February 5, 2025

Accurate Meditech Inc.
% Douglas Herrington
Consultant
Herrington Consulting LLC
No 64, Haijing 3rd St.
Sanzhi District
New Taipei City, 252002
Taiwan

Re: K242352
Trade/Device Name: Accurate Mini Non-invasive blood pressure monitor (AMB-001)
Regulation Number: 21 CFR 870.1130
Regulation Name: Noninvasive Blood Pressure Measurement System
Regulatory Class: Class II
Product Code: DXN
Dated: August 1, 2024
Received: August 8, 2024

Dear Douglas Herrington:

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

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)*

K242352

Device Name

Accurate Mini Non-invasive blood pressure monitor (AMB-001)

Indications for Use *(Describe)*

The device is a wrist-worn digital monitor intended for use in measuring blood pressure and pulse rate in adult patients of ages 20 -70 with wrist circumference from 13.5 cm to 21.5 cm and BMI<40.

The Accurate Mini Non-invasive BPM is intended for spot-checking of adult patients in hospitals, clinics, long-term care, and home use. The measurement results are stored locally in the device.

The Accurate Mini Non-invasive BPM measures blood pressure based on Pulse Wave Transit Time (PWTT) obtained Local Pulse Wave Velocity (PWV) from dual Piezo Sensors and radial artery parameters from Near InfraRed Spectroscopy (NIRS) Optic sensor.

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

This summary of 510(k) information is submitted as required by requirements of SMDA and 21 CFR Part 807.92

Submitter

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Contact Person: Kuan-Jen, Wang

Date Prepared: 2024/5/23

Subject Device Information

Trade/Device Name	Accurate Mini Non-invasive blood pressure monitor (AMB-001)
Model	AMB-001
Common Name	Non-invasive blood pressure monitor
Regulatory Classification	Class II 870.1130 Noninvasive blood pressure measurement system
Submission type	Traditional 510(k)
Product Code	DXN

Predicate Device Information

Predicate Device	Sponsor: Accurate Meditech Inc. Device: Accurate 24 BPM 510(K) Number: K222658

Device Description:

Accurate Mini Non-Invasive blood pressure monitor device is a small, lightweight, handheld device intended to measure and display blood pressure trending (Systolic and Diastolic) and spot-check of pulse rate. Measurement is performed on the wrist at the radial artery. This blood pressure monitor uses the pulse wave transit time with the hemodynamic method to measure the systolic and diastolic blood pressure and pulse rate. This device serves to measure the systolic and diastolic blood pressure and pulse rate of adults in a non-invasive manner.

Indications for Use:
The device is a wrist-worn digital monitor intended for use in measuring blood pressure and pulse rate in adult patients (age 20-70) population with wrist circumference ranging from 13.5 cm to 21.5 cm and BMI<40.

The Accurate Mini Non-invasive BPM is intended for spot-checking of adult patients in hospitals, clinics, long-term care, and home use and is able to obtain results. The measurement results are stored in the device locally.

The Accurate Mini Non-invasive BPM measures blood pressure based on Pulse Wave Transit Time (PWTT) obtained Local Pulse Wave Velocity (PWV) from dual Piezo Sensors and radial artery parameters from NIRS Optic sensors.

Comparison to the Predicate Device

The intended use of Accurate Mini BPM has the same intended use as predicate device Accurate 24 BPM(K222658). The technological characteristics of Accurate Mini BPM are substantially the same as the technological characteristics of the predicate device Accurate 24 BPM(K222658). The subject device and predicate device are considered Non Invasive Blood Pressure Monitors (NIBP) monitors; both the subject device and predicate device are based on obtaining pulse wave transit time for blood pressure and pulse rate calculation.

At a high level, The subject and predicate devices are based on the following technological elements:

Device	New Device Accurate Mini BPM	Predicate Device Accurate 24 BPM	Comparison
K number	Not Yet Assigned	K222658	N/A
Indication for use	The device is a wrist-worn digital monitor intended for use in measuring blood pressure and pulse rate in adult patients of ages 20 -70 with wrist circumference from 13.5 cm to 21.5 cm and BMI<40. The Accurate Mini Non-invasive BPM is intended for spot-checking of adult patients in hospitals, clinics, long-term care, and home use. The measurement results are stored locally in the device. The Accurate Mini Non-invasive BPM measures blood pressure based on Pulse Wave Transit Time (PWTT) obtained Local	The device is a wrist-worn digital monitor intended for use in measuring blood pressure and pulse rate in adult patient (age 20-70) population with wrist circumference ranging from 13.5 cm to 21.5 cm and BMI<40. The Accurate 24 Non-invasive BPM is intended for spot-checking of adult patients in hospitals, clinics, long-term care, and home use and able to obtain results. The measurement results store in the device locally. The Accurate 24 Non-invasive BPM measures blood pressure based on Pulse Wave Transit Time	Identical

	Pulse Wave Velocity (PWV) from dual Piezo Sensors and radial artery parameters from Near InfraRed Spectroscopy (NIRS) Optic sensor.	(PWTT) obtained Local Pulse Wave Velocity (PWV) from dual Piezo Sensors and radial artery parameters from NIRS Optic sensors.	
Regulatory compliance	ISO 81060-2 Third edition 2018-11 / Amendment 1 (2020) IEEE Std 1708-2014 / IEEE Std 1708a-2019	ISO 81060-2 Third edition 2018-11 / Amendment 1 (2020) IEEE Std 1708-2014 / IEEE Std 1708a-2019	Identical
Non-Clinical Tests Submitted	IEC 60601-1 IEC 60601-1-2 IEC 60601-1-11 IEC 80601-2-30 ISO 10993-5 ISO 10993-10 ISO 10993-23 IEC 62366-1	IEC 60601-1 IEC 60601-1-2 IEC 60601-1-11 IEC 80601-2-30 ISO 10993-5 ISO 10993-10 ISO 10993-23 IEC 62366-1	Identical
Product Codes	DXN	DXN	Identical
Regulation No.	21 CFR 870.1130	21 CFR 870.1130	Identical
Classification	Class II	Class II	Identical
Classification Name	Non-invasive Blood Pressure Measurement System	Non-invasive Blood Pressure Measurement System	Identical
Use Population	Adults (age 20-70)	Adults (age 20-70)	Identical
User Environment	Hospitals, clinics, long-term care, and home use	Hospitals, clinics, long-term care, and home use	Identical
Monitoring	Spot-checking	Spot-checking	Identical
2 Piezo Sensors	Sensors for detecting tissue movements (Colleting radial artery vibrations data for PWV)	Sensors for detecting tissue movements (Colleting radial artery vibrations data for PWV)	Identical
Optical Sensor 1	NIRS Sensor for acquiring arterial changes	NIRS Sensor for acquiring arterial changes	Identical
Positioning Sensor	G Sensor (Position Sensor)	G Sensor (Position Sensor)	Identical
Optical Sensor: NIRS Sensor for aligning the radial artery	NIRS Sensor for aligning the radial artery	NIRS Sensor for aligning the radial artery	Different/ The Optic sensors are technically the same but have been reduced from 2 to 1. This change does not change the performance as can be seen in the clinical reports and as such does not raise new issues of safety or effectiveness.
Pressure Sensors: Sensing tightness of the wrist	Not Applicable	Sensing tightness of the wrist	Different/ It was determined that pressure sensors were not required. This change does not change the performance as can be

			seen in the clinical reports and as such does not raise new issues of safety or effectiveness.
Principle of Operation	Accurate Mini BPM estimates blood pressure based on the Moens-Korteweg equation. The dual piezo sensors obtain the pulse wave transit time by positioned in a fixed length on radial artery for PWV and pulse rate. By utilizing arterial changes captured by the first NIRS optic, hemodynamic process is able to conclude the pulse pressure for SBP and DBP.	Accurate 24 BPM estimates blood pressure based on the Moens-Korteweg equation. The dual piezo sensors obtain the pulse wave transit time by positioned in a fixed length on radial artery for PWV and pulse rate. By utilizing arterial changes captured by the first NIRS optic, hemodynamic process is able to conclude the pulse pressure for SBP and DBP.	Identical
Internal Power supply	Rechargeable lithium-polymer battery	Rechargeable lithium-polymer battery	Identical
Measurement Site	Wrist area and skin	Wrist area and skin	Identical
Measurement type	Spot	Spot	Identical
Measurement Range, Pulse rate	40 to 250 bpm	40 to 250 bpm	Identical
Pulse rate	±3%(Arms)	±5%	Identical
Measurement Range, BP	0 mmHg – 299 mmHg	0 mmHg – 299 mmHg	Identical
Accuracy blood Pressure	±5 mmHg	±5 mmHg	Identical
Contact material	Wrist Skin Cushion: Medical Silicone Wrist Holder: Nylon & Spandex, Polyurethane Plastic Parts: ABS	Wrist Skin Cushion: Medical Silicone Wrist Holder: Nylon and Fabric Plastic Parts: ABS	This change does not change the performance as can be seen in the clinical and biocompatibility reports and as such does not raise new issues of safety or effectiveness.
Data Display	TFT LCD on device.	PMOLED on device.	Component changed but function remains the same.
Screen	240(RGB)*240 Pixel	65K Full Color	Component changed but function remains the same.
Data Storage	Yes, Storage in the NAND flash.	Yes, Storage in the NAND flash.	Identical
Physical Dimension	38mm x 68.8mm x 14.4mm (not including the Wrist holder)	70mm x 60mm x 14mm (not including the Wrist holder)	Physical dimension changed but does not affect the performance as can be seen in the clinical reports and as

			such does not raise new issues of safety or effectiveness.
PCB Dimension	54mm x 32mm	70mm x 53mm	Component changed but function remains the same.

Performance Data

Performance Data - Bench Tests

The performance evaluation of the proposed Accurate Mini BPM included testing conducted following the FDA Guidance Documents and international standards:

- 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 Device Software Functions." The software for this device falls under Basic Documentation, as its failure or latent flaw is unlikely to result in serious injury or death to the patient or operator.
- Electrical safety and EMC testing were conducted on the Accurate Mini BPM device. The system complies with the IEC 60601-1、IEC 60601-1-11 and IEC80601-2-30 standards for safety and the IEC 60601-1-2 standard for EMC.
- Cytotoxicity, sensitization, irritation, and systemic toxicity of Accurate Mini BPM passed ISO 10993 requirements.

Performance Data - Clinical Tests

Our clinical study is evaluated according to ISO 81060-2:2018 and IEEE 1708:2014 [Including: Amendment 1(2019). In total, 367 subjects were included in the clinical validation study. The subjects were included according to the subject selection criteria outlined in ISO 81060-2:2018 and IEEE 1708-2014 [Including: Amendment 1(2019)]. At least 85 subjects were included for the following confounding factors: (1) Fitzpatrick Scale Type 5 and 6, (2) Subjects Ages 51-70 years, (3) Body Mass Index Grade I & II. All confounding factor groups were assessed independently.

The analysis results meet the accuracy requirements outlined in ISO 81060-2:2018. The obtained clinical results are as follows.

Characteristic	**Actual subjects**
Subject, n	367

Overall results for all study subjects

	Pass Requirements	**Achieved**	
		SBP	***DBP***
Means (*mmHg*)	±5	-0.24	0.35
SD (*mmHg*)	≤8	4.85	4.75
Results		**pass**	**pass**
Criterion 2			

SD (*mmHg*)	≤6.95/6.95	2.33	2.16
Results		**pass**	**pass**

The Mean Absolute Percentage Error (MAPE) calculated that there is a 1.164% difference between Accurate Mini BPM and the reference device, which is less than 5% and meets the accuracy of the specification.

Characteristic	**Actual subjects**
Subject, n	40

Overall results for all study subjects

	Pass Requirements	**Achieved**
		Pulse Rate
MAPE	<5%	1.164%
Results		**PASS**

General study participants (The subject requirements for ISO 81060-2:2018) of accuracy study:

This was a study of 98 subjects. Participants' age ranged from 20 – 70 and 63 were male and 35 were female. The study was conducted in accordance with ISO 81060-2:2018 standard. The Accurate Mini BPM accuracy was compared to "Welch Allyn DuraShock DS66 Trigger Aneroid Sphygmomanometer ".

Primary endpoint
The results of the Subject Device compared to the Welch Allyn DuraShock DS66 Trigger Aneroid Sphygmomanometer measurement in the accuracy validation data set were as follows: (1) mean bias of systolic BP: -0.89 ± 4.39 and (2) mean bias of diastolic BP: 1.19 ± 4.18 mmHg.

Those results are within the acceptance criteria for the accuracy of blood pressure monitors. The study demonstrated that the Subject Device is accurate, and the study population and results comply with the ISO standard requirements.

Confounding factors of the study participants accuracy study:

This were three groups (Group-01: Fitzpatrick Skin Type 5 & Type 6), Group-02:Age 51-70 years and Group-03:BMI Grade I & II) are independently recruited participants study of 286 subjects. The Accurate Mini BPM accuracy was compared to Welch Allyn DuraShock DS66 Trigger Aneroid Sphygmomanometer.

Primary endpoint

- The results of the Subject Device compared to the Welch Allyn DuraShock DS66 Trigger Aneroid Sphygmomanometer in the Fitzpatrick Scale (Type 5 & Type 6) population validation data set were as follows: (1) mean bias for systolic BP: -0.57 ± 4.14 mmHg (2) mean bias of diastolic BP: -0.05 ± 3.89 mmHg

- The results of the Subject Device compared to the Welch Allyn DuraShock DS66 Trigger Aneroid Sphygmomanometer in the Age (51-70 years) population validation data set were as follows: (1) mean bias for systolic BP: 1.26 ± 4.56 mmHg and (2) mean bias of diastolic BP: 0.21 ± 5.83 mmHg.

- The results of the Subject Device compared to the Welch Allyn DuraShock DS66 Trigger Aneroid Sphygmomanometer in the BMI (Grade I & II) population validation data set were as follows: (1) mean bias for systolic BP: -0.77 ± 5.03 mmHg and (2) mean bias of diastolic BP: -0.13 ± 4.80 mmHg.

These results are within the acceptance criteria for the accuracy of blood pressure monitors. The study demonstrated that the Subject Device is accurate, and the study population and results comply with the ISO standard requirements.

Conclusion

The Accurate Mini BPM is as safe and effective as the predicate device. The Accurate Mini BPM has the same intended uses and indications, technological characteristics, and principles of operation. In addition, the minor technical differences between the Accurate Mini BPM and its predicate device raise no new issues of safety or effectiveness. Performance data demonstrate that the Accurate Mini BPM is as safe and effective as the predicate. Thus, the Accurate Mini BPM is substantially equivalent.