K101275
p1/3

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:

MAY 28 2010

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

Date Summary Prepared: April 28, 2010

Contact: Mr. Gerhard Frick

2. Name of the Device:

Upper Arm Automatic Digital Blood Pressure Monitor, Model WatchBP Office AFIB (TWIN200 AFS)

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

a. Microlife Upper Arm Automatic Digital Blood Pressure Monitor, Model WatchBP Office (Twin200), K082357, 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 Office AFIB (TWIN200 AFS) is designed to measure systolic and diastolic blood pressure, pulse rate, pulse pressure (PP) and mean arterial pressure (MAP) of an individual by using a non-invasive technique in which one (or two) inflatable cuff(s) is (are) wrapped around the single (or dual) upper arm(s). 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, pulse pressure (PP) and mean arterial pressure (MAP), which is a well - known technique in the market called the "oscillometric method".

The device has <<AUSCULTATION>>, <<SCREEN>> and <<ROUTINE>> measurement modes and has atrial fibrillation detection function, inflation pressure setting function, measurement intervals setting function etc.

The <<AUSCULTATION>> mode is selected for blood pressure measurement of patients to confirm if a patient is suitable for the oscillometric method.

The <<SCREEN>> mode is selected to complete a fully-automated triple measurements on both arms according to recommended ESH/AHA blood pressure measurement protocols for a patient's first office visit.

The <<ROUTINE>> mode is selected to perform an automated duplicate measurements on the preferred arm for prompt and accurate office measurements.

5. Intended Use:

The Microlife Upper Arm Automatic Digital Blood Pressure Monitor, Model WatchBP Office AFIB (TWIN200 AFS) is a device intended to measure the systolic and diastolic blood pressure, pulse rate, pulse pressure (PP) and mean arterial pressure (MAP) of an adult individual by using a non-invasive oscillometric technique in one (or two) inflatable cuff(s) is (are) wrapped around the single (or dual) upper arm(s).

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

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

The subject modified device, Model WatchBP Office AFIB (TWIN200 AFS) and our predicate device, Model WatchBP Office (Twin200), use the well-known oscillometric method within the software algorithm to determine the systolic and diastolic blood pressure and pulse rate. Upper arm cuff(s) is (are) inflated automatically, deflation rate is controlled by one (or two) factory set exhaust valve(s) and the deflation pressures are transferred via tubing to one (or two) sensor(s).

The sole differences between the two models are the measurement mode names, sensor type and additional features such as atrial fibrillation detection function. However, the differences do not affect the accuracy and normal use of this device.

The atrial fibrillation detection function is the same with what is used in our predicate device Model BP3MQ1-2D, 510(k) cleared under K080337.

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

Testing information demonstrating safety and effectiveness of the subject modified Microlife Upper Arm Automatic Digital Blood Pressure Monitor, Model WatchBP Office AFIB (TWIN200 AFS) 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 our testing demonstrated any design characteristics that violated the requirements of the Reviewer Guidance or resulted in any safety hazards. It was our conclusion that the subject modified device tested, Microlife Upper Arm Automatic Digital Blood Pressure Monitor, Model WatchBP Office AFIB (TWIN200 AFS) met all relevant requirements of the aforementioned tests.

8. Discussion of Clinical Tests Performed:

a) Clinical Validation Concerning the Compliance of ANSI/AAMI SP10:

The subject modified device, Model WatchBP Office AFIB (TWIN200 AFS), is from the technical point of view, identical to our predicate device Model WatchBP Office (Twin200). The differences between these devices do not affect the clinical accuracy in terms of blood pressure detection. Based on Microlife's risk analysis and internal clinical test and simulator test report, repeated clinical testing in accordance with ANSI/AAMI SP10 is therefore not required. The clinical test report included in our Model WatchBP Office (Twin200), K082357, is applicable to our subject modified device, WatchBP Office AFIB (TWIN200 AFS).

b) Clinical Evaluation Concerning Atrial Fibrillation (AF) Detection:

The atrial fibrillation detection technique utilized in the subject modified device Model WatchBP Office AFIB (TWIN200 AFS), is from the technical point of view, identical to what is utilized in our predicate device Model BP3MQ1-2D. The clinical test report included in our Model BP3MQ1-2D, K080337, is applicable to our subject modified WatchBP Office AFIB (TWIN200 AFS).

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:

We have demonstrated that there are no significant differences between the subject modified Microlife Upper Arm Automatic Digital Blood Pressure Monitor, Model WatchBP Office AFIB (TWIN200 AFS) and our predicate devices, Model WatchBP Office (Twin200) 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
Official Correspondent
mdi Consultants, Inc.
55 Northern Boulevard, Suite 200
Great Neck, NY 11021

MAY 2 8 2010

Re: K101275
Trade/Device Name: Microlife Upper Arm Automatic Digital Blood Pressure Monitor, Model WatchBP Office AFIB (TWIN200 AFS)
Regulatory Number: 21 CFR 870.1130
Regulation Name: Non-Invasive Blood Pressure Measurement System
Regulatory Class: II (two)
Product Code: 74 DXN
Dated: May 3, 2010
Received: May 6, 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.

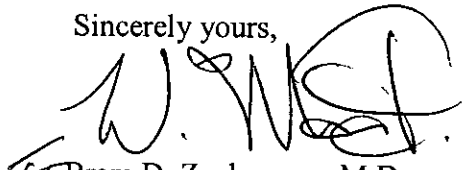
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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

K101275

Exhibit B

Indications for Use

510(k) Number (if known): _____

Device Name: Microlife Upper Arm Automatic Digital Blood Pressure Monitor, Model WatchBP Office AFIB (TWIN200 AFS)

Indications For Use:

The Microlife Upper Arm Automatic Digital Blood Pressure Monitor, Model WatchBP Office AFIB (TWIN200 AFS) is a device intended to measure the systolic and diastolic blood pressure, pulse rate, pulse pressure (PP) and mean arterial pressure (MAP) of an adult individual by using a non-invasive oscillometric technique in one (or two) inflatable cuff(s) is (are) wrapped around the single (or dual) upper arm(s).

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

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

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K101275