

K970139

APR 30 1998

ATTACHMENT #12b
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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: K970139

1. **Submitter's Identification:**

Micro Weiss Electronics
89 Bell Street
West Babylon, NY 11704

Date Summary Prepared:

August 22, 1997

2. **Name of the Device:**

MicroLife Manual Blood Pressure Monitor, Model BP-2BIO

3. **Predicate Device Information:**

The MicroLife Manual Blood Pressure Monitor, Model BP-2BIO is substantially equivalent to the Omron Oscillometric Digital Blood Pressure Monitor, Model HEM-405C, K#903133.

4. **Device Description:**

The BP-2BIO Digital Blood Pressure Monitor is designed to measure the systolic and diastolic blood pressure and pulse rate of an individual by using a non-invasive technique which an inflatable cuff is wrapped around the upper arm. Our method to define systolic and diastolic pressures is similar to the auscultatory method but uses an electronic capacitive pressure sensor rather than stethoscope and mercury manometer. The sensor converts tiny alteration in cuff pressure to electrical signals; by analyzing those signals to define the systolic, diastolic and calculating pulse rate is a well known technique in the market so called "oscillometric method".

5. Intended Use:

The BP-2BIO Digital Blood Pressure Monitor 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.

6. Comparison to Predicate Devices:

Both devices use the well known oscillometric method within the software algorithm to determine the systolic, diastolic and pulse rate. A similar arm cuff is inflated automatically, deflate rate is controlled but a factory set bleed valve and the deflation pressures are transferred via tubing to a sensor in both units. Each device uses a similar capacitance-type pressure sensor to translate the pressure variations to electrical signals that can be interpreted by an integrating circuit. Once the reading is determined each unit operates a solenoid valve to release the pressure to zero. Our Digital Blood Pressure Monitor, Model BP-B2IO, differs from the predicate device in the software interface to the sensor which determines the system accuracy.

The interface between the sensor and the microprocessor determines the system's accuracy. For our Digital Blood Pressure Monitor, Model BP-B2IO, the software is capable of a split slope resolution to improve accuracy over the entire range. Since the range is "split" into three sections (0 to 100mmHg) (100 to 200mmHg) (200 to 300mmHg) error due to nonlinearity is reduced by the ability to adjunct the slope to best fit the output curve. A nonlinearity of 1% is reduced to .33% by splitting the span into three separate linear relations. This way the sensor is matched to the software by using a series of jumpers that profile the slopes to the output of the sensor.

The Digital Blood Pressure Monitor Model BP-B2IO has field calibration access; this mode is initiated by depressing both the start and the on button for over 5 seconds. A sleeve on the input tube fitting can be removed so that the fitting can be inserted into the unit in a manner to bypass the pressure bleed valve to close the pressure system and enable it to respond to the input pressure for calibration check.

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

Testing information demonstrating safety and effectiveness of the MicroLife Manual Blood Pressure Monitor (Manual Inflate) Model BP-2BIO) 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. General Functions Test
- b. Reliability Test-Operation Conditions
- c. Reliability Test-Drop Testing
- d. Reliability Test-Storage
- e. Reliability Test-Vibration Testing
- f. EMC Test Report
- g. EN1060 Regulations and Test Report
- h. CE Certification

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 the MicroLife Manual Blood Pressure Monitor (manual inflate), Model BP-2BIO tested met all relevant requirements of the aforementioned tests.

8. Discussion of Clinical Tests Performed:

ANSI/AAMI SP-10-1992 "National Standard for Electronic or Automated Sphygmomanometers" testing was performed. All relevant sections were addressed and testing conducted. The BP-2BIO met all relevant requirements of this standard.

9. Conclusions:

We have demonstrated that the MicroLife Manual Blood Pressure Monitor, Model BP-2BIO is as safe and effective as the predicate, the Omron Oscillometric Digital Blood Pressure Monitor, Model HEM-405C based on electrical, mechanical and environmental testing results as well as the FDA DCRND November 1993 Draft "Reviewer Guidance for Premarket Notification Submissions," and, the ANSI/AAMI Voluntary Standard, SP-10-1992 testing results.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

APR 30 1998

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Susan D. Goldstein-Falk
Official Correspondent for
Micro Weiss Electronics
89 Bell Street
W. Babylon, NY 11704

Re: K970139
MicroLife Manual Blood Pressure Monitor (Manual Inflate)
Regulatory Class: II (Two)
Product Code: DPW
Dated: April 13, 1998
Received: April 15, 1998

Dear Ms. Goldstein-Falk:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

Page 2 - Ms. Susan Goldstein-Falk

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>."

Sincerely yours,



Thomas J. Callahan, Ph.D.
Director
Division of Cardiovascular, Respiratory,
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K970139

Device Name: MicroLife Manual Blood Pressure Monitor,
Manual Inflate, Model BP-2BIO

Indications For Use:

The BP-2BIO Digital Blood Pressure Monitor 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.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices

510(k) Number K970139

Prescription Use
(Per 21 CFR 801.109)

OR

Over-The-Counter Use

(Optional Format 1-2-96)