September 3, 2025

AViTA Corporation
Rex Hsieh
Regulatory Affairs
9F, No.78, Sec.1, Kwang-Fu Road, Sanchong Dist.
New Taipei, 24158
Taiwan

Re: K250765
Trade/Device Name: AViTA Arm Type Blood Pressure Monitor Cuff
Regulation Number: 21 CFR 870.1120
Regulation Name: Blood Pressure Cuff
Regulatory Class: Class II
Product Code: DXQ
Dated: August 4, 2025
Received: August 4, 2025

Dear Rex Hsieh:

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,

Aneesh S. Deoras -S

for

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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K250765

Please provide the device trade name(s).

AViTA Arm Type Blood Pressure Monitor Cuff

Please provide your Indications for Use below.

The cuff is compatible with non-invasive blood pressure monitors to measure blood pressure.
It is intended for use by healthcare professionals (prescription use) and by laypersons in home settings (over-the-counter use).
The cuff is designed for adult patients. It is non-sterile and reusable.

Please select the types of uses (select one or both, as applicable).

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

510(k) Summary

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.

1 APPLICANT INFORMATION

Applicant:	AViTA Corporation
Address:	9F, No.78, Sec.1, Kwang-Fu Rd., San-Chung District, New Taipei City 24158, Taiwan
Applicant Establishment Number:	9617543
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Date of Submission:	Feb 24, 2025

2 SUBJECT DEVICE

Trade/Proprietary Name:	AViTA Arm Type Blood Pressure Monitor Cuff
Common Name:	AViTA Arm Type Blood Pressure Monitor Cuff
Review Panel:	Cardiovascular
Classification Product Code:	DXQ
Regulation Number:	870.1120
Device Class:	II

3 PREDICATE DEVICE

510(k) Number:	K231961
Trade Name:	Reusable NIBP Cuff
Manufacturer:	Shenzhen SINO-K Medical Technology Co., Ltd

4 DEVICE DESCRIPTION

The primary components of the AViTA blood pressure cuff include an inflatable bladder and an outer fabric layer with a hook-and-loop fastening system. The cuff is designed to wrap securely around the patient's upper arm, allowing for accurate measurement of blood pressure when used with AViTA blood pressure monitors.

The AViTA blood pressure cuffs are available in five different sizes to accommodate a range of arm circumferences:

Model.	Limb Range (Unit: cm)
6NRUI-K	22-42 cm
6NRLI-K	33-42 cm
6NRXI-K	42-52 cm
6NRSI-K	15-22 cm
6NRMI-K	22-33 cm

During operation, the cuff inflates and deflates to occlude and release arterial blood flow, utilizing the oscillometric method to detect systolic and diastolic pressure. The cuff is constructed with durable materials to withstand repeated inflation cycles and ensure long-term performance.

The AViTA blood pressure cuff is designed for compatibility with AViTA blood pressure monitors, ensuring optimal performance and measurement accuracy.

5 INDICATIONS FOR USE

The cuff is compatible with non-invasive blood pressure monitors to measure blood pressure.
It is intended for use by healthcare professionals (prescription use) and by laypersons in home settings (over-the-counter use).
The cuff is designed for adult patients. It is non-sterile and reusable.

6 IDENTIFICATION OF THE PREDICATE DEVICE

NO.	Device Name	Limb Range	Manufacture	Classification and Code	Classification regulation	510K number

Subject Device	AViTA Arm Type Blood Pressure Monitor Cuff	15-52cm	AViTA Corporation	Class II DXQ	870.1120	TBD
Predicate Device	Reusable NIBP Cuff	6-66cm	Shenzhen SINO-K Medical Technology Co., Ltd	Class II DXQ	870.1120	K231961

7 NON-CLINICAL TESTING

A series of safety, essential performance, and biocompatibility tests were conducted to evaluate the safety and effectiveness of the AViTA Arm Type Blood Pressure Monitor Cuff. The tests listed below were conducted in accordance with:

- ISO 81060-1: Non-invasive sphygmomanometers – Part 1: Requirements and test methods for non-automated measurement type.
- ISO 10993-1: Biological Evaluation of medical devices – Part 1: Evaluation and testing within a risk management process.
- ISO 10993-5: Biological Evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity.
- ISO 10993-10: Biological evaluation of medical devices – Part 10: Tests for Sensitization.
- ISO 10993-23: Biological evaluation of medical devices – Part 23: Tests for irritation.

8 CLINICAL PERFORMANCE TESTING

Clinical validation of the subject device was conducted in accordance with ISO 81060-2:2018 requirements for non-invasive sphygmomanometers. Validation studies were performed across a broad population with arm circumferences spanning the full intended range.

The following cuff models were included in the validation:

- 6NRSI-K Cuff (15–22 cm arm circumference)
- 6NRMI-K Cuff (22–33 cm arm circumference)
- 6NRLI-K Cuff (33–42 cm arm circumference)
- 6NRXI-K Cuff (2–52 cm arm circumference)
- 6NRUI-K Cuff (22–42 cm arm circumference)

All clinical testing followed the ISO 81060-2:2018 protocol, comparing device measurements against simultaneous auscultatory reference measurements obtained by trained observers using a mercury sphygmomanometer.

Results:
For each cuff model, the subject device met the accuracy requirements of ISO 81060-2:2018:

- Criterion 1 (mean difference and standard deviation): Within the allowable limits of ±5 mmHg (mean) and ≤8 mmHg (standard deviation).
- Criterion 2 (per-subject distribution of differences): Variability across subjects was within acceptance criteria.

Conclusion:
The validation studies confirmed that the subject device provides accurate and reliable blood pressure measurements across the full intended range of arm circumferences. All five cuff models listed above have been clinically validated in compliance with ISO 81060-2:2018.

9 DEVICE COMPARISON TABLE

Item	Proposed Device	Predicate Device	Comparison
Product Name	AViTA Arm Type Blood Pressure Monitor Cuff	Reusable NIBP Cuff	--
K number	TBD	K231961	

Applicant	AViTA Corporation	Shenzhen SINO-K Medical Technology Co., Ltd	
510(k) Information			
Regulation Number	870.1120	870.1120	Identical
Classification	Class II	Class II	Identical
Product Code	DXQ	DXQ	Identical
Indication for Use			
Statement	The cuff is compatible with non-invasive blood pressure monitors to measure blood pressure. It is intended for use by healthcare professionals (prescription use) and by laypersons in home settings (over-the-counter use). The cuff is designed for adult patients. It is non-sterile and reusable.	The reusable blood pressure cuff is an accessory used in conjunction with noninvasive blood pressure measurement systems. The cuff is non-sterile and may be reused. It is available in neonate, infant, child and adult sizes. The cuff is not designed, sold, or intended for use except as indicated.	Substantially Equivalent . (Note 1)
Population	adults	adults/pediatrics	Identical
Tube number	one	one	Identical
Principles of operation	Bladder is wrapped around the patient's limb and secured by hook and loop closure Air hose is connected to the noninvasive blood pressure measurement systems	Bladder is wrapped around the patient's limb and secured by hook and loop closure Air hose is connected to the noninvasive blood pressure measurement systems	Identical
Limb Circumference (Range in cm)	6NRMI-K (22-33cm) 6NRUI-K (22-42cm) 6NRLI-K (33-42cm)	Neonatal (6-11cm) Infant (10-19cm) Child (18-26cm)	Substantially Equivalent *Note 2

	6NRXI-K(42-52cm) 6NRSI-K (15-22cm)	Small Adult (20-28cm) Adult (25-35cm) Adult Long (25-35cm) Large Adult (33-47cm) Adult Thigh (44-66cm)	
Pressure Range	0~330mmHg	0~330mmHg	Identical
Max. Leakage	< 4mm Hg/Min	< 4mm Hg/Min	Identical
Biocompatibility	Comply with ISO 10993-5 ISO 10993-10 ISO 10993-23	Comply with ISO 10993-5 ISO 10993-10	Substantially Equivalent *Note 3
Sterility	Non-sterile	Non-sterile	Identical
Repeated inflation	10,000 inflations 3,000 hook and loop closures	Unknown	*Note 4

***Note 1**

Both devices are intended to be used with non-invasive BP monitors. The subject device expands labeling to include OTC use for adults, but this does not impact fundamental technology or performance.

***Note 2**

Although the predicate device includes cuffs intended for neonatal, infant, child, and adult populations, the subject device is intended only for adult patients, with five cuff sizes covering the full adult arm circumference range (15–52 cm). Clinical validation has been performed in accordance with ISO 81060-2:2018 across all five subject cuff sizes. Therefore, while the intended user population is narrower (adults

only), the differences do not raise new questions of safety or effectiveness, and the subject device remains substantially equivalent to the predicate device.

***Note 3**

Although the subject device has undergone additional biocompatibility testing (ISO 10993-23, in addition to ISO 10993-5 and ISO 10993-10), it remains substantially equivalent to the predicate device. The additional compliance with ISO 10993-23 ensures further safety validation regarding irritation and skin sensitization, but does not introduce new risks. Therefore, these differences do not negatively impact the overall safety and effectiveness of the device.

***Note 4**

The subject device has been tested for durability, undergoing 10,000 inflation cycles and 3,000 hook-and-loop closure tests to ensure long-term performance and reliability. The predicate device does not specify repeated inflation test results in publicly available documentation. However, this difference does not impact substantial equivalence, as both devices are intended for the same use and expected to perform reliably over their lifespan

10 SUBSTANTIAL EQUIVALENCE CONCLUSIONS

Based on the non-clinical and clinical performance data, the AViTA Arm Type Blood Pressure Monitor Cuff has been shown to be substantially equivalent to the legally marketed predicate device.