August 3, 2018

Avita Corporation
% Anita Chen
Advisor
ZhengCheng Consulting Company
NO. 19, 335 Lane, Fu-Xi Road
Shulin District, New Taipei City
New Taipei, Taiwan 238

Re: K180155
Trade/Device Name: AViTA Arm Type Blood Pressure Monitor BPM64R
Regulation Number: 21 CFR 870.1130
Regulation Name: Noninvasive Blood Pressure Measurement System
Regulatory Class: Class II
Product Code: DXN
Dated: January 13, 2018
Received: July 5, 2018

Dear Anita Chen:

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.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

for

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

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

# Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
*See PRA Statement below.*

510(k) Number *(if known)*
K180155

Device Name
AViTA Arm Type Blood Pressure Monitor BPM64R

Indications for Use *(Describe)*
BPM64R automatically measures human's Systolic, Diastolic blood pressure and heart rate by using the oscillometric method during inflation. All values can be read out in one LCD panel. Measurement position is at human being's Arm. The intended use of this over-the-counter device is for adults aged 18 years and older with Arm circumference ranging 220 ~ 420 mm (approx. 9 ~ 17 inch) and for home use.

Type of Use *(Select one or both, as applicable)*

☐ Prescription Use (Part 21 CFR 801 Subpart D) ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

**CONTINUE ON A SEPARATE PAGE IF NEEDED.**

This section applies only to requirements of the Paperwork Reduction Act of 1995.

***DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.***

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
*PRAStaff@fda.hhs.gov*

*"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."*

# 510(k) Summary

## 510(k) Summary of Safety and Effectiveness

This 510(k) summary of safety and effectiveness information is submitted as part of the Premarket Notification in compliance with requirements of CFR Part 807, Subpart E and Section 807.92.

The assigned 510(k) Number: K180155

1. Submitter

| | |
|---|---|
| Mailing Address | **AViTA Corporation**<br>9F, NO.78, SEC.1, Kwang-Fu Road,<br>San-Chung District, New Taipei City,<br>24158, Taiwan, R.O.C.<br>Phone: +886-2-85121568<br>Establishment Registration No.: NA (1st submission) |
| Contact Person | Anita Chen /Steven Jhou |
| Phone: | +886-939855759/ +8862-8512-1568 #5306 |
| Fax: | +886-2-85121347 |
| E-mail: | M9104303@gmail.com /<br>steven_jhou@avita.com.tw |
| Date Prepared | 2018.01.05 |

2 **Device Name**

| | |
|---|---|
| Trade or Proprietary Name | AViTA Arm Type Blood Pressure Monitor |
| Model | BPM64R |
| Common or usual name | Blood Pressure Monitor |
| Product Code | DXN |
| Device | Blood Pressure Monitor |
| CFR Classification | CFR Part 870.1130 |
| Device Class | II |
| Classification Panel | Cardiovascular |

3 **Predicate Device Name**

| | |
|---|---|
| 510(k) number: | K151869 |
| Trade or proprietary or model name: | Microlife BP3NF1-2B Automatic Blood Pressure Monitor |
| Manufacturer: | Microlife Intellectual Property Gmbh |

4 **Device Description:**

Blood Pressure Monitor is a device intended for use in automatically measures human's Systolic, Diastolic blood pressure and heart rate. The Blood Pressure Monitor, BPM64R uses an inflatable cuff which is wrapped around the patient's upper arm. The cuff is inflated automatically by an internal pump in the device. The systolic and diastolic blood pressures are determined by oscillometric method and silicon integrate pressure sensor technology. The deflation rate is controlled by a preset mechanical valve at a constant rate. The pressure of the cuff is completely released automatically at the end of the measurement. At the same time, the measurements are displayed on the LCD display for three minute. There is a maximum pressure safety setting at 300 mmHg. The device will not inflate the cuff higher than 300 mmHg.

5. **Indications for Use:**

BPM64R automatically measures human's Systolic, Diastolic blood pressure and heart rate by using the oscillometric method during inflation. All values can be read out in one LCD panel. Measurement position is at human being's Arm. The intended use of this over-the-counter device is for adults

| | | |
|---|---|---|
| | | aged 18 years and older with Arm circumference ranging 220 ~ 420 mm (approx. 9 ~ 17 inch) and for home use. |
| 6. | **Technological Characteristics and Substantial Equivalence Comparison with Predicate:** | A comparison of the device features, intended use, and other information demonstrates that the Product name is substantially equivalent to the predicate device as summarized in ***Table 1***. The differences raise no new question of safety and effectiveness. |

**7. Performance Testing**

Performance testing has been carried out to demonstrate that this device meets the performance specifications for its intend use. The following tests were performed on the device. Compliant to the standard of ISO 81060-2: Second Edition 2013-05-01 Non-invasive sphygmomanometers- Part 2: Clinical validation of automated measurement type. The results of this clinical investigation show that the required limits for mean difference and standard deviation are fulfilled by the subject device.

**8. Non-Clinical Tests Performed:**

a. EMC Test: IEC 60601-1-2, Medical Electrical Equipment - Part 1-2: General requirements for safety - collateral standard: Electromagnetic compatibility - Requirements and Tests

b. Radio Frequency Wireless Test: The EUT was performed according to FCC Part 15 Subpart C Section 15.247 procedure and setup followed by ANSI C63.10.2013 requirements.

c. Safety Test:
-IEC 60601-1:2005+A1:2012, Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
-IEC 60601-1-11:2010, Medical electrical equipment-Part 1-11: General Requirement for basic safety and essential performance– Collateral Standard: Requirements for medical electrical systems used in the home healthcare environment

d. Biocompatibility testing

The biocompatibility evaluation and testing of the Product name was conducted in accordance with the following standards and guidance, as recognized by the FDA:

- FDA Draft Guidance - Use of International Standard ISO- 10993, "Biological Evaluation of Medical Devices, Part 1: Evaluation and Testing".
- ISO 10993-5, Biological evaluation of medical devices- Part 5: Tests for in vitro cytotoxicity
- 10993-10, Biological evaluation of medical devices- Part 10: Tests for irritation and skin sensitization
- ISO 10993-11, Biological evaluation of medical devices- Part 11: Tests for systemic toxicity.

e. Reliability Test:

IEC 80601-2-30 Edition1.1 2013-07 Medical electrical equipment-Part 2-30: Particular requirements for the basic safety and essential performance of automated non-invasive sphygmomanometers

f. Software Verification and Validation:

IEC 62304:2006/AC: 2008 standard and FDA Guidance for the Content of Pre-Market Submission for Software Contained in Medical Devices standard.

g. Usability Validation:

IEC 60601-1-6:2010+A1:2013 Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance –Collateral Standard: Usability.

IEC 62366:2007+A1:2014 Medical Devices-Application of usability engineering to medical device.

EN ISO 14971:2012 - Medical devices - Application of risk management to medical devices (ISO 14971:2007, Corrected version 2007-10-01 )

## 9. Conclusion

Based on the intended use and/or indications for use, technological characteristics, performance testing and comparison to the predicate device, the subject device is substantially equivalent to the predicate device and raises no new questions of safety or effectiveness.