K140572

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510(k) SUMMARY

This summary of 5l0(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA l990 and 21 CFR §807.92.

The assigned 5l0(k) number is: K 140572

1. Submitter's Identification:

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

Date Summary Prepared: May 15, 2014

Contact: Mr. Gerhard Frick
Vice President of Technical and Service
Microlife Intellectual Property GmbH, Switzerland
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2. Name of the Device:

Microlife Upper Arm Automatic Digital Blood Pressure Monitor, Model BP3MW1-4X(R)

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):

a. Microlife Upper Arm Automatic Digital Blood Pressure Monitor, Model BP3MC1-PC, K061471, Microlife Intellectual Property GmbH.

b. Microlife Upper Arm Automatic Digital Blood Pressure Monitor, Model WatchBP Home (BP3MX1-1), K073198, Microlife Intellectual Property GmbH.

4. Device Description:

Microlife Upper Arm Automatic Digital Blood Pressure Monitor, Model BP3MW1-4X(R) is designed to measure systolic and diastolic blood pressure, pulse rate of an individual 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 two resistive pressure sensors rather than a stethoscope and mercury manometer. The sensors 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, which is a well - known technique in the market called the "oscillometric method".

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

The device detects the appearance of irregular heartbeat during measurement, and the symbol "  "is displayed after the measurement. In addition, the device can be used in connection with your personal computer **(PC)** running the software. The memory data can be transferred to the PC by connecting the monitor with the PC
via cable.

5. Intended Use:

The Microlife Upper Arm Automatic Digital Blood Pressure Monitor, Model BP3MW1-4X(R) is a device intended to measure the systolic and diastolic blood pressure, pulse rate of an adult individual by using a non-invasive oscillometric technique in one inflatable cuff is wrapped around the single upper arm.

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

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

The device can be used in connection with your personal computer (PC) running the Microlife Blood Pressure Analyzer (BPA) software. The memory data can be transferred to the PC by connecting the monitor via cable with the PC.

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

The modified subject device model BP3MW1-4X(R) and the predicate device model BP3MC1-PC use the well-known oscillometric method within the software algorithm to determine the systolic and diastolic blood pressure and pulse rate. Upper arm cuff is inflated automatically, deflation rate is controlled by one factory set exhaust valve and the deflation pressures are transferred via tubing to one (or two) sensor(s).

They differ by the early preeclampsia function, AM/PM average function and the operating button. The button of the predicate device is a traditional button, and the buttons of the subject device are touch pad "buttons" which operate similarly to traditional buttons, but require only a light touch of the finger to operate.

Although the cuff used with the subject BP3MW1-4X(R) is changed to a WRR conical cuff, it is the same cuff as cleared in BP3AP1-3E, K111652.
The subject device now includes an early pre-eclampsia function, validated according to the ANSI/AAMI/ISO 81060-2:2009 protocol. The

addition of the early pre-eclampsia function to the subject device does not affect the accuracy and normal use. The other differences also do not affect the accuracy and normal use of this device based on the clinical declaration of identity and clinical testing comparing different functions.

The modified device model BP3MW1-4X(R) uses the same oscillometric method as the predicate device WatchBP Home(BP3MX1-1). The have the same AM/PM average function. 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 substantial equivalence to the predicate device and safety and effectiveness of the Microlife Upper Arm Automatic Digital Blood Pressure Monitor, Model BP3MW1-4X(R) 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:

a. Reliability Test – Storage test
b. Reliability Test – Operating test
c. Reliability Test – Vibration test
d. Reliability Test – Drop test
e. Reliability Test – Life test
f. EMC Test
g. IEC 60601-1 Safety Test

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 BP3MW1-4X(R) tested met all relevant requirements of the aforementioned tests.

8. Discussion of Clinical Tests Performed:

Included in the submission was a clinical validation report of an automated Microlife blood pressure measurement device used during pregnancy and preeclampsia according to the ANSI/AAMI/ISO 81060-2:2009 protocol. The test results satisfied the validation criterion of the AAMI SP10 protocol.

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:

We have demonstrated that there are no significant differences between the Microlife Upper Arm Automatic Digital Blood Pressure Monitor, Model BP3MW1-4X(R) and the predicate devices, Model BP3MC1-PC and Model WatchBP Home(BP3MX1-1), in terms of safety and effectiveness based on electrical, mechanical and environmental test results per the FDA DCRND November 1993 Draft "Reviewer Guidance for Premarket Notification Submissions", and the ANSI/AAMI Voluntary Standard, SP10: 2008.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

July 2, 2014

Microlife Intellectual Property Gmbh, Switzerland
% Susan Goldstein-Falk
Official Correspondent
MDI Consultants, Inc.
55 Northern Blvd. Suite 200
Great Neck, New York 11021

Re: K140572
Trade/Device Name: Microlife Upper Arm Automatic Digital Blood Pressure Monitor (Model BP3MW1-4X (R))
Regulation Number: 21 CFR 870.1130
Regulation Name: Auto-Inflation Oscillometric Blood Pressure Monitor
Regulatory Class: Class II
Product Code: DXN
Dated: May 19, 2014
Received: May 21, 2014

Dear Susan Goldstein-Falk,

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

K140572

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K140572

Device Name
Microlife Upper Arm Automatic Digital Blood Pressure Monitor, Model BP3MW1-4X(R)

Indications for Use *(Describe)*
The Microlife Upper Arm Automatic Digital Blood Pressure Monitor, Model BP3MW1-4X(R) is a device intended to measure the systolic and diastolic blood pressure, pulse rate of an adult individual by using a non-invasive oscillometric technique in one inflatable cuff is wrapped around the single upper arm.

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

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

The device can be used in connection with your personal computer (PC) running the Microlife Blood Pressure Analyzer (BPA) software. The memory data can be transferred to the PC by connecting the monitor via cable with the PC.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

FDA Date: 2014.07.02 12:36:05 -04'00'

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