August 6, 2025

Microlife Corporation
% Vaibhav Arvind Rajal
Senior Regulatory Affairs Consultant
mdi Consultants, Inc.
55 Northern Blvd., Suite 200
Great Neck, New York 11021

Re: K251120
Trade/Device Name: Microlife Upper Arm Automatic Digital Blood Pressure Monitor, Model BP Progress (BP3T01-1B)
Regulation Number: 21 CFR 870.1130
Regulation Name: Noninvasive Blood Pressure Measurement System
Regulatory Class: Class II
Product Code: DXN
Dated: July 2, 2025
Received: July 2, 2025

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 System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 systems (QS) regulation (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

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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K251120
Please provide the device trade name(s).	
Microlife Upper Arm Automatic Digital Blood Pressure Monitor, Model BP Progress (BP3T01-1B)	
Please provide your Indications for Use below.	
The Upper Arm Automatic Digital Blood Pressure Monitor, Model BP Progress (BP3T01-1B) 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 40cm. 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. The measurement data can be transferred to a smart phone running the Microlife Connected Health+ mobile software (App).	
Please select the types of uses (select one or both, as applicable).	☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

510(k) SUMMARY

The assigned 510(k) number is:

1. **Submitter's Identification:**

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

Date Summary Prepared: February 12, 2025

Contact: Mrs. Ariel Wang
Global Regulatory Affairs & Quality management Director
Microlife Corporation
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 BP Progress (BP3T01-1B)

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 BP3KV1-5K, K230075, Microlife Intellectual Property GmbH.

4. **Device Description:**

The Upper Arm Automatic Digital Blood Pressure Monitor, Model BP Progress (BP3T01-1B) is designed to measure systolic and diastolic blood pressure, pulse rate of an individual with arm circumference sizes ranging from 22 to 40 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 Microlife Connected Health+ mobile software (App) 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 Automatic Digital Blood Pressure Monitor, Model BP Progress (BP3T01-1B) 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 40cm.

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. The measurement data can be transferred to a smart phone running the Microlife Connected Health+ mobile software (App).

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

Based on information from the comparison chart:

The differences and changes are the cuff type 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 device BP Progress (BP3T01-1B) uses the same oscillometric method as the predicate device BP3KV1-5K 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 device BP Progress (BP3T01-1B) and the predicate device BP3KV1-5K have traffic light function, MAM function, IHD function, Bluetooth Function, IMT technology, Cuff fit check function, 28 days Average Function and MyCheck function.

The differences between these devices are:

1) Physical Dimension

The physical dimension of the subject device BP Progress (BP3T01-1B) is 145 x 67 x 28 mm, while predicate device BP3KV1-5K is 157.5 x 105 x 61.5 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, AAMI/ANSI/ES 60601-1 Safety Test Report and IEC 80601-2-30 Test Report.

2) PC link function/ Blood pressure Analyzer Software

The subject device BP Progress (BP3T01-1B) does not has PC link function, whereas the predicate device BP3KV1-5K have the function. 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). This USB data transfer function is independent of the device blood pressure measurement function and does not affect the measurement function or results.

3) MyBP function

The subject device BP Progress (BP3T01-1B) does not has the MyBP function, whereas the predicate device BP3KV1-5K 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 has 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.

4) Power Source

The power supply of the subject device BP Progress (BP3T01-1B) is only AAA batteries, whereas the predicate device BP3KV1-5K is compatible with not only AA batteries but also AC/DC Adaptor. Because there is no AC power supply on BP Progress (BP3T01-1B), there will be no danger posed by alternating current electricity. 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, AAMI/ANSI/ES60601-1 Safety Test Report and IEC 80601-2-30 Test Report.

5) Touch Pad Technology

The subject device BP Progress (BP3T01-1B) has the touch pad technology, whereas the predicate device BP3KV1-5K does not have the function. The evaluation of usability of the subject device BP Progress (BP3T01-1B) has been proceeded with Usability Engineering File (Attachment 9.3). It is approved that this doesn't affect the device essential performance and user operation.

6) Cuff Type and Size

The compatible cuff type and sizes of the subject device BP Progress (BP3T01-1B) is without tube and 22–40 cm, whereas the cuff type and sizes of the predicate device BP3KV1-5K is with tube, and 22-52 cm. without tube, 22-40 cm soft cuff was verified in Clinical Test Report of Microlife BP3T01-1B and confirm it does not affect performance and accuracy.

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 BP Progress (BP3T01-1B) 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 & A1:2012, C1:2009/(R)2012 & A2:2010/(R)2012 (Cons. Text) [Incl. AMD2:2021]
2. IEC 60601-1-2:2014 + AMD1:2020 Medical electrical equipment Part 1-2: General requirements for safety and essential performance – Collateral standard: Electromagnetic Disturbances - Requirements and tests.
3. ISO 14971: 2019 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 80601-2-30:2018 Medical electrical equipment – Part 2-30: Particular requirements for the basic safety and essential performance of automated non-invasive sphygmomanometers
7. AAMI/ANSI/ISO 10993-5:2009/(R)2014, Biological evaluation of medical devices – Part 5: Tests for In Vitro Cytotoxicity
8. IEC 60601-1-11:2020 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 Upper Arm Automatic Digital Blood Pressure Monitor, Model BP Progress (BP3T01-1B) tested met all relevant requirements of the aforementioned tests

8. Discussion of Clinical Tests Performed:

The subject modified device blood pressure monitor model BP Progress (BP3T01-1B) is from a technical point of view, identical to the predicate blood pressure monitor model BP3KV1-5K.

The differences between two models are in (Please see Comparison Chart for more details):

- Model name
- Industrial and mechanical design.
- User Interface
- Cuff type and size
- Non-clinical features: PC link function, My BP average, Power Source, Touch pad technology

Most of differences 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 device share common blood pressure measurement technological architecture and algorithm.

The main difference between BP Progress (BP3T01-1B) and BP3KV1-5K is Cuff type and size. Clinical Validation Concerning the Compliance of ANSI/AAMI/ISO 81060-2: A clinical validation was conducted in accordance with ISO 81060-2 testing. Results were passing and the subject device was found to be substantially equivalent to the predicate 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”.

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.