February 3, 2023

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

Re: K222153
Trade/Device Name: Microlife Upper Arm Automatic Digital BPM, Model WatchBP Office Vascular (TWIN200 VSR)
Regulation Number: 21 CFR 870.1130
Regulation Name: Noninvasive Blood Pressure Measurement System
Regulatory Class: Class II
Product Code: DXN
Dated: December 28, 2022
Received: January 4, 2023

Dear Vaibhav Rajal:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Robert T. Kazmierski -S

for

LCDR Stephen Browning
Assistant Director
Division of Cardiac Electrophysiology,
Diagnostics, and Monitoring Devices
Office of Cardiovascular Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K222153

Device Name
WatchBP Office Vascular (TWIN200 VSR)

Indications for Use *(Describe)*
The Microlife Upper Arm Automatic Digital Blood Pressure and Cardiovascular Screening Monitor Model WatchBP Office Vascular (TWIN200 VSR) is a non-invasive digital blood pressure device using the 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 (5.5-20.5 inches).

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 gives a warning signal together with the measured blood pressure value if atrial fibrillation is detected.

The device provides aortic blood pressure parameters, including central systolic blood pressure (cSBP), central pulse pressure (cPP) and central diastolic blood pressure (cDBP), non-invasively through the use of a brachial cuff. This was validated against invasive blood pressure measurement and showed that the device determines central blood pressure measurement with high accuracy.

The device provides a validated method for determining the ankle-brachial index (ABI) which may be useful in diagnosing Peripheral Artery Disease (PAD).

The device is only intended to provide a numerical value of brachial-ankle pulse wave velocity (baPWV) for blood flow inside the intended blood vessel, without any diagnosis.

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

The device is intended for use by healthcare professionals in clinical practice.

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: K222153

1. Submitter's Identification:

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

Date Summary Prepared: December 27, 2022

Contact: Ms. Ariel Wang
Global Regulatory Affairs and Quality management Director
Microlife Intellectual Property GmbH, Switzerland
Tel: 886 2 8797 1288 ext. 366
E-Mail: ariel.wang@microlife.com.tw

2. Name of the Device:

Microlife Upper Arm Automatic Digital Blood Pressure Monitor, Model WatchBP Office Vascular(TWIN200 VSR)

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 WatchBP Office (BP3SK1-3B), K200297, Microlife Intellectual Property GmbH.

Reference Predicate:

b. Microlife Upper Arm Automatic Digital Blood Pressure Monitor, Model WatchBP Office ABI (TWIN200 ABI), K112845, Microlife Intellectual Property GmbH.

c. BP-203RPE II Series VP-1000 monitor, K013434, Colin Corporation.

4. Device Description:

Microlife Upper Arm Automatic Digital Blood Pressure Monitor, Model WatchBP Office Vascular (TWIN200 VSR) 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 settings of measurement. One setting is for measurement on one arm or on both arms simultaneously. The measurement program of the device can be set when the measurement of one arm or both arm is selected, including Number of Measurements, Resting Time (Countdown Time), Interval Time, AFIB Detector, CBP Measurement, and Average Calculation (Discard 1st measurement or not).The other setting is for measurement on one arm with one leg, this measurement is selected when assessing brachial-ankle Pulse Wave Velocity (baPWV) and Ankle Brachial Index (ABI) measurement.

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 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 "  "is displayed on the LCD screen if any atrial fibrillation signal has been detected.

The device provides aortic blood pressure parameters, including 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 provides a validated method for determining the ankle-brachial index (ABI) which may be useful in diagnosing Peripheral Artery Disease (PAD).

The device is only intended to provide a numerical value of brachial-ankle pulse wave velocity (baPWV) for blood flow inside the intended blood vessel, without any diagnosis.

The device is for hospital use only.

5. Indications for Use:

The Microlife Upper Arm Automatic Digital Blood Pressure and Cardiovascular Screening Monitor Model WatchBP Office Vascular (TWIN200 VSR) is a non-invasive digital blood pressure device using the 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 (5.5-20.5 inches).

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 gives a warning signal together with the measured blood pressure value if atrial fibrillation is detected.

The device provides aortic blood pressure parameters, including central systolic blood pressure (cSBP), central pulse pressure (cPP) and central diastolic blood pressure (cDBP), non-invasively through the use of a brachial cuff. This was validated against invasive blood pressure measurement and showed that the device determines central blood pressure measurement with high accuracy.

The device provides a validated method for determining the ankle-brachial index (ABI) which may be useful in diagnosing Peripheral Artery Disease (PAD).

The device is only intended to provide a numerical value of brachial-ankle pulse wave velocity (baPWV) for blood flow inside the intended blood vessel, without any diagnosis.

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

The device is intended for use by healthcare professionals in clinical practice.

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

Subject (Modified) Device Compared to Primary Predicate WatchBP Office (BP3SK1-3B) (K200297):

Based on information from the Comparison Chart:
The modified device model WatchBP Office Vascular (TWIN200 VSR) uses the same oscillometric method as the primary predicate device WatchBP Office (BP3SK1-3B). The blood pressure cuff is inflated automatically by the pump, the deflation rate is controlled by factory set exhaust valve and the cuff 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) central systolic blood pressure (cSBP) and central diastolic pressure (cDBP), central pulse pressure (cPP) and atrial fibrillation detection. The

cuffs are suitable for use in adults and pediatrics (but not neonates) with arm circumference sizes ranging from 14-52 cm (5.5-20.5 inches).
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 has one measuring location (upper arm). The brachial cuffs and their upper arm measuring function in terms of blood pressure measurement, atrial fibrillation detection, and central blood pressure measurement are identical. Therefore, the change does not affect the safety and performance of the subject device for brachial blood pressure measurement and atrial fibrillation detection.

2) F/W reversion of Algorithm

The Subject device model WatchBP Office Vascular (TWIN200 VSR) is capable of taking measurements with two inflatable cuffs simultaneously in both arms or an arm and an ankle. The brachial blood pressure measurement algorithm, atrial fibrillation detection algorithm and Central blood pressure indices (#1, #2, #3, #4) are identical to the primary predicate devices.
The added feature of the subject device WatchBP Office Vascular includes Ankle-brachial index (ABI) and brachial-ankle Pulse Wave Velocity (baPWV) assessment are taken with simultaneously double cuffs measurement in an arm and an ankle. The Ankle-brachial index (ABI) feature of the Subject device is identical to the second predicate device WatchBP Office ABI (TWIN200 ABI). The clinical performance and feasibility of using the Subject device for Brachial-ankle Pulse Wave Velocity (baPWV) assessment is supported by the clinical investigation report (VOL_010,002).

3) Firmware: U/I related

The subject device and primary predicate device both allow 1 to 6 consecutive measurements with selectable resting time and interval time of 15, 30, 60, 120, 180, 240 or 300 seconds. The U/I of the subject device includes the selection of the measurement arm or/and ankle while the primary predicate device has two measurement modes (MANUAL/AUTO mode). The U/I for reviewing measurement readings are similar. All these U/I relative changes do 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.

4) Accessories

The subject device is equipped with necessary accessories for Medium Cuff (Non D-ring) for ankle circumference 22-32cm x 1pcs for ankle blood pressure measurement. Extra optional accessories includes large cuff for ankle circumference 32-42cm. The differences between the accessories do not affect the safety or effectiveness of the subject device.

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

Subject (Modified) Device Compared to Reference Predicate WatchBP Office ABI (TWIN200 ABI) (K112845):

Based on information from the Comparison Chart:
The modified device model WatchBP Office Vascular (TWIN200 VSR) uses the same oscillometric method as the reference predicate device WatchBP Office ABI (TWIN200 ABI). The blood pressure cuff is inflated automatically by a pump, the deflation rate is controlled by a factory set exhaust valve and the cuff pressures are transferred via tubing to the sensors in these two units. They both use the same cuffs for the same intended arm/ ankle circumference.

The differences between the devices are:

1) Firmware: U/I related

The U/I of the subject device model WatchBP Office Vascular (TWIN200 VSR) includes the selection of the arm or/and ankle for the measurement while the reference predicate device has the design of three measurement modes (ROUTINE/ SCREEN/ ABI) for single-arm, simultaneous double arms or one arm and one ankle measurement. The subject device allows 1 to 6 consecutive measurements with more selectable resting times, and the reference device only allows fix number of measurements of the modes and fewer selectable interval time options. The subject device also has an added U/I for baPWV assessments. All these U/I relative changes do 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 change does not affect the safety or effectiveness of the subject device according to the safety and essential performance testing.

2) Power Source

The subject device adds an optional main adapter compared with the reference device. The changes do not affect the safety or effectiveness of the subject device according to the safety and essential performance testing.

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3) Connectivity

The Bluetooth connectivity is added to the subject device compared with the reference predicate device. The Bluetooth module and functions of the subject device are identical to the primary predicate device.

4) Number of Measurements and Resting Time and Measurement Interval Time Setting Function

The subject device allows 1 to 6 consecutive measurements with more selectable resting time and measurement interval time options compared with the reference device only allows fix number of measurements of the modes and fewer

selectable resting time and measurement interval time options. The difference is U/I-related features. The change does not cause any new or significantly modified risks according to the Risk Management File. It does not affect the clinical performance of the subject device. The change does not affect the safety or effectiveness of the subject device according to the safety and essential performance testing.

5) Inflation Pressure Setting Function

The highest inflation pressure of the subject device can be set to 160 180, 200, 220, or 240 mmHg and auto '- - -'. This feature is identical to the primary predicate device. The reference predicate device only allows auto-determination by the device. The difference 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.

6) Accessories

The subject device is equipped with a rechargeable battery pack 4.8V C2400mAh and the reference predicated device is equipped with a rechargeable battery pack 4.8V C3500mAh. The differences between the accessories does not cause any new or significantly modified risks according to the Risk Management File and does not affect the clinical performance of the subject device.

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

Subject (Modified) Device Compared to reference Predicate VP-1000 (K013434)

1) Device description of Pulse Wave Velocity (PWV)

The WatchBP Office Vascular (TWIN200 VSR) is designed to perform non-invasive physiologic measurements for PWV. Pulse wave velocity is the speed at which the pulse is transmitted from the heart to the end artery when blood is expelled during contraction. The WatchBP Office Vascular (TWIN200 VSR) uses the waveform from the cuffs. Then, PWV is calculated using the subject's body height and △T(△T, here, represents the time difference between the pulse waves that are transmitted to the brachial and ankle arteries.) derived from the cuff waveform signal on the brachial and ankle sites.

2) Intended use

Both the subject device and the VP-1000 predicate device have the common intended use, having the capability of measuring PWV. The measurement made by the predicate device VP-1000 is used for the same purposes as the subject device – having the capability of calculating PWV. Specifically, both the subject and predicate devices are intended to monitor physiologic parameters noninvasively. The subject device and predicate device are used for the patients

in professional settings and a medical professional is responsible for interpreting the data / determining its significance related to the patient's health.

3) Technological characteristics

In contrast to the invasive arterial line catheterization PWV technique, both the subject and predicate equipment are made to calculate PWV non-invasively. Both subject and predicate devices measure the △T, which is the time taken for the arterial pulse pressure wave to travel from the aortic valve to a peripheral site, using a pair of cuffs to detect brachial and ankle pulsations. Subject and predicate devices use the same concept- use pulse waveform from brachial and ankle cuffs to get △T data. After that, PWV is determined by dividing the corresponding estimated proximal-distal distances by the observed △T.

The subject and predicate devices both have their own automated algorithms to determine △T based on the brachial and ankle cuff waveform measurements, to compute PWV. The primary differences between the predicate and subject device are the content of the algorithm they use and the formula to calculate the distance between the brachial and ankle. WatchBP Office Vascular's Pulse Wave Velocity (PWV) feature is the same as VP-1000 (K013434) in technological characteristics and intended use. In the predicate device (K013434), a complicated measurement (using ECG as a timing reference) was required to measure the arterial signals.

The information submitted in the 510(k) application shows that, when compared to the VP-1000 predicate device, any differences in technological attributes do not raise new or different concerns about safety and efficacy. The WatchBP Office Vascular (TWIN200 VSR) was designed to increase the convenience of baPWV measurement functionality, without altering the intended use or risk profile, relative to the VP-1000 predicate device (K013434).

The WatchBP Office Vascular (TWIN200 VSR) has been carefully compared to the legally marketed predicate device (VP-1000, K013434) with respect to intended use/indications for use, technological characteristics, performance, safety characteristics, and labeling. The data submitted in the 510(k) application shows that, when compared to the VP-1000 predicate device, any differences in technological attributes do not raise new or different concerns about safety and efficacy.

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 Vascular (TWIN200 VSR) 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, 2018

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 Vascular (TWIN200 VSR) 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 Vascular (TWIN200 VSR) is from the technical point of view, identical to the predicate blood pressure monitor WatchBP Office (BP3SK1-3B).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, and both intended to detect AFIB and measure CBP&CPP (Central Blood Pressure& Central Pulse. Although they are different in some features of 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 feature related to brachial blood pressure algorithm, atrial fibrillation detection algorithm and central blood pressure indices algorithm are identical. The fundamental scientific technology of the modified WatchBP Office

Vascular (TWIN200 VSR) device is the same as the predicate device WatchBP Office (BP3SK1-3B). 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 Vascular (TWIN200 VSR) and atrial fibrillation detection algorithm detects AFIB and central blood pressure indices algorithm that measures CBP&CPP are substantially equivalent with the predicate device WatchBP Office (BP3SK1-3B) 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, detect AFIB and measure CBP&CPP to support WatchBP Office Vascular as the subject device WatchBP Office Vascular (TWIN200 VSR) can leverage the clinical validation of WatchBP Office (BP3SK1-3B) that was proven in K200297. Repeat clinical testing in accordance with the standard AAMI / ANSI /ISO81060-2 for the subject device WatchBP Office Vascular (TWIN200 VSR) 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, detect AFIB and measure CBP&CPP are therefore not necessary.

Moreover, the subject device Model WatchBP Office Vascular (TWIN200 VSR) is also intended to perform ankle-arm measurements to assess the ankle-brachial index (ABI). The subject device Model WatchBP Office Vascular (TWIN200 VSR) is from the technical point of view, identical to the predicate blood pressure monitor WatchBP Office ABI (TWIN200 ABI).Although they are different in some features of 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 ankle–brachial index algorithm are identical. The fundamental scientific technology of the modified WatchBP Office Vascular (TWIN200 VSR) device is the same as the predicate device WatchBP Office ABI (TWIN200 ABI).Therefore the performance of the WatchBP Office Vascular (TWIN200 VSR) in terms of brachial blood pressure measurement, atrial fibrillation detection and perform ankle-arm measurements to assess the ankle-brachial index (ABI) would be essential equivalent with performance of the predicate device WatchBP Office ABI (TWIN200 ABI). There was no repeated clinical testing required for brachial blood pressure measurement, atrial fibrillation detection and perform ankle-arm measurements to assess the ankle-brachial index (ABI) to support WatchBP Office Vascular as the subject device WatchBP Office Vascular (TWIN200 VSR) can leverage the clinical validation of WatchBP Office ABI (TWIN200 ABI) that was proven in K112845. Repeat clinical testing in accordance with the standard AAMI / ANSI/IEC81060-2 for the subject device WatchBP Office Vascular (TWIN200 VSR) regarding brachial blood pressure measurement, atrial fibrillation detection and perform ankle-arm measurements to assess the ankle-brachial index (ABI) is therefore not necessary.

Besides, the subject device Model WatchBP Office Vascular (TWIN200 VSR) has an additional feature: brachial-ankle Pulse Wave Velocity (baPWV) assessment, which is taken with simultaneously double cuffs measurement in an arm and an ankle. The subject device's PWV feature is the same as predicate device, VP-1000 (K013434), in terms of technological characteristic.

The clinical performance and feasibility of using the subject device for

Brachial-ankle Pulse Wave Velocity (baPWV) assessment is validated by the clinical investigation report (VOL_010,002). Briefly, this study evaluated automated brachial-ankle PWV (baPWV) taken by the Microlife WatchBP Office Vascular(TWIN200 VSR) versus reference cfPWV (Complior device). Total of 97 subjects were analyzed (age 58.3 ± 11.4 years, men 70%, hypertensives 76%, diabetics 17%, cardiovascular disease 10%, smokers 23%) in the study. Both the results from the baPWV of the subject device (TWIN200 VSR) and cfPWV of the gold standard were correlated with age. Automated baPWV measurement by using a professional oscillometric blood pressure monitor (TWIN200 VSR) is feasible and observer-independent. The results showed the baPWV values differ from those by cfPWV, yet they are closely correlated.
Therefore, the subject device could provide with a numerical value of baPWV for blood flow inside the intended blood vessel for the healthcare professionals in diagnosing the increased arterial stiffness.

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.