the test device and reference BP per individual (N = 85) was 6.09/5.13 mmHg (systolic/diastolic; threshold ≤ 6.84/6.95 mmHg).

Based on Declaration of Identity, the Microlife wrist blood pressure monitor BPHJG5-G is from the technical point of view identical to the Microlife wrist blood pressure monitor W2 Slim (model number BP3GK1-4E).

The clinical validation results of W2 Slim are applicable to BPHJG5-G. The study participants were recruited from two clinical sites: the Department of Outpatients and Cardiology at the Second Hospital of Xi'an City / Xijing Hospital (Xi'an, China), and the Department of Cardiology at Taipei Veterans General Hospital (Taipei, Taiwan). All participants provided written informed consent prior to enrolment.

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 device.