510(k) SUMMARY

This summary of 5l0(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA l990 and 21 CFR §807.92.

The assigned 5l0(k) number is: K101512

1. Submitter's Identification:

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

JUL - 1 2010

Date Summary Prepared: May 25, 2010

Contact: Mr. Gerhard Frick
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Microlife Intellectual Property GmbH, Switzerland
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2. Name of the Device:

Upper Arm Automatic Digital Blood Pressure Monitor, Model WatchBP Office Target (BP3MD1-4)

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 Upper Arm Automatic Digital Blood Pressure Monitor, Model BP3BT0-K013485, Microlife Corporation.
b. Microlife Upper Arm Automatic Digital Blood Pressure Monitor, Model WatchBP Office (Twin200), K082357, Microlife Intellectual Property GmbH.

4. Device Description:

Microlife Upper Arm Automatic Digital Blood Pressure Monitor, Model WatchBP Office Target (BP3MD1-4) is designed to measure systolic and diastolic blood pressure, pulse rate and pulse pressure (PP) 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 a resistive 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 target blood pressure value 140/90 mmHg is used for hypertensive patient. The target blood pressure value 130/80 mmHg is used for hypertension patients with diabetes, coronary heart disease or chronic kidney disease. If both the measured systolic and diastolic blood pressure values are below the set target values (140/90 or 130/80), the screen will light in green with two <<OK>> signs and show the pulse pressure (PP). If either the measured systolic or diastolic result is above the set target value (140/90 or 130/80), the screen will light in red with the difference to the goal value shown in display as number.

5. Intended Use:

The Microlife Upper Arm Automatic Digital Blood Pressure Monitor, Model WatchBP Office Target (BP3MD1-4) is a device intended to measure the systolic and diastolic blood pressure, pulse rate and pulse pressure (PP) of an adult individual by using a non-invasive oscillometric technique in which an inflatable cuff is wrapped around the upper arm.

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

a) Subject Modified Device Compared to BP3BT0-1 Predicate, K013485:

The subject modified device, Model WatchBP Office Target (BP3MD1-4) and the predicate device model BP3BT0-1, 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 differences between the two models are the sensor type and additional features such as blood pressure targets setting function, red/green backlight function and PP automatically calculation function. However, the differences do not affect the accuracy and normal use of this device based on the internal clinical tests comparing different sensors and cuff bladder materials.

b) Subject Modified Device Compared to WatchBP Office (Twin200) Predicate, K082357:

The subject modified device, WatchBP Office Target (BP3MD1-4) uses the same oscillometric method as the predicate WatchBP Office (Twin200) to determine the systolic and diastolic blood pressure, pulse rate and pulse pressure (PP). 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 differ by the intended use, measuring location, measuring mode, power source type, MAP automatically calculation function etc., however, the differences do not affect the accuracy and normal use of this device because they use the same fundamental scientific technology. Based upon the aforementioned information, the two devices are substantially equivalent.

The intended use of the subject modified device, the WatchBP Office Target (BP3MD1-4), has not changed from the 510(k) cleared predicate device labeling

since it is a combination of the two (2) predicate devices stated in this submission. All comparison parameters stated in our comparison chart (included in the submission) come from either one of the predicate devices cited.

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 Office Target (BP3MD1-4) 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 Office Target (BP3MD1-4) tested met all relevant requirements of the aforementioned tests.

8. Discussion of Clinical Tests Performed:

The subject modified device Model WatchBP Office Target (BP3MD1-4) is from the technical point of view, identical to the blood pressure monitor Model BP3BT0-1. 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.

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 Microlife Upper Arm Automatic Digital Blood Pressure Monitor, Model WatchBP Office Target (BP3MD1-4) and the predicate devices, 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
Ms. Susan D. Goldstein-Falk
mdi Consultants, Inc.
55 Northern Blvd., Suite 200
Great Neck, NY 11021

JUL -1 2010

Re: K101512
Device Name: Upper Arm Automatic Digital Blood Pressure Monitor, Model WatchBP Office Target (BP3MD1-4)
Regulation Number: 21 CFR 870.1130
Regulation Name: Noninvasive blood pressure measurement system
Regulatory Class: Class II (Two)
Product Code: DXN
Dated: May 26, 2010
Received: June 1, 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. 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 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

Exhibit B

Indications for Use

510(k) Number (if known): K101512

Device Name: Microlife Upper Arm Automatic Digital Blood Pressure Monitor, Model WatchBP Office Target (BP3MD1-4)

Indications For Use:

The Microlife Upper Arm Automatic Digital Blood Pressure Monitor, Model WatchBP Office Target (BP3MD1-4) is a device intended to measure the systolic and diastolic blood pressure, pulse rate and pulse pressure (PP) of an adult individual by using a non-invasive oscillometric technique in which an inflatable cuff is wrapped around the upper arm.

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

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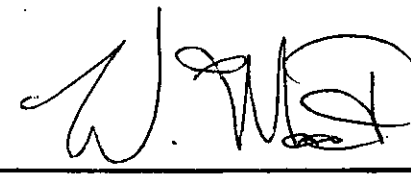
Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K101512