



Food and Drug Administration
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December 16, 2015

Microlife Intellectual Property Gmbh
Ms. Susan Goldstein-Falk
Official Correspondent For Microlife Intellectual Property, Gmbh
55 Northern Blvd. Suite 200
Great Neck, New York 11021

Re: K153450
Trade/Device Name: Microlife Upper Arm Automatic Digital Blood Pressure Monitor,
Model BP3MS1-4A (BP A200 Comfort)
Regulation Number: 21 CFR 870.1130
Regulation Name: Noninvasive Blood Pressure Measurement System
Regulatory Class: Class II
Product Code: DXN
Dated: November 24, 2015
Received: November 30, 2015

Dear Ms. 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,

A handwritten signature in black ink, appearing to read 'Bram D. Zuckerman', is written over a faint, large, stylized 'FDA' logo.

for Bram D. Zuckerman, M.D.

Director

Division of Cardiovascular Devices

Office of Device Evaluation

Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K153450

Device Name

Microlife Upper Arm Automatic Digital Blood Pressure Monitor, Model BP3MS1-4A (BP A200 Comfort)

Indications for Use (Describe)

The Microlife Upper Arm Automatic Digital Blood Pressure Monitor, Model BP3MS1-4A (BP A200 Comfort) is a device intended to measure the systolic and diastolic blood pressure, pulse rate of an adult individual with arm circumference sizes ranging from 14 -52 cm by using a non-invasive oscillometric technique in which an inflatable cuff is wrapped around the single upper arm.

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

The device can be used in connection with 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)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) SUMMARY

The assigned 510(k) number is:_____.

1. Submitter's Identification:

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

Date Summary Prepared: November 24, 2015

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 BP3MS1-4A (BP A200 Comfort)

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 BP3MC1-PC, K061471, Microlife Intellectual Property GmbH.

4. Device Description:

Microlife Upper Arm Automatic Digital Blood Pressure Monitor, Model BP3MS1-4A (BP A200 Comfort) 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 uses a 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 detects the appearance of irregular heartbeat during measurement, and the symbol “  “is displayed after the measurement. In addition, the memory data can be transferred to the PC (personal computer) running the Microlife Blood Pressure Analyzer (BPA) software by connecting the monitor via cable.

5. Indications for Use:

The Microlife Upper Arm Automatic Digital Blood Pressure Monitor, ModelBP3MS1-4A (BP A200 Comfort) is a device intended to measure the systolic and diastolic blood pressure, pulse rate of an adult individual with arm circumference sizes ranging from 14 - 52 cm 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 measurement, and gives a warning signal with the reading once the irregular heartbeat is detected.

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 device model BP3MS1-4A (BP A200 Comfort) uses the same algorithm to determine the systolic and diastolic blood pressure and pulse rate. An upper arm cuff is inflated by an electrical pump, the inflation pressure is transferred via tubing to a sensor in the device.

Although the cuff used with the subject BP3MS1-4A(BP A200 Comfort) is changed to WRS conical cuff, it is the same with the one cleared in BP3GT1-6X, which was proved in K131346. The other differences also do not affect the accuracy and usability of the modified device based on the clinical declaration of identity and clinical testing comparing different functions.

The nylon material used for the cuff (WRS Conical Cuff) is identical to the cuff material of the Microlife BP3GT1-6X, as it was approved in K131346 meets ISO 10993-1 requirements and does not need make biocompatibility test.

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, ModelBP3MS1-4A (BP A200 Comfort) 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 1988 A1:1991 A21995
- 2) IEC 60601-1-2 Medical electrical equipment Part 1-2: General requirements for safety and essential performance – Collateral standard: Electromagnetic compatibility 3:2007-03
- 3) EN 1060-1 Non-invasive sphygmomanometers Part 1: General requirements 1995: Amendment 2, 2009
- 4) EN 1060-3 Non-invasive sphygmomanometers Part 3: Supplementary requirements for electro-mechanical blood pressure measuring systems. 1997: Amendment 2, 2009
- 5) ISO 14971 Medical devices – Application of risk management to medical devices.2007
- 6) AAMI/ANSI/ISO 10993-1-1 Biological evaluation of medical devices – Part 1: Evaluation and testing. 2010
- 7) AAMI/ANSI/ISO 10993-5 Biological evaluation of medical devices – Part 5: Tests for In Vitro Cytotoxicity, 2009

- 8) AAMI / ANSI / ISO 10993-10:2010, Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization
- 9) 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

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 BP3MS1-4A (BP A200 Comfort) 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:

A clinical validation was conducted in accordance with ISO 81060-2 testing. Results were passing and the subject device was found to be substantially equivalent to the predicate device.

9. Software information:

Software validation was conducted in accordance with a moderate level of concern designation in accordance with the FDA November 2005 document “Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices “.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 device.