June 18, 2020

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: K200297
Trade/Device Name: Microlife Upper Arm Automatic Digital Blood Pressure Monitor, Model WatchBP Office (BP3SK1-3B)
Regulation Number: 21 CFR 870.1130
Regulation Name: Noninvasive Blood Pressure Measurement System
Regulatory Class: Class II
Product Code: DXN
Dated: May 14, 2020
Received: May 20, 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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K200297

Device Name
Microlife Upper Arm Automatic Digital Blood Pressure Monitor, Model WatchBP Office (BP3SK1-3B)

Indications for Use *(Describe)*
The Microlife Upper Arm Automatic Digital Blood Pressure Monitor,Model WatchBP Office (BP3SK1-3B) is a non-invasive digital blood pressure device using oscillometric technique and an upper-arm blood pressure cuff to measure systolic and diastolic blood pressures, pulse rate, mean arterial pressure (MAP) for use in adults and pediatrics (but not neonates) with arm cuff circumference sizes ranging from 14 -52 cm.

The device can accurately measure blood pressure in pregnant patients including those with known or suspected pre-eclampsia.

The device provides aortic blood pressure parameters, includes central systolic blood pressure (cSBP), central pulse pressure (cPP) and central diastolic blood pressure (cDBP), non-invasively through the use of a brachial cuff.

The device detects the appearance of atrial fibrillation during measurement and gives a warning signal together with the measured blood pressure value if atrial fibrillation is detected.

The memory data can be transferred to the PC (personal computer) running the WatchBP Analyzer software by connecting the monitor via USB cable or Bluetooth.

The device is for hospital use only.

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: K200297

1. Submitter's Identification:

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

Date Summary Prepared: June 17, 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 Office (BP3SK1-3B)

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 ProBP 2400, K152770, Microlife Intellectual Property GmbH.

Reference Predicate:

b. Microlife Upper Arm Automatic Digital Blood Pressure Monitor, Model WatchBP Office Central (TWIN200 CBP), K171937, Microlife Intellectual Property GmbH.

4. Device Description:

Microlife Upper Arm Automatic Digital Blood Pressure Monitor, Model WatchBP Office (BP3SK1-3B) is designed to measure systolic and diastolic blood pressure, pulse rate, and mean arterial pressure (MAP) of the adults and pediatrics (but not neonates) populations with arm circumference sizes ranging from 14 -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 use a resistive pressure sensor rather than a stethoscope and mercury manometer. The sensor convert tiny alterations in cuff pressure to electrical signals, by analyzing those signals to define the systolic and diastolic blood pressure and calculating pulse rate, mean arterial pressure (MAP), central systolic blood pressure (cSBP), central pulse pressure (cPP) and central diastolic pressure (cDBP) which is a well - known technique in the market called the “oscillometric method”.

The device has two measurement modes that can be used :<< AUTO>> mode and << MANUAL>> mode. It has number of measurements setting function, resting time setting function, measurement intervals setting function, atrial fibrillation detection function, Central Blood Pressure (CBP) measurement function etc. In addition, the device can be used in connection with your personal computer (PC) running the WatchBP Analyzer software. The memory data can be transferred to the PC by connecting the monitor with the PC via USB cable or Bluetooth.

The measurement program in << AUTO>> mode of the device can be set, includes Number of Measurements, Resting Time (Countdown time), Interval Time, AFIB detector, CBP measurement, HIDE and Average calculation (Discard 1st measurement). Select << AUTO>> mode, press the button to perform automatic measurements based on the settings of << AUTO>> mode. The device shows all the settings and then starts counting down the Resting Time before the first measurement. The average measurement reading is displayed and saved after the measurements are complete.

The measurement program in << MANUAL>> mode can be set to preferences. The program includes setting the Highest Cuff Pressure and Hide Cuff Pressure during deflation. Select the << MANUAL>>mode if auscultatory blood pressure measurement is preferred above oscillometric blood pressure measurement. In << MANUAL>> mode, the device serves as a pressure gauge. No oscillometric measurements will be taken. Systolic and diastolic Korotkoff sounds are determined by the physician using a stethoscope placed over the brachial artery.

The device can accurately measure blood pressure in pregnant patients including those with known or suspected pre-eclampsia.

The device detects the appearance of atrial fibrillation during measurement and the atrial fibrillation symbol “AFIB“is displayed on the LCD screen if any atrial fibrillation signal has been detected.

The device is for hospital use only.

5. Indications for Use:

The Microlife Upper Arm Automatic Digital Blood Pressure Monitor,Model WatchBP Office (BP3SK1-3B) is a non-invasive digital blood pressure device using oscillometric technique and an upper-arm blood pressure cuff to measure

systolic and diastolic blood pressures, pulse rate, mean arterial pressure (MAP) for use in adults and pediatrics (but not neonates) with arm cuff circumference sizes ranging from 14 -52 cm.

The device can accurately measure blood pressure in pregnant patients including those with known or suspected pre-eclampsia.

The device provides aortic blood pressure parameters, includes central systolic blood pressure (cSBP), central pulse pressure (cPP) and central diastolic blood pressure (cDBP), non-invasively through the use of a brachial cuff.

The device detects the appearance of atrial fibrillation during measurement and gives a warning signal together with the measured blood pressure value if atrial fibrillation is detected.

The memory data can be transferred to the PC (personal computer) running the WatchBP Analyzer software by connecting the monitor via USB cable or Bluetooth.

The device is for hospital use only.

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

Subject (Modified) Device Compared to Primary Predicate ProBP 2400 (K152770):

Based on information from the Comparison Chart:

The modified device model WatchBP Office (BP3SK1-3B) uses the same oscillometric method as the predicate device ProBP 2400 with the same software algorithm to determine the systolic and diastolic blood pressure, pulse rate and mean arterial pressure (MAP). 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 are both intended to measure systolic and diastolic blood pressures, pulse rate, mean arterial pressure (MAP) for use in pregnant patients including those with known or suspected pre-eclampsia, adults and pediatrics (but not neonates) with arm cuff circumference sizes ranging from 14 -52 cm.

The differences between the devices are:

1) Measurement mode

The subject device has two measurement modes (auto mode, manual mode) while the primary predicate device has three measurement modes(1x mode，3x mode, manual mode). With a press of start/ Stop button, the <auto mode> of the subject device allows 1 to 6 consecutive measurements and give the average readings after all the measurements are finished. The number of measurement of <Auto mode> is selectable from the button operation. For the primary predicate device, <1 x mode> allows single measurement, <3x mode> allows 3 consecutive measurements. Number of measurements are just the U/I relative feature, not relative to the accuracy of BP measurement or AFIB detection. The manual mode

of both the subject device and primary predicate device is designed to have the deflation rate of 2-3 mmHg/s for the professionals can use the device and stethoscope to take manual blood pressure measurement. The firmware revision is due to the need of different U/I design but not relative to the algorithm in BP measurement, atrial fibrillation detection. The change does not cause any new or significantly modified risks according to the Risk Management File and it does not affect the clinical performance of the subject device. The changes of the U/I of the subject device with the flexibility to take 1-6 consecutive measurement is designed complying to AAMI/ANSI/IEC 80601-2-30. Therefore, the changes do not affect the safety or effectiveness of the subject device according to the safety and essential performance testing.

2) Microprocessor

They are different in some features of microprocessor. However different features of microprocessor are all U/I related features (Microprocessor #2, #3, #4), which do not affect the clinical performance of the device. And all features related to brachial blood pressure algorithm are identical (Microprocessor #6, #7, #8).The added features of atrial fibrillation detection and the central blood pressure measurement are identical to reference predicate device (#9). Therefore, the change does not affect the accuracy and efficacy for brachial blood pressure measurement. 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, number measurement settings, resting time, interval time settings, hide reading functions, USB and Bluetooth connectivity which are not relative to clinical performance of the devices. The brachial blood pressure measurement algorithm related specifications (#1, #2, #3, #4) are identical to both predicate devices. The added features of atrial fibrillation detection and the central blood pressure measurement are identical to reference predicate device (#4, #5). Therefore, the change does not affect the accuracy and efficacy for brachial blood pressure measurement. 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 BP measurement, atrial fibrillation detection. U/I difference that needs F/W revision are addressed in other separated items, includes bluetooth connectivity, measurement modes, Number of Measurements Setting Function, Resting Time Setting Function, Measurement interval time Setting Function.

4) Atrial Fibrillation Detection Function

The Atrial Fibrillation Detection Function is added to the subject device, and the change does not affect the clinical performance for the brachial blood pressure measurement of the subject device. The function is identical to reference

predicate device. Therefore, the change does not affect the accuracy and efficacy for brachial blood pressure measurement. And the change does not affect the safety or effectiveness of the subject device according to the safety and essential performance testing.

5) Atrial Fibrillation Detected Indicator

It's only a visual indicator (ion: ) of the Atrial Fibrillation Detection Function.

6) Review Memory

Due to the differences of the measurement modes between the subject device and predicate device, the subject device allows the user to review the last set of Auto mode measurements that consist average and individual 1- 6 measurements and the predicate device allows the user to review the last measurement of 1x mode and average of 3 measurements and individual measurements of 3X mode. The difference is U/I related features and not affect the safety or effectiveness of the subject device.

7) PC-link Function

The PC-link Function is added to the subject device, it makes the device use series port to USB cable to connect with the PC, but this function is only a way to transfer the data and 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 safety and essential performance testing.

8) Blood Pressure Analyzer

Blood Pressure Analyzer is added to the subject device. The memory data can be transferred to the PC (personal computer) running the Blood Pressure Analyzer software (WatchBP Analyzer) by connecting the monitor via USB cable or Bluetooth. This function is only a way to transfer the data and 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.

9) Bluetooth Function

The Bluetooth Function is added to the subject device, it makes the device use Bluetooth (BT4.2) to connect with the PC running the Blood Pressure Analyzer software (WatchBP Analyzer), but this function is only a way to transfer the data and 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 FCC Certification Bluetooth RF Test Report, and Bluetooth RF Exposure Evaluation Report.

10) Number of Measurements Setting Function

Due to different U/I related features of F/W reversion of algorithm, the subject device has the Number of Measurements Setting Function of 1 to maximum 6 measurements while the primary predicate has fixed number of measurement at each measurement modes. The difference is U/I related features. The change does not cause any new or significantly modified risks according to the Risk Management File and it does not affect the clinical performance of the subject device. Therefore, the change does not affect the safety or effectiveness of the subject device according to the safety and essential performance testing.

11) Resting Time Setting Function

The subject device has the Number of Resting Time Setting Function while the primary predicate has not the function. The resting time of subject device includes 15, 30, 60, 120, 160, 240 and 300 seconds, are selectable by the user. The difference is U/I related features of F/W reversion of algorithm. The change does not cause any new or significantly modified risks according to the Risk Management File and it does not affect the clinical performance of the subject device. Therefore, the change does not affect the safety or effectiveness of the subject device according to the safety and essential performance testing.

12) Measurement Intervals Setting Function

The Measurement Intervals Setting Function of the predicate devices has the interval of 15, 30, 45 and 60 seconds and the subject device has 15, 30, 60, 120, 180, 240 and 300 seconds. The difference is U/I related features of F/W reversion of algorithm. The change does not cause any new or significantly modified risks according to the Risk Management File and it does not affect the clinical performance of the subject device. Therefore, the change does not affect the safety or effectiveness of the subject device according to the safety and essential performance testing.

13) CBP&CPP (Central Blood Pressure& Central Pulse Pressure) Measurement Function

The CBP&CPP (Central Blood Pressure& Central Pulse Pressure) Measurement Function is added to the subject device, and the change does not affect the clinical performance for the brachial blood pressure measurement of the subject device. The function is identical to reference predicate device. Therefore, the change does not affect the accuracy and efficacy for brachial blood pressure measurement. And the change does not affect the safety or effectiveness of the subject device according to the safety and essential performance testing.

14) Hide Function

Due to different U/I related features of F/W reversion of algorithm, the subject device has the Hide Function while the primary predicate has not the function. But the change does not affect the use of the subject device, it does not cause any new or significantly modified risks according to the Risk Management File and it does not affect the clinical performance of the subject device. Therefore, the change does not affect the safety or effectiveness of the subject device according to the safety and essential performance testing.

15) Irregular Heartbeat Detection Function

The Irregular Heartbeat Detection Function is removed from the subject device. Therefore, the change does not affect the accuracy and efficacy for brachial blood pressure measurement. And the change does not affect the safety or effectiveness of the subject device according to the safety and essential performance testing.

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

Subject (Modified) Device Compared to Reference Predicate WatchBP Office Central (TWIN200 CBP) (K171937):

Based on information from the Comparison Chart:

The subject WatchBP Office (BP3SK1-3B) uses the same oscillometric method as the predicate WatchBP Office Central (TWIN200 CBP) with the same software algorithm to determine the systolic and diastolic blood pressure, pulse rate, mean arterial pressure (MAP), central pulse pressure (cPP) ,central systolic blood pressure (cSBP) and central diastolic pressure (cDBP). 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) Measuring Location

The subject device has two measuring locations (upper arm and ankle) while the primary predicate device only has one measuring location (upper arm).Their upper arm measuring function is identical. The ankle measuring function is removed from the subject device. Therefore, the change does not affect the accuracy and efficacy for brachial blood pressure measurement. And the change does not affect the safety or effectiveness of the subject device according to the safety and essential performance testing.

2) Measurement mode

The subject device has two measurement modes (auto mode, manual mode) while the primary predicate device has three measurement modes (SCREEN/ CENTRAL /ABI mode). With a press of start/ Stop button, the <auto mode> of the subject device allows 1 to 6 consecutive measurements and give the average readings after all the measurements are finished. The number of measurement of <Auto mode> is selectable from the button operation. For the reference predicate device, the <SCREEN mode> allow three consecutive measurements simultaneously on both arms. The CENTRAL mode allows 2 BP measurements, includes central BP indices, on single arm. The ABI mode allows the BP measurement on one arm and one ankle and calculate ankle brachial index after the finished of the measurement. The firmware revisions to suit for different modes, number of measurements, singe cuff or double cuffs (arm or ankle) are due to the need of different U/I design but not relative to the algorithm in BP measurement, atrial fibrillation detection or central BP indices, not affect the clinical performance of the subject device. The changes of the U/I of the subject device with the flexibility to take 1-6 consecutive measurement is designed complying to AAMI/ANSI/IEC 80601-2-30. Therefore, the changes do not affect the safety or effectiveness of the subject device according to the safety and essential performance testing.

3) Microprocessor

They are different in some features of microprocessor. However different features of microprocessor are all U/I related features (Microprocessor #2, #3, #4), which do not affect the clinical performance of the device. And all features related to brachial blood pressure algorithm are identical (Microprocessor #6, #7, #8).Their features of atrial fibrillation detection and the central blood pressure measurement are also identical (#9). Therefore, the change does not affect the accuracy and efficacy for brachial blood pressure measurement, atrial fibrillation detection and the central blood pressure measurement. And the change does not affect the safety or effectiveness of the subject device according to the safety and essential performance testing.

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4) 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, number measurement settings, resting time, interval time settings, hide reading functions, USB and Bluetooth connectivity which are not relative to clinical performance of the devices. The brachial blood pressure measurement algorithm related specifications (#1, #2, #3, #4) are identical to both predicate devices. Their features of atrial fibrillation detection and the central blood pressure measurement are also identical (#4, #5). Therefore, the change does not affect the accuracy and efficacy for brachial blood pressure measurement, atrial fibrillation detection and the central blood pressure measurement. 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 revisions to suit for different modes, number of measurements, singe cuff or double cuffs (arm or ankle) are due to the need of different U/I design but not relative to the algorithm in BP measurement, atrial fibrillation detection or central BP indices, not affect the clinical performance of the subject device. U/I difference that needs F/W revision are addressed in other separated items, includes bluetooth connectivity, measurement modes, Number of Measurements Setting Function, Resting Time Setting Function, Measurement interval time Setting Function, inflation pressure setting, inflation cuff selection, ABI calculation function.

5) Review Memory

Due to the differences of the measurement modes between the subject device and reference predicate device, the subject device allows the user to review the last set of Auto mode measurements that consist average and individual 1- 6 measurements and the predicate device allows the user to review the average and individual reading of SCREEN and CENTRAL mode and the last measurement of ABI. The difference is U/I related features and not affect the safety or effectiveness of the subject device.

6) Blood Pressure Analyzer Software

The subject device and the reference 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.

7) Bluetooth Function

The Bluetooth Function is added to the subject device, it makes the device use Bluetooth (BT4.2) to connect with the PC running the Blood Pressure Analyzer software (WatchBP Analyzer), but this function is only a way to transfer the data and 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 FCC Certification Bluetooth RF Test Report, and Bluetooth RF Exposure Evaluation Report.

8) Number of Measurements Setting Function

Due to different U/I related features of F/W reversion of algorithm, the subject device has the Number of Measurements Setting Function while the primary predicate has not the function. But the change does not affect the use of the subject device, it does not cause any new or significantly modified risks according to the Risk Management File and it does not affect the clinical performance of the subject device. Therefore, the change does not affect the safety or effectiveness of the subject device according to the safety and essential performance testing.

9) Resting Time Setting Function

Due to different U/I related features of F/W reversion of algorithm, the subject device has the Resting Time Setting Function while the primary predicate has not the function. But the change does not affect the use of the subject device, it does not cause any new or significantly modified risks according to the Risk Management File and it does not affect the clinical performance of the subject device. Therefore, the change does not affect the safety or effectiveness of the subject device according to the safety and essential performance testing.

10) Measurement Intervals Setting Function

Due to different U/I related features of F/W reversion of algorithm, the subject device has the Measurement Intervals Setting Function which can be set to 15, 30, 60, 120, 180, 240 and 300 seconds for Auto mode while the reference predicate device can be set to 15, 30, 45 or 60 seconds only in ROUTINE Mode. The change does not cause any new or significantly modified risks according to the Risk Management File. It does not affect the safety or effectiveness of the subject device according to the safety and essential performance testing.

11) Inflation Pressure Setting Function

Due to different U/I related features of F/W reversion of algorithm, the subject device has the Inflation Pressure Setting Function while the primary predicate has not the function. But the change does not affect the use of the subject device, it does not cause any new or significantly modified risks according to the Risk Management File and it does not affect the clinical performance of the subject device. Therefore, the change does not affect the safety or effectiveness of the subject device according to the safety and essential performance testing.

12) Inflation Cuff Selecting Function

Due to different U/I related features of F/W reversion of algorithm, the subject device has not the Inflation Cuff Selecting Function while the primary predicate has the function. But the change does not affect the use of the subject device, it does not cause any new or significantly modified risks according to the Risk Management File and it does not affect the clinical performance of the subject device. Therefore, the change does not affect the safety or effectiveness of the subject device according to the safety and essential performance testing.

13) PP Automatically Calculation Function

The PP Automatically Calculation Function is removed from the subject device. Therefore, the change does not affect the accuracy and efficacy for brachial blood pressure measurement. And the change does not affect the safety or effectiveness of the subject device according to the safety and essential performance testing.

14) ABI(Ankle Brachial Index) Calculating Function

The ABI (Ankle Brachial Index) Calculating Function is removed from the subject device. Therefore, the change does not affect the accuracy and efficacy for brachial blood pressure measurement. And the change does not affect the safety or effectiveness of the subject device according to the safety and essential performance testing.

15) Validated in preeclampsia

The subject device can accurately measure blood pressure in pregnant patients including those with known or suspected pre-eclampsia while the reference predicate device can't. But the function is the same as the primary predicate device. Therefore, the change does not affect the accuracy and efficacy for brachial blood pressure measurement. And the change does not affect the safety or effectiveness of the subject device according to the safety and essential performance testing.

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 Office (BP3SK1-3B) 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 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) 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 Office (BP3SK1-3B) tested met all relevant requirements of the aforementioned tests.

8. Discussion of Clinical Tests Performed:

Clinical Validation Concerning the Compliance of ANSI/AAMI/ ISO 81060-2: The subject device Model WatchBP Office (BP3SK1-3B) is from the technical point of view, identical to the predicate blood pressure monitor ProBP 2400.They both intended to measure systolic and diastolic blood pressures, pulse rate, mean arterial pressure (MAP) for use in pregnant patients including those with known or suspected pre-eclampsia, adults and pediatrics (but not neonates) with arm cuff circumference sizes ranging from 14 -52 cm. Although they are different in some features of microprocessor and F/W reversion of algorithm, the different features are all U/I related features which are not relative to clinical performance of the devices and all features related to brachial blood pressure algorithm are identical. The fundamental scientific technology of the modified WatchBP Office (BP3SK1-3B) device is the same as the predicate device ProBP 2400. Therefore the brachial blood pressure measurement algorithm detection in pregnant patients including those with known or suspected pre-eclampsia, adults and pediatrics (but not neonates) with arm cuff circumference sizes ranging from 14 -52 cm of WatchBP Office (BP3SK1-3B) is substantially equivalent with the predicate device ProBP 2400 and repeated clinical testing for aforementioned parameters is not required. There was no repeated clinical testing required for brachial blood pressure in pregnant patients including those with known or suspected pre-eclampsia, adults and pediatrics (but not neonates) with arm cuff circumference sizes ranging from 14 -52 cm to support WatchBP Office as the subject device WatchBP Office (BP3SK1-3B) can leverage the clinical validation of ProBP 2400 that was proven in K152770. Repeat clinical testing in accordance with the standard AAMI / ANSI /ISO81060-2 for the subject device WatchBP Office (BP3SK1-3B) regarding brachial blood pressure measurement in pregnant patients including those with known or suspected pre-eclampsia, adults and pediatrics (but not neonates) with arm cuff circumference sizes ranging from 14 -52 cm is therefore not necessary.

Moreover, the subject device Model WatchBP Office (BP3SK1-3B) is also intended to detect AFIB and measure CBP&CPP (Central Blood Pressure& Central Pulse. The subject device Model WatchBP Office (BP3SK1-3B) is from the technical point of view, identical to the predicate blood pressure monitor WatchBP Office Central (TWIN200 CBP).Although they are different in some features of microprocessor and F/W reversion of algorithm, the different features are all U/I related features which are not relative to clinical performance of the devices and all features related to brachial blood pressure algorithm , atrial fibrillation detection and the central blood pressure measurement are identical. The fundamental scientific technology of the modified WatchBP Office (BP3SK1-3B) device is the same as the predicate device WatchBP Office Central (TWIN200 CBP).Therefore the performance of the WatchBP Office Central (TWIN200 CBP) in terms of brachial blood pressure measurement, AFIB detection and CBP&CPP measurement would be essential equivalent with performance of the predicate device WatchBP Office Central (TWIN200 CBP). There was no repeated clinical testing required for brachial blood pressure, AFIB detection and CBP&CPP measurement to support WatchBP Office as the subject device WatchBP Office (BP3SK1-3B) can leverage the clinical validation of WatchBP Office Central (TWIN200 CBP) that was proven in K171937.Repeat clinical testing in accordance with the standard AAMI / ANSI/IEC81060-2 for the subject device WatchBP Office (BP3SK1-3B) regarding brachial blood pressure measurement, AFIB detection and CBP&CPP measurement for use in adults is therefore 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”. 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 1999 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 devices.