August 7, 2023

Accurate Meditech Inc.
% Douglas Herrington
Official Correspondent
Herrington Consulting LLC
No 64, Haijing 3rd St
Sanzhi District
New Taipei City, 252
Taiwan

Re: K222658
Trade/Device Name: Accurate 24 Non-invasive blood pressure monitor
Regulation Number: 21 CFR 870.1130
Regulation Name: Noninvasive blood pressure measurement system
Regulatory Class: Class II
Product Code: DXN

Dear Douglas Herrington:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change related to your previous substantial equivalence (SE) determination letter dated June 21, 2023. Specifically, FDA is updating this SE Letter to correct the official contact name as an administrative correction.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact Stephen Browning OHT2: Office of Cardiovascular Devices, 240-402-5241, Stephen.Browning@fda.hhs.gov.

Sincerely,

Stephen C. Browning -S

Stephen Browning
Assistant Director
DHT2A: Division of Cardiac
Electrophysiology, Diagnostics
and Monitoring Devices
OHT2: Office of Cardiovascular Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

June 21, 2023

Accurate Meditech Inc.
Wang Kuan-Jen
General Manager
8F-10, No. 12, Lane 609, Sec. 5, Chongxin Rd.,
Sanchong Dist.,
New Taipei City, 241406
Taiwan

Re: K222658
Trade/Device Name: Accurate 24 Non-invasive blood pressure monitor
Regulation Number: 21 CFR 870.1130
Regulation Name: Noninvasive Blood Pressure Measurement System
Regulatory Class: Class II
Product Code: DXN
Dated: May 15, 2023
Received: May 15, 2023

Dear Wang Kuan-Jen:

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,

Robert T. Kazmierski -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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K222658

Device Name
Accurate 24 Non-invasive blood pressure monitor

Indications for Use *(Describe)*
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 (PWTT) obtained Local Pulse Wave Velocity (PWV) from dual Piezo Sensors and radial artery parameters from NIRS Optic sensors.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
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PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

5. 510(k) Summary

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

5.1 Submitter

Accurate Meditech Inc.
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Sanchong Dist., New Taipei City 241406, Taiwan

Phone: +886 2 2999 1596
Fax: +886 2 2999 1196
Contact Person: Kuan-Jen, Wang

Date Prepared: 2023/6/17

5.2 Subject Device Information

Trade/Device Name	Accurate 24 Non-invasive blood pressure monitor
Model	Accurate 24 BPM
Common Name	Non-invasive blood pressure monitor
Regulatory	Class II
Classification	870.1130 Noninvasive blood pressure measurement system
Submission type	Traditional 510(k)
Product Code	DXN

5.3 Predicate Device Information

Predicate Device	Sponsor: Biobeat Technologies Ltd.
	Device: BB-613 WP
	510(K) Number: K190792

5.4 Device Description:

Accurate 24 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 of 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.

5.5 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 24 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 store in the device locally.

The Accurate 24 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.

5.6 Comparison to the Predicate Device

The intended use of Accurate 24 BPM has the same intended use as predicate device BB-613 WP(K190792). The technological characteristics of Accurate 24 BPM are substantially similar to the technological characteristics of the predicate device BB-613 WP(K190792). The subject device and predicate device are considered 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 same technological elements:

Functionality	New Device Accurate 24 BPM	Predicate Device BB-613WP
Indications for use	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 (PWTT) obtained Local Pulse Wave Velocity (PWV) from dual Piezo Sensors and radial artery parameters from NIRS Optic sensors.	The BB-613 WP is a wrist-worn or skin attached device indicated for use in measuring and displaying functional oxygen saturation of arterial hemoglobin (%SpO2) and pulse rate. The BB-613WP can also track changes in blood pressure based on Pulse Wave Transit Time (PWTT) which is obtained utilizing pulse measurements from the integrated SpO2 sensor, following a calibration process using oscillometric blood pressure monitor. The BB-613WP is intended for spot-checking of adult patients in hospitals, clinics, long-term care, and home use.
Product Codes	DXN	DXN, DQA, DRG
Regulation No.	21 CFR 870.1130	21 CFR 870.1130
Classification	Class II	Class II
Classification Name	Noninvasive Blood Pressure	Noninvasive Blood Pressure

	Measurement System	Measurement System
Use Population	Adults (age 20-70)	Adults
User Environment	Hospitals, clinics, long-term care, and home use	Hospitals, clinics, long-term care, and home use
Monitoring	Spot-checking	Spot-checking
Principle of Operation	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.	Pulse reflectance technology, Four LED (red + IR) and photo diode absorbs reflected light. Tracking changes of blood pressure is done by pulse wave transit time which is obtained utilizing pulse measurements from the integrated skin attached SpO2 sensor
Internal Power supply	Rechargeable lithium-polymer battery	Rechargeable lithium-polymer battery
Measurement Site	Wrist area and skin	Wrist area and skin
Measurement type	Spot	Spot
Measurement Range, Pulse rate	40 to 250 bpm	40 to 250 bpm
Pulse rate	±5%	±3%(Arms)
Measurement Range, BP	0 mmHg – 299 mmHg	0 mmHg – 299 mmHg
Accuracy blood Pressure	±5 mmHg	±5 mmHg
Contact material	Wrist Skin Cushion: Medical Silicone Wrist Holder: Nylon and Fabric Plastic Parts: ABS	Polycarbonate, photodiode window, silicone, adhesive patch
Data Display	PMOLED on device.	LCD on device or handheld display unit (e.g., mobile phone)
Screen	65K Full Color	Black and White
Data Storage	Yes, Storage in the NAND flash.	No, but can transmit the data to handheld device

5.7 Performance Data

Performance Data - Bench Tests

The performance evaluation of the proposed Accurate 24 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 Software Contained in Medical Devices." The software for this device was considered a "major" concern since a failure or latent flaw in the software could directly result in serious injury or death to the patient or operator.
- Electrical safety and EMC testing were conducted on the Accurate 24 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 Accurate24 BPM passed ISO 10993 standard.

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

Characteristic		**Actual subjects**	
Subject, n		376	
overall results for all study subjects			
	Pass requirements	**Achieved**	
		SBP	***DBP***
Means (*mmHg*)	± 5	1.67	1.01
SD (*mmHg*)	≤ 8	4.04	5.32
Results		**pass**	**Pass**
Criterion 2			
SD (*mmHg*)	≤ 6.76/6.87	2.73	3.55
Results		**pass**	**pass**

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

This was a study of 114 subjects. Participants' age ranged from 20 – 70 and 73 were male and 41 were female. The study was conducted in accordance with ISO 81060-2:2018 standard. The Accurate 24 BPM accuracy was compared to "Welch Allyn DuraShock DS66 Trigger Aneroid".

Primary endpoint
The results of the Subject Device compared to the Welch Allyn DuraShock DS66 Trigger Aneroid measurement in the accuracy validation data set were as follows: (1) mean bias of systolic BP: 2.00±2.97 and (2) mean diastolic bias: 1.33 ±4.17 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 24 BPM accuracy was compared to Welch Allyn DuraShock DS66 Trigger Aneroid.

Primary endpoint

- The results of the Subject Device compared to the Welch Allyn DuraShock DS66 Trigger Aneroid in the Fitzpatrick Scale (Type 5 & Type 6) population validation data set were as follows: (1) mean bias for systolic BP: 1.81 ± 4.44 mmHg (2) mean bias of diastolic BP: -0.90 ± 5.13 mmHg (3) PR accuracy: 0.175 beats/min.

- The results of the Subject Device compared to the Welch Allyn DuraShock DS66 Trigger Aneroid in the Age (51-70 years) population validation data set were as follows: (1) mean bias for systolic BP: 1.53 ± 4.04 mmHg and (2) mean bias of diastolic BP: 2.13 ± 6.50 mmHg.

- The results of the Subject Device compared to the Welch Allyn DuraShock DS66 Trigger Aneroid in the BMI (Grade I & II) population validation data set were as follows: (1) mean bias for systolic BP: 1.11 ± 4.55 mmHg and (2) mean bias of diastolic BP: 1.36 ± 4.87 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.

5.9 Conclusion

The Accurate 24 BPM is as safe and effective as the predicate devices. The Accurate 24 BPM has the same intended uses and similar indications, technological characteristics, and principles of operation. In addition, the minor technical differences between the Accurate 24 BPM and its predicate devices raise no new issues of safety or effectiveness. Performance data demonstrate that the Accurate 24 BPM is as safe and as effective as the predicate. Thus, the Accurate 24 BPM is substantially equivalent.