October 22, 2024

AViTA Corporation
Maggie Chao
Adm. Manager
9F, No.78, Sec.1, Kwang-Fu Road, Sanchong Dist.,
Taipei, 24158
Taiwan

Re: K242193
Trade/Device Name: Arm Type Blood Pressure Monitor (BPM82)
Regulation Number: 21 CFR 870.1130
Regulation Name: Noninvasive Blood Pressure Measurement System
Regulatory Class: Class II
Product Code: DXN
Dated: July 22, 2024
Received: July 26, 2024

Dear Maggie Chao:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Stephen C. Browning -S

LCDR 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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*

K242193

Device Name

Arm Type Blood Pressure Monitor (BPM82)

Indications for Use *(Describe)*

The product automatically measures human being's Systolic, Diastolic blood pressure and pulse rate by oscillometric method. The measurement results are displayed on the LCD. Measurement position is at human being's upper arm. The intended use of this over-the-counter device is for adults with upper arm circumference ranging from 150 mm to 520 mm (Approx.6 ~ 21 inches) and for home use. When the device detects the appearance of irregular heartbeats during measurement, an indicated symbol will appear with measuring readings. This device is designed only for adults.

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.

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Traditional 510(k)

Applicant:	AViTA Corporation
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Date of Submission:	August 21, 2024

DEVICE

Trade/Proprietary Name:	AViTA Arm Type Blood Pressure Monitor
Common Name:	Arm Type Blood Pressure Monitor
Model:	BPM82
Review Panel:	Cardiovascular
Classification Product Code:	DXN
Regulation Number:	870.1130
Device Class:	II

PREDICATE DEVICE

The predicate device for AViTA Arm Type Blood Pressure Monitor is Arm Type Blood Pressure Monitor – **Model: BPM64R** (K112825), also manufactured by us. AViTA Arm Type Blood Pressure Monitor is manufactured/packaged by AViTA Corporation. This device is a reusable.

DEVICE DESCRIPTION

The AViTA Arm Type Blood Pressure Monitor (Model BPM82) consists of a main unit with an LCD display and four buttons, along with a cuff component. The device is designed for accurate and convenient monitoring of an individual's blood pressure and pulse rate through the application of oscillometric methodology. Specifically engineered for use on the upper arm, this over-the-counter device is tailored to adults with upper arm circumferences ranging from 150 mm to 520 mm (Approx. 6~ 21 inches) for in-home use.

This unit features our unique Hypertension Indicator. Hypertension Indicator is following Classification of blood pressure levels according to 1999 WHO-ISH Guidelines for the Management of Hypertension.

- Optimal blood pressure (Green): DIA<80, SYS<120,
- Normal blood pressure (Green): DIA<85, SYS<130,
- High-normal systolic value (Green): DIA<90, SYS<140,
- Mild blood hypertension (Yellow): DIA<100, SYS<160,
- Moderate hypertension (Orange): DIA<110, SYS<180,
- Severe hypertension (Red): DIA≥ 110, SYS≥ 180.

In addition to providing standard blood pressure readings, this device incorporates an advanced feature designed to detect irregular heartbeats during measurements. The device will display corresponding indicator symbol to indicate the detection of irregular heartbeat rhythm as defined as a rhythm is more than or less than 25%

The AViTA Arm Type Blood Pressure Monitor employs an inflatable cuff that automatically wraps around the patient's upper arm. The cuff inflation is managed internally by the device's pump, and deflation is regulated by a preset mechanical valve at a consistent rate. Importantly, the cuff pressure is entirely released upon completion of the measurement. The results are promptly displayed on the high-resolution LCD screen for a duration of 2 minutes, ensuring easy accessibility for the user.

The Irregular HeartBeat (IHB) parameters are recorded while the cuff is held at a fixed pressure lower than systolic pressure. By comparison, traditional blood pressure monitors inflate the cuff to a pressure higher than systolic, and then begin to deflate the cuff.

For safety assurance, the device is equipped with a maximum pressure setting at 300 mmHg, guaranteeing that the cuff will not be inflated beyond this limit. This feature adds an extra layer of security to the measurement process, ensuring the well-being of the user.

INDICATIONS FOR USE

The product automatically measures human being's Systolic, Diastolic blood pressure and pulse rate by oscillometric method. The measurement results are displayed on the LCD. Measurement position is at human being's upper arm. The intended use of this over-the-counter device is for adults with upper arm circumference ranging from 220 mm to 520 mm (Approx.6 ~ 21 inches) and for home use. When the device detects the appearance of irregular heartbeats during

measurement, an indicated symbol will appear with measuring readings. This device is designed only for adults. The Indications for Use statement for the subject device, AViTA Arm Type Blood Pressure Monitor BPM82, is not identical to the predicate device; however, the differences do not alter the intended use of the device nor do they affect the safety and effectiveness of the device relative to the predicate. Both the subject and predicate devices have the same intended use for measuring blood pressure and pulse, hypertension indication, and IHB indication.

COMPARISON WITH PREDICATE DEVICE

There is a device currently on the US market that has the same clinical, Technical and biological characteristic as the subject device AVITA Arm Type Blood Pressure Monitor (model BPM 82). After comparison, this device was identified as equivalent to the subject device. The basic information of the predicate device is as follows:

- **Trade or proprietary or model name:** AViTA Arm Type Blood Pressure Monitor, (Model No. BPM64R)
- **510(k) number:** K112825
- **Manufacturer:** AVITA CORPORATION.

In Clinical terms, Subject Device and Predicate device have the same intended uses for blood pressure/ pulse measurement, hypertension indicator, and IHB indicator, and are applicable to the same patient groups, users, and usage environments. In Technical terms, the two have exactly the same working principle, performance specifications and Cuff size. In Biological terms, the parts that contact the human body are exactly the same in terms of materials, process, contact time and contact location.

The following technological differences exist between the subject and predicate devices:

- **About clinical difference (differences in intended use)**
  Physical Status value and level is an additional reference information that is not intended to be used for the diagnosis, assessment, treatment, monitoring, or management of psychological conditions (including but not limited to stress, emotional distress, somatic symptom disorder (SSD), depression, etc.)
- **About technical difference (differences in Power Supply, Data Link, Dimensions, Weight, and Number of Push Button)**
  Regarding the difference in power supply, both have passed the relevant tests of IEC 60601-1.
  Regarding the differences in the number of memories, keys and weight, and the difference in data transmission function, the two have passed the usability verification of IEC60601-1-6 and IEC62366.

In conclusion, the difference in intended use is because the measurement function of PS is not used for. diagnosis, assessment, treatment, monitoring, or management of psychological conditions. Therefore, the Subject device, AVITA Arm Type Blood Pressure Monitor (model BPM 82) is essentially equivalent to the Predicate device, AViTA Arm Type Blood Pressure Monitor, (Model No. BPM64R).

PERFORMANCE DATA

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 / EN ISO 81060-2 Non-invasive sphygmomanometers — Part 2: Clinical investigation of intermittent 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.

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.

Cleaning and Disinfecting Test

The Blood Pressure Monitor is a medical device that does not supply sterilized. This product has passed the cleaning verification of 1000 times of 75% alcohol and Lint-free cloth wiping, confirming that the product can be used continuously without any functional abnormalities.

EMC Test: IEC 60601-1-2,

Medical Electrical Equipment - Part 1-2: General requirements for safety - collateral standard: Electromagnetic compatibility - Requirements and Tests

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

Software Verification and Validation Testing

Software verification and validation testing were conducted and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." The software for this device was considered as a "major" level of concern, since a failure or latent flaw in the software could directly result in serious injury or death to the patient or operator.

Usability Validation:

- IEC 60601-1-6:2010+A1:2013+A2:2020 Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance –Collateral Standard: Usability.
- IEC 62366:2015 Medical devices - Part 1: Application of usability engineering to medical devices
- EN ISO 14971:2019 - Medical devices - Application of risk management to medical devices

Clinical Studies

The method adhered to the ISO 81060-2 / EN ISO 81060-2 Non-invasive sphygmomanometers validation protocol, utilizing the same arm sequential method with multiple arm cuff size of 22 to 52 cm (size: XS~XL) for measuring systolic and diastolic blood pressures. Sequential measurements were taken in 90 adult subjects (255 valid paired) following the validation protocol, using a mercury sphygmomanometer (two observers) and the AViTA Blood Pressure Monitor. The outcomes of this study affirm that the AViTA Arm Type Blood Pressure Monitor successfully passed validation for both systolic and diastolic blood pressures in accordance with the International Standard ISO 81060-2 / EN ISO 81060-2 and ISO14155. The clinical investigation indicated that all subjects experienced no discomfort during measurements, highlighting the safety and efficacy of the AViTA Arm Type Blood Pressure Monitor.

CONCLUSION

Because of the differences in intended use between subject device and predicate device, and because comparison of bench testing and clinical results for such devices is not well understood, clinical testing is required to support substantial equivalence. The non-clinical data support the safety of the device and the hardware and software verification and validation demonstrate that the AViTA BPM82 Arm Type Blood Pressure Monitor should perform as intended in the specified use conditions. The clinical data demonstrate that the AViTA BPM82 Arm Type Blood Pressure Monitor performs comparably to the predicate device that is currently marketed for the same intended use.