December 17, 2020

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

Re: K200346
Trade/Device Name: Wrist Type Blood Pressure Monitor
Regulation Number: 21 CFR 870.1130
Regulation Name: Noninvasive Blood Pressure Measurement System
Regulatory Class: Class II
Product Code: DXN
Dated: November 7, 2020
Received: November 19, 2020

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

LT Stephen Browning
Assistant Director
Division of Cardiac Electrophysiology, Diagnostics and Monitoring Devices
Office of Cardiovascular Devices
Office of Product Evaluation and Quality
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K200346

Device Name

Wrist Type Blood Pressure Monitor

Indications for Use *(Describe)*
BPM16B 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 wrist. The intended use of this over-the-counter device is for adults aged 18 years and older with wrist circumference ranging 125 ~ 210 mm (approx. 4.9 ~ 8.3 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.

Section 5 510(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

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The assigned 510(k) Number: TBD

1. Submitter

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Date Prepared	2018.01.05

2 **Device Name**

Proprietary Name:	Wrist Type Blood Pressure Monitor
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:	K102624
Trade or proprietary or model name:	AViTA BPM16 Wrist Type Blood PressureMonitor
Manufacturer:	AViTA Corporation
510(k) number:	K182166
Trade or proprietary or model name:	BP4350 Automatic Wrist Blood Pressure Monitor
Manufacturer:	Omron Healthcare, Inc..

4 **Device Description:** Blood Pressure Monitor is a device intended for use in automatically measures human's Systolic, Diastolic blood pressure and heart rate.

5. **Intended Use:** BPM16B 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 wrist. The intended use of th years and older with wrist circumference ranging 125 ~ 210 mm (approx. 4.9 ~ 8.3 inch) and for home use.

Special Conditions for Use Statement(s): For patient only

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.

Table 1 predicate device

	Comparison table between test	Predicate Devices	Predicate Devices	
SE Comparisons	Subject(AViTA BPM16B Wrist Type Blood Pressure Monitor)	AViTA BPM16 Wrist Type Blood Pressure Monitor **K102624**	Predicate (BP4350 Automatic Wrist Blood Pressure Monitor) **K182166**	Comment
Classification	21CFR 870.1130	21CFR 870.1130	21CFR 870.1130	Same
Product Code	DXN	DXN	DXN	Same
FDA Class	II	II	II	Same

	Comparison table between test	Predicate Devices	Predicate Devices	
Intended Use	BPM16B device automatically measures systolic and diastolic blood pressure and pulse rate by the oscillometric method. The measurement position is at the wrist. The device is intended to be used by adults with a wrist circumference ranging from 125 mm to 210 mm (approx. 4.9 ~ 8.3 inches). The device is intended for home use. When the device detects irregular heartbeats during measurement, an irregular heartbeat symbol will appear along with the measured readings.	The AViTA BPM lx Series device automatically measures systolic and diastolic blood pressure and pulse rate by the oscillometric method. The measurement position is at the wrist. The device is intended to be used by adults with a wrist circumference ranging from 125 mm to 210 mm (approx. 4.9 ~ 8.3 inches). The device is intended for home use. When the device detects irregular heartbeats during measurement, an irregular heartbeat symbol will appear along with the measured readings.	The device is a digital monitor intended for use in measuring blood pressure and pulse rate in adult patient population with wrist circumference ranging from 5.3 inches to 8.5 inches (13.5cm to 21.5cm). The device detects the appearance of irregular heartbeats during measurement and gives a warning signal with readings.	Same as The AViTA BPM lx Series
Method of measurement	Oscillimetric	Oscillimetric	Oscillimetric	Same
Measurement Type	During inflation	During deflation	During inflation	Same as BP4350
Range of measurement	Rated Range of Cuff Pressure: 0~ 300mmHg, Rated Range of Determination: 40~255mmHg, Pulse 40~199 Beats/minute	Rated Range of Cuff Pressure: 0~ 300mmHg, Rated Range of Determination: 30~280mmHg, Pulse 40~199 Beats/minute	Rated Range of Cuff Pressure: 0~ 299mmHg, Rated Range of Determination: 40~260mmHg, Pulse 40~180 Beats/minute	Similar
Accuracy	Pressure ± 3mmHg Pulse ± 4%	Pressure ± 3mmHg Pulse ± 4%	Pressure ± 3mmHg Pulse ± 5%	Same as The AViTA BPM lx Series
Inflation	Automatic	Automatic	Automatic	Same

	Comparison table between test	Predicate Devices	Predicate Devices	
Deflation	Automatic	Automatic	Automatic	Same
Pressure Changed Rate	2-5 mmHg/sec.	2-5 mmHg/sec.	2-5 mmHg/sec.	Same
Display	Liquid Crystal Digital	Liquid Crystal Digital	Liquid Crystal Digital	Same
Power Supply	2 ”AAA(LR03)(1.5 V)” Alkaline Batteries	2 ”AAA(LR03)(1.5 V)” Alkaline Batteries	2 ”AAA(LR03)(1.5 V)” Alkaline Batteries	Same
Storage/ Transportation Environment	- 20℃ ~ + 50℃ ≦ 85% R.H.	- 20℃ ~ + 50℃ ≦ 85% R.H.	- 20℃ ~ + 60℃, 15% ~ 90% R.H.	Same as The AViTA BPM lx Series
Operating Environment	10℃ ~ 40℃ ≦ 85% R.H. 700~1060 hPa	10℃ ~ 40℃ ≦ 85% R.H. 700~1060 hPa	10℃ ~ 40℃ 15% ~ 90% R.H. 800~1060 hPa	Same as The AViTA BPM lx Series
Material	ABS housing	ABS housing	ABS housing	Same
Sets of memory	1*90	2*90, total 180	2*100, total 200	Similar
Number of Push Button	2 keys	4 keys	5 keys	Similar
Storage pouch	Yes	Yes	Yes	Same
Cuff size	Wrist circumference approx. 125 ~ 210 mm (Approx. 4.9~8.3 inches)	Wrist circumference approx. 125 ~ 210 mm (Approx. 4.9~8.3 inches)	Wrist circumference approx. 135 ~ 215 mm (approx. 5.3 ~ 8.4 inches)	Same as The AViTA BPM lx Series
Unit Weight	approx. 106g (exclude batteries)	approx. 120g (exclude batteries)	Approx. 91 g	Similar

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: Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
-IEC 60601-1-11:, 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. Performance Test:
IEC 80601-2-30 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 standard and FDA Guidance for the Content of Pre-Market Submission for Software Contained in Medical Devices standard.

g. Usability & risk management:
IEC 60601-1-6: Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance –Collateral Standard: Usability.
IEC 62366: Medical Devices-Application of usability engineering to medical device.
EN ISO 14971 - Medical devices - Application of risk management to medical devices

9. Conclusion

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