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: K073397

1. Submitter's Identification:

Microlife Intellectual Property GmbH, Switzerland

Espenstrasse 139
9443 Widnau / Switzerland

DEC 2 0 2007

Date Summary Prepared: April 28, 2007

2. Name of the Device:

Microlife Upper Arm Manual Blood Pressure Monitor, Model BP3MR1-H(BP A50)

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

Microlife Upper Arm Manual Blood Pressure Monitor, Model BP2BI0, K#970139.
Pls refer to Exhibit#2 for 510(K) summary of BP2BI0.
Microlife Upper Arm Automatic Blood Pressure Monitor, Model BP3BT0-AP, K#041411.Pls refer to Exhibit#3 for 510(K) summary of BP3BT0-AP.

4. Device Description:

Microlife Upper Arm Manual Blood Pressure Monitor, Model BP3MR1-H(BP A50) is designed to measure the 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 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 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.

5. Intended Use:

The Microlife Upper Arm Manual Blood Pressure Monitor, Model BP3MR1-H(BP A50) 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 irregular heartbeat during measurement, and gives a warning signal with the reading once the irregular heartbeat is detected.

Pls also refer to the "Indications for Use" statement, which is attached as Exhibit#B.

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

The modified model BP3MR1-H(BP A50) has the same intended of use and is similar in terms of design to our original 510(K) cleared device, model BP2BI0.

The model BP3MR1-H(BP A50) and the model BP2BI0 are identical in functionality and performance. The solely differences between these two models are the additional features such as irregular heartbeat detection function.
However, the difference does not affect the accuracy and normal use of this device. Pls refer to Exhibit#4.

Irregular heartbeat detection technology is same as what is used in Microlife Upper Arm Automatic Blood Pressure Monitor, model BP3BT0-AP, with 510(K) cleared number K#041411. Pls refer to Exhibit#3 for the summary of BP3BT0-AP.

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 Manual Blood Pressure Monitor, Model BP3MR1-H(BP A50) 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 equirements.

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 Manual Blood Pressure Monitor, Model BP3MR1-H(BP A50) tested met all relevant requirements of the aforementioned tests.

8. Discussion of Clinical Tests Performed:

Relevant tests in accordance with ANSI/AAMI SP10: 2002 "National Standard for Manual, Electronic or Automated Sphygmomanometers" had been performed in the cleared device, BP2BI0. All relevant sections were addressed and tested. Since the measurement algorithm and the program codes of the BP3MR1-H(BP A50) remain unchanged and the fundamental scientific technology of the modified device is the same as that of the 510(k) cleared device, BP2BI0. Clinical performance of the modified device will remain unchanged; therefore another clinical test for the modified device, BP3MR1-H(BP A50) is not required. Please refer to the Exhibit#10 for a copy of this signed statement by a company designated individual.

9. Conclusions:

It has been demonstrated that there is no difference between the Microlife Upper Arm Manual Blood Pressure Monitor Model BP3MR1-H(BP A50) and the predicate model BP2BI0 in terms of safety and effectiveness based on electrical, mechanical and environmental test results, the FDA DCRND November 1993 Draft "Reviewer Guidance for Premarket Notification Submissions", and the ANSI/AAMI Voluntary Standard, SP10: 2002 test results.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 2 0 2007

Microlife Intellectual Property GmbH
c/o Ms. Susan Goldstein-Falk
Official Correspondent
MDI Consultants, Inc.
55 Northern Blvd, Suite 200
Great Neck, NY 11021

Re: K073397
Microlife Upper Arm Manual Blood Pressure Monitor, Model BP3MR1-H (BP A50)
Regulation Number: 21 CFR 870.1130
Regulation Name: Noninvasive Blood Pressure Measurement System
Regulatory Class: Class II (two)
Product Code: DXN
Dated: November 30, 2007
Received: December 3, 2007

Dear Ms. Goldstein-Falk:

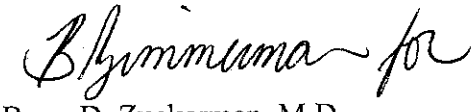
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 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 such 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); 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.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Exhibit#B

Indications for Use

510(k) Number (if known): K073397

Device Name: Microlife Upper Arm Manual Blood Pressure Monitor, Model BP3MR1-H(BP A50)

Indications For Use:

The Microlife Upper Arm Manual Blood Pressure Monitor, Model BP3MR1-H(BP A50) 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 irregular heartbeat during measurement, and gives a warning signal with the reading once the irregular heartbeat is detected.

• rescription Use _____ **AND/OR** **Over-The-Counter Use** __X____
(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)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K073397