



Food and Drug Administration  
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Silver Spring, MD 20993-0002

July 14, 2015

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

Re: K151330  
Trade/Device Name: Microlife Wrist Watch Blood Pressure Monitor,  
Model BP3NN1-3E  
Regulation Number: 21 CFR 870.1130  
Regulation Name: Non-Invasive Blood Pressure Measurement System  
Regulatory Class: Class II  
Product Code: DXN  
Dated: May 18, 2015  
Received: May 19, 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

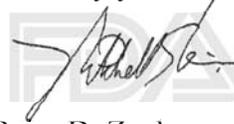
<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go 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, light-colored watermark of the FDA logo.

for Bram D. Zuckerman, M.D.

Director

Division of Cardiovascular Devices

Office of Device Evaluation

Center for Devices and Radiological Health

Enclosure

**510(k) Number (if known):**  K151330

**Device Name:**  Microlife Wrist Watch Blood Pressure Monitor, Model BP3NN1-3E

**Indications For Use:** The Wrist Watch Blood Pressure Monitor, Model BP3NN1-3E is a device intended to measure the systolic and diastolic blood pressure and pulse rate of an adult individual by using a non-invasive oscillometric technique in which an inflatable cuff is wrapped around the wrist for a circumference range from 13.5 to 21.5cm.

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

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Concurrence of CDRH, Office of Device Evaluation (ODE)

**Prescription Use** \_\_\_\_\_  
(Per 21 CFR 801.109)

OR

**Over-The-Counter Use**  X

## **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: May 18, 2015

Contact: Mr. Gerhard Frick  
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### **2. Name of the Device:**

Microlife Wrist Watch Blood Pressure Monitor, Model BP3NN1-3E

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 Wrist Watch Blood Pressure Monitor, Model BP3MO1-3P, K120430, Microlife Intellectual Property GmbH.
- b. Microlife Wrist Watch Blood Pressure Monitor, Model BP3AX1, K040002, Microlife Intellectual Property GmbH

### **4. Device Description:**

Microlife Wrist Watch Blood Pressure Monitor, Model BP3NN1-3E is designed to measure systolic and diastolic blood pressure and pulse rate of an individual by using a non-invasive technique in which an inflatable cuff is wrapped around the wrist. Our method to define systolic and diastolic pressure is similar to the auscultatory method but uses a semiconductor 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 can detect electrical signals while inflating . And the device has Irregular Heartbeat Detection (IHD) function. It detects the appearance of irregular heartbeat

during measurement and the irregular heart beat symbol “” is displayed on the LCD screen if any irregular heart beat signal has been detected. In addition, the device has traffic light function.

**5. Intended Use:**

The Wrist Watch Blood Pressure Monitor, Model BP3NN1-3E is a device intended to measure the systolic and diastolic blood pressure and pulse rate of an adult individual by using a non-invasive oscillometric technique in which an inflatable cuff is wrapped around the wrist for a circumference range from 13.5 to 21.5cm.

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

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

The subject BP3NN1-3E uses the same oscillometric method as the predicate BP3MO1-3P with the same fundamental scientific technology to determine the systolic and diastolic blood pressure and pulse rate. Wrist cuff is inflated automatically by pump and the pressures are transferred via tubing to a sensor in these two units.

The subject BP3NN1-3E and the predicate BP3MO1-3P both have a traffic light function, IHD function, and IMT technology. They differ by the sensor they use. The sensor of the modified device is changed to semi-conductor, while the sensor of predicate device is capacitive. However, the sensor difference has no impact on the clinical accuracy in terms of blood pressure detection according to the internal clinical test compared semi-conductor and capacitive sensor.

The sensor is the same as used in the predicate device, Model BP3AX1, with 510(k) cleared number K040002.

**7. Discussion of Non-Clinical Tests Performed for Determination of Substantial Equivalence are as follows:**

Testing information demonstrating safety and effectiveness of the Microlife Wrist Watch Blood Pressure Monitor, Model BP3NN1-3E 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) AAMI/ANSI SP10 Manual, electronic, or automated sphygmomanometers 2002 (R) 2008, 2002 A1:2003
- 4) EN 1060-1 Non-invasive sphygmomanometers Part 1: General requirements 1995: Amendment 2, 2009
- 5) EN 1060-3 Non-invasive sphygmomanometers Part 3: Supplementary requirements for electro-mechanical blood pressure measuring systems. 1997: Amendment 2, 2009
- 6) ISO 14971 Medical devices – Application of risk management o medical devices. 2007
- 7) AAMI/ANSI/ISO 10993-1-1 Biological evaluation of medical devices – Part 1: Evaluation and testing. 2010
- 8) AAMI/ANSI/ISO 10993-5 Biological evaluation of medical devices – Part 5: Tests for In Vitro Cytotoxicity, 2009
- 9) AAMI/ANSI/ISO 10993-10 Biological evaluation of medical devices – Part 10) Tests for Irritation and skin sensitization, 2010
- 11) 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 Wrist Watch Blood Pressure Monitor, Model BP3NN1-3E tested met all relevant requirements of the aforementioned tests.

#### **8. Discussion of Clinical Tests Performed:**

The subject device Model BP3NN1-3E is from the technical point of view, identical to the predicate blood pressure monitor. Moreover, the measurement algorithm and its program codes of BP3NN1-3E remain unchanged. The fundamental scientific technology of the modified BP3NN1-3E device is the same as the predicate device BP3MO1-3P. Therefore the performance of the BP3NN1-3E in terms of blood pressure measurement would be identical with performance of the predicate device BP3MO1-3P. Repeat clinical testing in accordance with the standard ANSI/AAMI IEC81060-2 for the subject device BP3NN1-3E is therefore not necessary as clinical testing results were not affected by the changes to the subject modified 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".

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.