July 23, 2020

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

Re: K200738
Trade/Device Name: Microlife Upper Arm Automatic Digital Blood Pressure Monitor, Model WatchBP Home A BT (BP3MX1-3C)
Regulation Number: 21 CFR 870.1130
Regulation Name: Noninvasive Blood Pressure Measurement System
Regulatory Class: Class II
Product Code: DXN
Dated: June 24, 2020
Received: June 25, 2020

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,

LT 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

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: March 20, 2020

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 WatchBP Home A BT (BP3MX1-3C)

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 WatchBP Home N (BP3MX1-4), K100763, Microlife Intellectual Property GmbH.

4. Device Description:

Microlife Upper Arm Automatic Digital Blood Pressure Monitor, Model WatchBP Home A BT (BP3MX1-3C) is designed to measure systolic and diastolic blood pressure and pulse rate of an adult individual with arm circumference sizes ranging from 22 -42 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 a resistive pressure 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 has <<USUAL>> and <<DIAG.>> measurement modes. The <<USUAL>> mode is selected for a regular single measurement. The <<DIAG.>> mode is selected for diagnosis or follow-up.

The device detects the appearance of atrial fibrillation during measurement and gives a warning signal with the reading once the atrial fibrillation is detected. If atrial fibrillation is detected during all readings of the triple measurements in usual mode or all four readings of one day in diagnostic mode, the Afib icon  is displayed.

In addition, the memory data can be transferred to the PC (personal computer) running the WatchBP Analyzer Home software by connecting the monitor via cable. The device can also be used in connection with smart mobile devices running the APP and via Bluetooth.

The device is intended for use by patient at home or by health care givers in primary care settings.

5. Indications for Use:

The Microlife Upper Arm Automatic Digital Blood Pressure Monitor, Model WatchBP Home A BT (BP3MX1-3C) is a device intended to measure the systolic and diastolic blood pressure and pulse rate of an adult individual with arm cuff circumference sizes ranging from 22 -42 cm by using a non-invasive oscillometric technique in one inflatable cuff being wrapped around the upper arm.

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

The memory data can be transferred to the PC (personal computer) running the WatchBP Analyzer Home software by connecting the monitor via cable. The device can also be used in connection with smart mobile devices running the APP and via Bluetooth.

The device is intended for use by patient at home or by health care givers in primary care settings.

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

Subject (Modified) Device Compared to Predicate Device WatchBP Home N (BP3MX1-4) (K100763):

Based on information from the Comparison Chart:

The subject WatchBP Home A BT (BP3MX1-3C) uses the same oscillometric method as the predicate device WatchBP Home N (BP3MX1-4) 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. They both detect the appearance of atrial fibrillation during measurement and give a warning signal with the reading once the atrial fibrillation is detected.

The differences between the devices are:

1) Measurement Mode

The subject device has two measurement modes (USUAL Mode, DIAG Mode) while the predicate device has three measurement modes (USUAL Mode, DIAG Mode,

NOCTURNAL Mode). The USUAL Mode and DIAG Mode for both the subject device and predicate device are identical, the NOCTURNAL Mode is removed from the subject device. Therefore, the change will not affect the accuracy and efficacy of the use. And the change does not affect the safety or effectiveness of the subject device according to the safety and essential performance testing.

2) Microprocessor

The main clock of the microprocessor utilized by the subject device has higher frequency (18.432 MHz) compared with the microprocessor used by the predicate device (4 MHz). Due to the sampling rate of the devices are the same (43Hz), both the processors are capable of working well with the sampling rate and the changes will not affect the accuracy and efficacy of the devices in blood pressure measurement and atrial fibrillation detection. Therefore, the change of microprocessor does not affect the accuracy and efficacy of the use. And the change does not affect the safety or effectiveness of the subject device according to the safety and essential performance testing.

3) F/W reversion of Algorithm (base on the items of “Microprocessor”)

For F/W reversion of algorithm, they are only different in U/I, including measurement modes, memories, medication record function and bluetooth connectivity which are not relative to clinical performance of the devices. The algorithm related specifications (#1, #2, #3, #4) are identical to the predicate device. Therefore, the change does not affect the accuracy and efficacy of the use. And the change does not affect the safety or effectiveness of the subject device according to the safety and essential performance testing.

The F/W revision is due to the need of different U/I design but not relative to the algorithm in blood pressure measurement and atrial fibrillation detection. U/I difference that needs F/W revision are addressed in other separated items, includes measurement modes, memories, medication record function and bluetooth connectivity.

4) Sensor

The subject device uses a resistive pressure sensor while the predicate device uses a capacitive pressure sensor. The capacitive pressure sensor used by the predicate device provides durability of 30k cycles blood pressure measurement while the resistive pressure sensor used by the subject device provides durability of 100k cycles blood pressure measurement. The difference is relative to the durability but not relative to the accuracy of blood pressure measurement and atrial fibrillation detection. Thus the difference does not affect the clinical performance of the subject device. And the change does not affect the safety or effectiveness of the subject device according to the safety and essential performance testing.

5) Memory Stored

The memory stored numbers under USUAL Mode and DIAG Mode for both the subject device and predicate device are identical. Due to the NOCTURNAL Mode and Medication Record Function is removed from the subject device, the Memory Stored feature of NOCTURNAL Mode and Medication Record Function is also

removed. Therefore, the change will not affect the accuracy and efficacy of the use. And the change does not affect the safety or effectiveness of the subject device according to the safety and essential performance testing.

6) Medication Record Function

The Medication Record Function is removed from the subject device. Therefore, the change will not affect the accuracy and efficacy of the use. And the change does not affect the safety or effectiveness of the subject device according to the safety and essential performance testing.

7) Blood Pressure Analyzer Software

The subject device and the predicate device both have Blood Pressure Analyzer Software, they are just different in the version of the Blood Pressure Analyzer Software. The change will not affect the accuracy and efficacy of the use. Therefore, the change does not affect the safety or effectiveness of the subject device according to the Verification and Validation Documentation of the Blood Pressure Analyzer Software.

8) Bluetooth Function

The Bluetooth Function is added to the subject device, it makes the device use Bluetooth (BT4.2) to connect with the smart mobile devices running the APP, but this function is only a way to transfer the data and will not affect the accuracy and efficacy of the use. Bluetooth is not active when the blood pressure monitor device is recording data. The blood pressure monitor device will not sound any alarm with or without Bluetooth. The Bluetooth is used only to transfer data form point A to point B. Therefore, the change does not affect the safety or effectiveness of the subject device according to the FCC Certification, Bluetooth RF Test Report, and Bluetooth RF Exposure Evaluation Report. The Bluetooth on the subject device is for transfer of records only. It cannot be used to start or stop the blood pressure device. Bluetooth cannot be used during blood pressure measurement. Please refer to our “Draft Instruction Manual for WatchBP Home A BT (BP3MX1-3C)”. Bluetooth functionality can be classified as a medical device data system (MDDS).

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 WatchBP Home A BT (BP3MX1-3C) 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) 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 Non-Invasive Sphygmomanometers – Part 2: Clinical Validation of Automated Measurement Type. 2013

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 WatchBP Home A BT (BP3MX1-3C) tested met all relevant requirements of the aforementioned tests.

8. Discussion of Clinical Tests Performed:

From a clinical validation standpoint, the subject device is identical to the 510(k) cleared predicate device, WatchBP Home N (BP3MX1-4), K100763, in blood pressure measurement and atrial fibrillation detection.

Regarding clinical validation concerning the compliance of ANSI/AAMI/IEC 81060-2, the subject blood pressure monitor Model WatchBP Home A BT (BP3MX1-1C) is, from a technical point of view, identical to the predicate blood pressure monitor Model WatchBP Home N (BP3MX1-4).

The subject device WatchBP Home A BT (BP3MX1-1C) and the predicate device WatchBP Home N (BP3MX1-4) both intended to measure systolic and diastolic blood pressures, pulse rate for use in an adult individual with arm cuff circumference sizes ranging from 22 -42 cm. And they both detect the appearance of atrial fibrillation during measurement and give a warning signal with the reading once the atrial fibrillation is detected. The differences between the two models are addressed in the Comparison Chart. According to the information from the comparison chart, all the differences listed in the comparison chart do not affect the accuracy and normal use of this device because they use the same fundamental scientific technology. Therefore the performance of the WatchBP Home A BT (BP3MX1-3C) in terms of blood pressure measurement and atrial fibrillation detection would be essential equivalent with performance of the predicate device WatchBP Home N (BP3MX1-4). There was no repeated clinical testing required for blood pressure measurement and atrial fibrillation detection to support WatchBP Home A BT (BP3MX1-3C) as the subject device can leverage the clinical validation of WatchBP Home N (BP3MX1-4) that was proven in K100763.Repeat clinical testing in accordance with the standard AAMI / ANSI/IEC81060-2 for the subject device WatchBP Home A BT (BP3MX1-3C) regarding blood pressure measurement and atrial fibrillation detection for use in adults is therefore not warranted.

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 2019 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 as safe, effective, and performs as well as the predicate device.