July 10, 2019

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

Re: K190818
Trade/Device Name: Microlife Upper Arm Automatic Digital Blood Pressure Monitor, Model BP3GY1-2N
Regulation Number: 21 CFR 870.1130
Regulation Name: Noninvasive Blood Pressure Measurement System
Regulatory Class: Class II
Product Code: DXN
Dated: June 10, 2019
Received: June 11, 2019

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. 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,

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)*
K K190818

Device Name
Microlife Upper Arm Automatic Digital Blood Pressure Monitor, Model BP3GY1-2N

Indications for Use *(Describe)*
The Microlife Upper Arm Automatic Digital Blood Pressure Monitor, Model BP3GY1-2N is a device intended to measure the systolic and diastolic blood pressure, pulse rate of an adult individual with arm circumference sizes ranging from 22 -42 cm by using a non-invasive oscillometric technique in which an inflatable cuff is being wrapped around the upper arm.

The device is also validated for all adult diabetic users.

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 a smart phone running the APP. The memory data can be transferred to the smart phone via Bluetooth.

The blood pressure monitor is a fully automatic digital blood pressure measuring device for use by adults (also applicable for diabetic patients) on the upper arm at home or in your doctor's/nurse's office.

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:_____.

1. Submitter's Identification:

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

Date Summary Prepared: June 7, 2019

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 BP3GY1-2N

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 BP3GX1-5X (BP A3 PC), K183469, Microlife Intellectual Property GmbH.

Reference Predicate:

b. Microlife Upper Arm Automatic Digital Blood Pressure Monitor, Model BP3MW1-4B, K153077, Microlife Intellectual Property GmbH.

4. Device Description:

Microlife Upper Arm Automatic Digital Blood Pressure Monitor, Model BP3GY1-2N is designed to measure systolic and diastolic blood pressure, pulse rate of an individual with arm circumference sizes ranging from 22 -42 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 using 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 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 smart mobile devices running the APP and via Bluetooth.

The device is also validated for all adult diabetic users.

The blood pressure monitor is a fully automatic digital blood pressure measuring device for use by adults(also applicable to the diabetic patients) on the upper arm at home or in your doctor’s/nurse’s office.

5. Indications for Use:

The Microlife Upper Arm Automatic Digital Blood Pressure Monitor, Model BP3GY1-2N is a device intended to measure the systolic and diastolic blood pressure, pulse rate of an adult individual with arm circumference sizes ranging from 22 -42 cm by using a non-invasive oscillometric technique in which an inflatable cuff is being wrapped around the single upper arm.

The device is also validated for all adult diabetic users.

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 a smart phone running the APP. The memory data can be transferred to the smart phone via Bluetooth.

The blood pressure monitor is a fully automatic digital blood pressure measuring device for use by adults (also applicable for diabetic patients) on the upper arm at home or in your doctor’s/nurse’s office.

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

Subject (Modified) Device Compared to Primary Predicate BP3GX1-5X (BP A3 PC) (K183469):

The subject BP3GY1-2N uses the same oscillometric method as the predicate BP3GX1-5X (BP A3 PC) with the same algorithm to determine the systolic and diastolic blood pressure, pulse rate. 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.

The subject BP3GY1-2N and the predicate original BP3GX1-5X (BP A3 PC) both have MAM function, IHD function traffic light function and they are both validated for all adult diabetic users. They differ by the PC-link function, Bluetooth function and the way to operate the device. The PC-link function is removed from the subject device. The Bluetooth function is added to the subject device, but it's only a way to transfer the data. The way to operate the predicate device BP3GX1-5X (BP A3 PC) is to press the button, and the subject device requires a light touch of the finger on the screen. However, those differences do not affect the accuracy and normal use of this device because they use the same fundamental scientific technology. The declaration of identity and features comparison table (VOL 10, 001, VOL 10, 002) demonstrate that the subject device BP3GY1-2N can leverage the clinical test report of BP3GX1-5X (BP A3 PC) which was proved in K183469. Therefore, repeated clinical testing in accordance with the standard ANSI/AAMI/IEC 81060-2 for BP3GY1-2N is not warranted.

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

Subject (Modified) Device Compared to Reference Predicate BP3MW1-4B (K153077):

The modified device model BP3GY1-2N uses the same oscillometric method as the predicate device BP3MW1-4B with the same algorithm to determine the systolic and diastolic blood pressure, pulse rate. 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 have MAM function, IHD function, traffic light function and Bluetooth function. They have the same fundamental scientific technology.

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, ModelBP3GY1-2N 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) IEC 60601-1-11:2015 Medical Electrical Equipment - Part 1-11: General Requirements For Basic Safety And Essential Performance - Collateral Standard: Requirements For Medical Electrical Equipment And Medical Electrical Systems Used In The Home Healthcare Environment

9) 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, ModelBP3GY1-2N tested met all relevant requirements of the aforementioned tests.

8. Discussion of Clinical Tests Performed:

From a clinical validation standpoint, the subject device is identical to the 510(k) cleared primary predicate device, BP3GX1-5X (BP A3 PC), K183469, in detection.

Regarding clinical validation concerning the compliance of ANSI/AAMI/IEC 81060-2, the subject blood pressure monitor Model BP3GY1-2N is, from a technical point of view, identical to the predicate blood pressure Monitor Model BP3GX1-5X (BP A3 PC).

The only differences between the two models are in (please see VOL 10, 002 for more details):

- Model name and shape
- Touch screen technology
- Bluetooth function
- No PC-link function

The subject device BP3GY1-2N has added the function of transferring the memory data to the smart phone via Bluetooth. However, this function is only a way to transfer the data and will not affect the clinical accuracy. The other differences listed above do not affect the accuracy and normal use of this device because they use the same fundamental scientific technology. That said, BP3GY1-2N can leverage the clinical data of the primary predicate device BP3GX1-5X (BP A3 PC) which was proven in K183469 according to the standard ANSI/AAMI/IEC 81060-2 for the accuracy of blood pressure detection and validated in diabetics function. Therefore, repeated clinical testing in accordance with the standard ANSI/AAMI/IEC 81060-2 for BP3GY1-2N is not warranted.

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 devices.