November 26, 2024

Shenzhen IMDK Medical Technology Co., Ltd.
% Yijie You
Manager
Qimmiq Medical Consulting Service Co., Ltd
RM.406, Building C, Run Science Park
No.18 Shenzhou Road, Huangpu
Guangzhou, Guangdong 510663
China

Re: K243118
Trade/Device Name: Arm Blood Pressure Monitor (model: BPM-A7VL)
Regulation Number: 21 CFR 870.1130
Regulation Name: Noninvasive Blood Pressure Measurement System
Regulatory Class: Class II
Product Code: DXN
Dated: September 30, 2024
Received: September 30, 2024

Dear Yijie You:

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.

Submission Number *(if known)*

K243118

Device Name

Arm Blood Pressure Monitor (model: BPM-A7VL)

Indications for Use *(Describe)*

Arm Blood Pressure Monitor is intended to measure the blood pressure and pulse rate of person older than twelve (12) years in household or medical facilities.

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.

510(k) Summary

[As required by section 807.92(c)]

1. 510(k) owner (Applicant)

Establishment Registration number:		3015007456
Name:		Shenzhen IMDK Medical Technology Co., Ltd.
Address:		904, 9F, Guangming Tianan Cloud Park Building, 255 Zhenmei Road, Zhenmei Community, Xinhu Street, Guangming District, Shenzhen, 518107, PEOPLE'S REPUBLIC OF CHINA
Contact Person	**Name:**	Xia yuan
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	TEL:	+86-13662694320
	Email:	vicky-xia@imdker.com

2. Submission Correspondent (Authorized representative)

Name:	You Yijie
Company Name	Qimmiq Medical Consulting Service Co., Ltd
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3. Device Information

Purpose of the application: 510(K) submission
Submission Type: Traditional 510(K)
The reason for the 510(k): It is a new device

Trade Name: Arm Blood Pressure Monitor
Model: BPM-A7VL
Common name of the device: Arm Blood Pressure Monitor

Classification name: System, Measurement, Blood-Pressure, Non-Invasive
Regulation name: Noninvasive blood pressure measurement system

Review panel:	Cardiovascular
Product code:	DXN
Regulation Class:	II
Regulation Number:	21 CFR 870.1130

4. Predicate Device Information

510(k) submitter/holder:	ShenZhen GoodlyMed Technology Co., Ltd.
510(K) Number:	K241129
Trade name:	Upper Arm Electronic Blood Pressure Monitor
Model:	A02-SE4
Review Panel:	Cardiovascular
Product Code:	DXN
Regulation Class:	II
Regulation Number:	21 CFR 870.1130

5. Device description

Arm Blood Pressure Monitor, model: BPM-A7VL is a Noninvasive Blood Pressure Measurement System that is intended to measuring blood pressure through oscillation mensuration. The subject device will automatically start to take measurements after the inflation of the cuff is finished, the results will show the systolic pressure and diastolic pressure with pulse rate. The blood pressure monitor will store the measurements automatically; The record maybe revisited.

It measures blood pressure and pulse rate through inflating cuff which rounding the upper arm of patients. The BPM-A7VL is small, portable and used in home or medical facilities environment. The Arm Blood Pressure Monitor consists of two parts: main unit and cuffs. The BPM-A7VL is composed of PCBA, crystal oscillator, pump, valve, enclose, and LCD. Cuffs including cuff of size 23cm~33cm and cuff of size 33cm~47cm.

Principle of operation:

This product uses the Oscillometric Measuring method to detect blood pressure. When the cuff is fully inflated to reach a pressure above systolic pressure, no blood flow occurs through the artery. As the cuff is deflated below the systolic pressure, the reducing pressure exerted on the artery allows blood to flow through it and sets up a detectable vibration in the arterial wall. When the cuff pressure falls below the patient's diastolic pressure, blood flows smoothly through the artery in the usual pulses, without any vibration being set up in the wall. Vibrations occur at any point where the cuff pressure is sufficiently high that the blood has to push the arterial wall open in order to flow through the artery. The vibrations are transferred from the arterial wall, through the air inside the cuff, into a transducer in the monitor that converts the measurements into electrical signals. Hence when it starts inflating the arm cuff, meanwhile, the unit detects pressure oscillations generated by beat-to-beat pulsatile, which is used to determine the systolic and diastolic pressure, and pulse rate.

6. Indications for Use

Arm Blood Pressure Monitor is intended to measure the blood pressure and pulse rate of person older than twelve (12) years in household or medical facilities.

7. Summary of technological characteristics of device compared to the predicate devices (K241129)

SE Comparisons	**Subject device** (Arm Blood Pressure Monitor, model: BPM-A7VL)	**Predicate device** (Upper Arm Electronic Blood Pressure Monitor, Model: A02-SE4)	**Discussion of difference**
510K Number	/	**K241129**	***/***
Model	BPM-A7VL	A02-SE4	***/***
Classification	21CFR 870.1130	21CFR 870.1130	**Same**
Product Code	DXN	DXN	**Same**
FDA Class	II	II	**Same**
Indications for Use	Arm Blood Pressure Monitor is intended to measure the blood pressure and pulse rate of person older than twelve (12) years in household or medical facilities.	Upper Arm Electronic Blood Pressure Monitor is intended for used by a person older than twelve (12) years to measure the systolic and diastolic blood pressure and pulse rate.	**Same**
Patient Population	person older than twelve (12) years	person older than twelve (12) years	**Same**
Design	table type	table type	**Same**
Design Method	Oscillometric	Oscillometric	**Same**
Measurement Site	Upper Arm	Upper Arm	**Same**
Cuff Circumference	23cm~33cm; 33cm~47cm.	22cm~42cm; 32cm~52cm.	**Different** (Discussion is indicated in D1)
Deflation Method	Automatic Pressure Release Valve	Automatic Pressure Release Valve	**Same**
Display	Backlight LCD Digital Display	Backlight LCD Digital Display	**Same**
Memory Size	99 groups	Not public	**Different** (Discussion is indicated in D2)
Blood Pressure Measurement Range	**Measurement blood pressure range:** SYS:60mmHg~230mmHg DIA: 40mmHg~130mmHg	**BP Range:** 0 ~ 299 mmHg	**Different** (Discussion is indicated in D3)

Blood Pressure Measurement Accuracy	±3 mmHg	±3 mmHg	**Same**
Pulse Measurement Range	40~200 beats/min	40 ~ 199 beats/min	**Different** (Discussion is indicated in D4)
Pressurization Source	Automatic Internal Pump	Automatic Internal Pump	**Same**
Operating Environment	Ambient temperature: +5℃~ +40℃ Relative humidity (RH): 15%~85% Atmospheric pressure: 80 kPa~106kPa	Not public	**Different** (Discussion is indicated in D5)
Storage Environment	Ambient temperature: -20℃~+50℃ Relative humidity (RH): 15%~85% Atmospheric pressure: 80 kPa~106kPa	Not public	**Different** (Discussion is indicated in D6)
Energy Source	Internal power supply DC 6V (4X1.5V (AA) batteries; External power supply: USB interface DC 5V 1A	4 X AA batteries or AC adapter	**Different** (Discussion is indicated in D7)
Measurement Item	SYS, DYS, Pulse Rate	SYS, DYS, Pulse Rate	**Same**
Software Level Concern	Moderate	Moderate	**Same**
Wireless	NA	4G	**Different** (Discussion is indicated in D8)
Performance	ISO 81060-2 Third edition 2018-11 Amendment 1 2020-01	ISO 81060-2:2020	**Same**
Performance	IEC 80601-2-30: Edition 2.0 2018-03	IEC 80601-2-30	**Same**
Biocompatibility	ISO 10993-1, FDA Guidance, Tests included Cytotoxicity, Sensitization and Intracutaneous Reactivity	ISO 10993-1, FDA Guidance, Tests included Cytotoxicity, Sensitization and Intracutaneous Reactivity	**Same**
Electrical Safety	ANSI AAMI ES60601-1:2005/(R)2012 & A1:2012 C1:2009/(R)2012 & A2:2010/(R)2012 (Cons. Text) [Incl. AMD2:2021]	IEC60601-1	**Same**
EMC	IEC 60601-1-2: 2014+AMD1:2020	IEC 60601-1-2	**Same**
Home Use	IEC 60601-1-11:2015/2020	IEC 60601-1-11	**Same**
Material of Patient contact components	**Shell**: ABS757 **Display cover**: PMMA **M button and ON/Off button**: ABS757	Not public	**Different** (Discussion is indicated in D9)
Patient Interface	Cuff, button	Cuff, button	**Same**

Dimensions	110mm x 103mm x 103 (mm) (Length×Width×Height)	Not public	**Different** (Discussion is indicated in D10)
Weight	Approximate 280g. (Without battery)	Not public	**Different** (Discussion is indicated in D11)
Principle of operation	Oscillometric Measuring method	Oscillometric Measuring method	**Same**
User Interface	Cuff, button	Cuff, button	**Same**
Software	Embedded	Embedded	**Same**

The discussion of differences exist between the subject and predicate devices is listed in following:

D1: The difference of Cuff Circumference between subject device and predicate device is that the intended Cuff Circumference range of subject device is 23~33 cm & 33~47cm and predicate device is 22~42cm&32-52cm, the Cuff Circumference range of subject device is in the range of predicate device, and this difference is also addressed through clinical trial conducted with subject device according to ISO 81060-2 Third edition 2018-11 Amendment 1 2020-01, the results of clinical trial meet the requirements of ISO 81060-2 Third edition 2018-11 Amendment 1 2020-01, therefore, the difference of subject device with predicate device A02-SE4 (K241129) will not affect the safety and effectiveness.

D2: The Memory Size of subject device is different with predicate device predicate device A02-SE4 (K241129) which will not affect the safety and effectiveness.

D3: The difference of Blood Pressure Measurement Range between subject device and predicate device is that the Blood Pressure Indication Range of subject device is DIA: 40 mmHg~130mmHg & SYS: 60 mmHg~230mmHg and predicate device is BP Range: 0 ~ 299 mmHg, the Blood Pressure Indication Range of subject device is in the range of predicate device and meets the requirements of IEC 80601-2-30: Edition 2.0 2018-03, and this difference is also addressed through clinical trial conducted with subject device according to ISO 81060-2 Third edition 2018-11 Amendment 1 2020-01, the results of clinical trial meet the requirements of ISO 81060-2 Third edition 2018-11 Amendment 1 2020-01, therefore, the difference of subject device with predicate device A02-SE4 (K241129) will not affect the safety and effectiveness.

D4: The Measurement Pulse Range of subject device is tiny different with predicate device, and this difference is also addressed through clinical trial conducted with subject device according to ISO 81060-2 Third edition 2018-11 Amendment 1 2020-01, therefore, the difference of subject device with predicate device A02-SE4 (K241129) will not affect the safety and effectiveness.

D5: The operating Environment of subject device are different with predicate device A02-SE4 (K241129), the difference introduces risks mitigated by testing in accordance with IEC 60601-1-11 and ANSI AAMI ES60601-1 provided in this submission, therefore the difference does not raise new questions of safety and effectiveness.

D6: The Storage Environment of subject device is different with predicate device A02-SE4 (K241129), the difference introduces risks mitigated by testing in accordance with IEC 60601-1-11 and ANSI AAMI

ES60601-1 provided in this submission, therefore the difference does not raise new questions of safety and effectiveness.

D7: The Energy Source of subject device are different with predicate devices, the difference introduces risks mitigated by the electromagnetic compatibility and electrical safety testing in accordance with IEC 60601-1-2 and ANSI AAMI ES60601-1 provided in this submission, therefore the difference does not raise new questions of safety and effectiveness.

D8: The subject device does not have wireless function which will not affect the safety and effectiveness.

D9: The Material of Patient contact components of subject device has been validated for Cytotoxicity though testing against ISO 10993- 5, for Sensitization and Irritation though testing against ISO 10993-10 and ISO 10993-23 tested and all test results are positive, the difference of subject device with predicate device A02-SE4 (K241129) do not raise new questions of safety and effectiveness.

D10: The Dimensions of subject device is different with predicate device predicate device A02-SE4 (K241129) will not affect the safety and effectiveness.

D11: The Weight of subject device is tiny different with predicate device predicate device A02-SE4 (K241129) will not affect the safety and effectiveness.

8. Discussion of Non-Clinical Tests Performed for Safety and effectiveness are as follows

The recognized consensus standards for safety of medical electrical equipment: ANSI AAMI ES60601-1:2005/(R)2012 & A1:2012 C1:2009/(R)2012 & A2:2010/(R)2012 (Cons. Text) [Incl. AMD2:2021], IEC 60601-1-11:2015/2020, IEC 60601-1-2: 2014+AMD1:2020 for electromagnetic compatibility, IEC 80601-2-30: Edition 2.0 2018-03, ISO 81060-2 Third edition 2018-11 Amendment 1 2020-01 for performance, IEC 62304 Edition 1.1 2015-06 for software verification and ISO 10993-5:2009 for Cytotoxicity endpoints, ISO 10993-10:2021 and ISO 10993-23:2021 for Sensitization and Irritation endpoints are complied. See below table for details:

Standards	Standards Name
ANSI AAMI ES60601-1:2005/(R)2012 & A1:2012 C1:2009/(R)2012 & A2:2010/(R)2012 (Cons. Text) [Incl. AMD2:2021]	Medical Electrical Equipment - Part 1: General Requirements For Basic Safety And Essential Performance
IEC 60601-1-2: 2014+AMD1:2020	Medical Electrical Equipment - Part 1-2: General Requirements For Basic Safety And Essential Performance -- Collateral Standard: Electromagnetic Disturbances - Requirements And Tests
IEC 60601-1-11:2015/2020	Medical electrical equipment - Part 1-11: General requirements for basic safety and essential performance - Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment
IEC 80601-2-30: Edition 2.0 2018-03	Medical electrical equipment - Part 2-30: Particular requirements for the basic safety and essential performance of automated non-invasive sphygmomanometers

ISO 81060-2 Third edition 2018-11 Amendment 1 2020-01	Non-invasive sphygmomanometers - Part 2: Clinical investigation of intermittent automated measurement type
ISO 10993-5:2009	Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity
ISO 10993-10:2021	Biological evaluation of medical devices - Part 10: Tests for skin sensitization
ISO 10993-23:2021	Biological evaluation of medical devices - Part 23: Tests for irritation
IEC 62304 Edition 1.1 2015-06	Medical device software - Software life cycle processes

- **Electrical safety and electromagnetic compatibility (EMC)**
  Electrical safety and EMC testing were conducted on the subject device BPM-A7VL. The system complies with the AAMI ANSI ES60601-1, IEC 60601-1-11 for electrical safety, the IEC 60601-1-2 standard for EMC, IEC 80601-2-30 and ISO 81060-2 for performance.

- **Software Verification and Validation Testing**
  Software verification and validation was performed for the subject device in accordance with Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices - Guidance for Industry and FDA Staff, May 2005.

  Software Description:
  The software for this device was considered as a “moderate” level of concern, since a failure or latent flaw in the software could result in Minor Injury, either to a patient or to a user of the device. The software of the system, on the whole, is accountable for the system scheduler of the device, including Pressure and pulse signal acquisition, calculation and display, the button presses of end user, display the result of the measurement, measurement data storage and average calculation, memory data query, prompt of error message, low battery voltage detection and prompt, measurement Unit conversion.

9. Discussion of Clinical Accuracy Testing Performed

The clinical accuracy test report and data analysis followed the requirements of the ISO 81060-2 Third edition 2018-11 Amendment 1 2020-01.

The clinical accuracy testing evaluated 85 of subjects, division of all subjects:

Subjects requirement		**Number specified in ISO 81060-2 Third edition 2018-11 Amendment 1 2020-01**	**Actual number**
Total		A minimum of 85 people	85
Male		At least 26 people	39
Female		At least 26 people	46
Age > 12		100%	100%
Arm circumference range	23-33 cm;	At least 18 people	44
	33-47 cm;	At least 25 people	41

	23 ≤ x <29 cm	≥ 20%	28	32.94%
	29 ≤ x <35 cm	≥ 20%	20	23.53%
	35 ≤ x < 41 cm	≥ 20%	20	23.53%
	41 ≤ x ≤ 47 cm	≥ 20%	17	20.00%
	44 ≤ x ≤ 47 cm	≥10%	10	11.76%
	23 ≤ x ≤ 26 cm	≥10%	14	16.47%
Systolic BP	Systolic BP ≤ 100mmHg	≥5%	117	17.21%
	Systolic BP ≥ 160mmHg	≥5%	68	10.00%
	Systolic BP ≥140mmHg	≥20%	196	28.82%
Diastolic BP	Diastolic BP ≤ 60mmHg	≥5%	49	7.21%
	Diastolic BP ≥ 100mmHg	≥5%	134	19.71%
	Diastolic BP ≥ 85mmHg	≥20%	303	44.56%

The test data showed the clinical accuracy of the subject device complied with the requirements of ISO 81060-2 Third edition 2018-11 Amendment 1 2020-01.

Reference equipment used for measurements:

Name	Aneroid sphygmomanometer
Model	CM-BPM-D
Manufacturer	Shanghai Caremate Medical Device Co. Ltd
Measuring Method	Aneroid/auscultation method
K number	K211084

10. Conclusions

The Arm Blood Pressure Monitor, model: BPM-A7VL, have the same intended use and similar characteristics as the cleared predicate device Arm Blood Pressure Monitor, Model: A02-SE4. Moreover, bench testing contained in this submission supplied demonstrate that the differences existed between BPM-A7VL and A02-SE4 do not raise any new questions of safety or effectiveness.

The non-clinical tests support the safety of the device and the hardware and software verification and validation demonstrate that the Arm Blood Pressure Monitor, model: BPM-A7VL performs as intended in the specified use conditions are same with predicate device. The clinical performance tests demonstrate that the Arm Blood Pressure Monitor, model: BPM-A7VL performs comparably to the predicate device that is currently marketed for the same intended use. Thus, the Arm Blood Pressure Monitor, model: BPM-A7VL is Substantially Equivalent (SE) to the predicate device.