K100763

Exhibit#1

510(k) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

The assigned 510(k) number is:_____.

1. Submitter's Identification:

AUG 27 2010

Microlife Intellectual Property GmbH, Switzerland

Espenstrasse 139
9443 Widnau / Switzerland

Date Summary Prepared: Dec. 29, 2009

Contact: Gerhard Frick

2. Name of the Device:

Upper Arm Automatic Digital Blood Pressure Monitor, Model WatchBP Home N (BP3MX1-4)

3. Information for the 510(k) Cleared Device (Predicate Device):

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

b. Microlife Upper Arm Automatic Digital Blood Pressure Monitor, Model BP3MQ1-2D, K080337, Microlife Intellectual Property GmbH.

4. Device Description:

Microlife Upper Arm Automatic Digital Blood Pressure Monitor, Model WatchBP Home N (BP3MX1-4) is designed to measure systolic and diastolic blood pressure, pulse rate of an individual by using a non-invasive technique in which an inflatable cuff is wrapped around the upper arm. Our method to define systolic and diastolic pressure is similar to the auscultatory method but uses an electronic capacitive 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 has <<USUAL>>, <<DIAG.>> and <<NOCTURNAL>> measurement modes and has atrial fibrillation detection function, medication record function. In addition, the device can be used in connection with your personal computer **(PC)** running the WatchBP Analyzer Home N software. The memory data can be transferred to the PC by connecting the monitor with the PC via cable.

The <<USUAL>> mode is selected for a regular single measurement.

The <<DIAG.>> mode is selected for diagnosis or follow-up.

The <<NOCTURNAL>> mode is selected for measurements of blood pressure during sleep.

5. Intended Use:

The Microlife Upper Arm Automatic Digital Blood Pressure Monitor, Model WatchBP Home N (BP3MX1-4) is a device intended to measure the systolic and diastolic blood pressure and pulse rate of an adult individual by using a non-invasive technique in which an inflatable cuff is wrapped around the upper arm.

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

The device can be used in connection with your personal computer **(PC)** running the WatchBP Analyzer Home N 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 WatchBP Home N (BP3MX1-4) and the predicate device model WatchBP Home (BP3MX1-1) 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 to one sensor.

The solely differences between the two models are the <<NOCTURNAL>> measurement mode and additional features such as atrial fibrillation detection function and medication record function. However, the differences do not affect the accuracy and normal use of this device.

Atrial fibrillation detection function is same with what is used in predicate device model BP3MQ1-2D, with 510(k) cleared number K080337.

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 Home N (BP3MX1-4) 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

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 Home N (BP3MX1-4) tested met all relevant requirements of the aforementioned tests.

8. Discussion of Clinical Tests Performed:

a) Re: Clinical validation concerning the compliance of ANSI/AAMI SP10:

The modified device model WatchBP Home N (BP3MX1-4) is from the technical point of view identical to the blood pressure monitor model WatchBP Home (BP3MX1-1). The differences between them do not related to blood pressure measurement technology; therefore the clinical accuracy in terms of blood pressure detection will not be affected. Based on Microlife's risk analysis, repeated clinical testing in accordance with ANSI/AAMI SP10 is therefore not required.

b) Re: Clinical evaluation concerning Atrial Fibrillation (AF) Detection:

The Atrial Fibrillation Detection technique utilized in the modified device model WatchBP Home N (BP3MX1-4), is from the technical point of view identical to what is utilized in the predicate device model BP3MQ1-2D. The clinical test report of BP3MQ1-2D is applicable to WatchBP Home N (BP3MX1-4).

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 WatchBP Home N (BP3MX1-4) and the predicate devices, Model WatchBP Home (BP3MX1-1) and Model BP3MQ1-2D, 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 Room –WO66-G609
Silver Spring, MD 20993-0002

Microlife Intellectual Property GmbH
c/o Ms. Susan D. Goldstein-Falk
mdi Consultants, Inc.
55 Northern Blvd., Suite 200
Great Neck, New York 11021

AUG 27 2010

Re: K100763
Trade/Device Name: Microlife Upper Arm Automatic Digital Blood Pressure Monitor, Model WatchBP Home N (BP3MX1-4)
Regulatory Number: 21 CFR 870.1130
Regulation Name: Noninvasive Blood Pressure Measurement System
Regulatory Class: Class II (Two)
Product Code: DXN
Dated: July 27, 2010
Received: July 28, 2010

Dear Ms. 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.

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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

K100763

Exhibit B

Indications for Use

510(k) Number (if known): K100763

Device Name: Microlife Upper Arm Automatic Digital Blood Pressure Monitor, Model WatchBP Home N (BP3MX1-4)

Indications For Use:

The Microlife Upper Arm Automatic Digital Blood Pressure Monitor, Model WatchBP Home N (BP3MX1-4) 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 upper arm.

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

The device can be used in connection with your personal computer **(PC)** running the WatchBP Analyzer Home N software. The memory data can be transferred to the PC by connecting the monitor via cable with the PC.

Prescription Use __X____ **AND/OR** **Over-The-Counter Use** _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

W. Wheel

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K100763