June 25, 2020

Shenzhen Viatom Technology Co., Ltd.
c/o Lucy Yan, Consultant
4205-4210#, Shenzhen international Chamber of Commerce Tower
168#, Fuhua 3 Road, Futian District
Shenzhen, 518048
CHINA

Re: K193348
Trade/Device Name: Blood Pressure Monitor
Regulation Number: 21 CFR 870.1130
Regulation Name: Noninvasive Blood Pressure Measurement System
Regulatory Class: Class II
Product Code: DXN, DPS
Dated: April 24, 2020
Received: May 26, 2020

Dear Lucy Yan:

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,

LT 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K193348

Device Name
Blood Pressure Monitor

Indications for Use *(Describe)*
The Blood Pressure Monitor is indented to measure blood pressure or electrocardiogram (ECG) in home or healthcare facilities environment. The device is a blood pressure monitor intended for use in measuring blood pressure and pulse rate in adult population. The device is intended to measure, display, store and review adults' single-channel ECG rhythms and gives some suggested symptoms such as regular beat, irregular beat, low HR and high HR. The ECG part of the device is for Rx only, and the blood pressure part is for OTC.

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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510(k) Summary

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

1 Administrative Information

Submission Date	Nov. 25, 2019
Manufacturer information	Submitter's Name: Shenzhen Viatom Technology Co., Ltd. Address: 4E, Building 3, Tingwei Industrial Park, No.6 Liufang Road, Block 67, Xin'an Street, Baoan District, Shenzhen, 518101, Guangdong, China Contact person: Zhou Saixin TEL: +86-0755-86638929 FAX: +86-0755-22649904 E-Mail: zhousaixin@viatomtech.com
Submission Correspondent	Contact person: Miss Lucy.Yan E-Mail: lucyyan75@163.com 4205-4210#，Shenzhen International Chamber of Commerce Tower, 163# Fuhua 3 Road, Futian District, Shenzhen, Guangdong, P.R.China.
Establishment registration number	NA

2 Device Information

Common name of the device	System, Measurement, Blood-Pressure, Non-Invasive
Trade name of the device	Blood Pressure Monitor
Type/Model of the device	BP2, BP2A
Classification information	Classification panel: Cardiovascular Classification name: System, Measurement, Blood-Pressure, Non-Invasive Electrocardiograph Regulation Number: 870.1130, 870.2340 Device Class: II Product Code: DXN, DPS
Type of 510(k) submission	Traditional

3 Predicate Device Information

Sponsor:	Omron Healthcare, Inc.
Device:	Omron Model BP7900 Blood Pressure Monitor + EKG
510(K) Number:	K182579

4 Device Descriptions

Viatom Blood Pressure Monitor are designed to measure the systolic and diastolic blood pressure, pulse rate and ECG of an individual intended for home use.
By using a non-invasive technique in which an inflatable cuff is wrapped around the upper arm, the device inflates the arm cuff with an integral pump, then deflates the cuff via an electric valve. During inflation, the arm cuff pressure is monitored, and pulse waveform data is extracted. The extracted pulse waveform data is then analyzed by software which determines pulse rate, as well as systolic and diastolic blood pressure, which is a well-known technique in the market called the "oscillometric method".
In addition to the BP measurement, the device also incorporates electrodes capable of gathering ECG data from the user. This can be done as a separate function. To initiate the ECG, the user places one or more fingers in contact with the electrodes on the right and left side of the device. The electrodes measure a single-lead ECG between left and right fingers. The single-lead ECG data is displayed on the LCD.

The main components of the Blood Pressure Monitor are the main unit, cuff unit and ECG unit (only for BP2). The preformed cuff unit, which is applicable to arm circumference approximately between 220 and 420 mm, includes the inflatable bladder and Nylon and polyester shell. All models of the arm blood pressure monitor use a single size of cuff. The device consists of the microprocessor, the pressure sensor, the power on/off key, the pump, exhaust valve, bluetooth transmission, cuff and ECG circuit including the electrodes. The subject devices are powered by Li-ion Polymer Battery.
The device has Irregular beat: If the change speed of heart rate exceeds a certain threshold during measurement, is judged as irregular heartbeat.
The subject device includes bluetooth transmission which can transfer data to other device through the bluetooth connection such as smart phone.

5 Intended Use/ Indications for Use

The subject device is indented to measure blood pressure or electrocardiogram (ECG) in home or healthcare facilities environment.
The device is a blood pressure monitor intended for use in measuring blood pressure and pulse rate in adult population.
The device is intended to measure, display, store and review adults' single-channel ECG rhythms and gives some suggested symptoms such as regular beat, irregular beat, low HR and high HR.
The ECG part of the device is for Rx only, and the blood pressure part is for OTC.

6 SE Comparisons

Table 1. Substantial Equivalence Comparison

Characteristics	Subject device	Predicate device (K182579)	Remark
Device Name	Blood Pressure Monitor	Omron Model BP7900 Blood Pressure Monitor + EKG	NA
Device Model	BP2, BP2A	BP7900	NA
Manufacturer	Shenzhen Viatom Technology Co., Ltd.	Omron Healthcare, Inc.	NA

Intended Use/ Indication for Use	The subject device is indented to measure blood pressure or electrocardiogram (ECG) in home or healthcare facilities environment. The device is a blood pressure monitor intended for use in measuring blood pressure and pulse rate in adult population. The device is intended to measure, display, store and review adults' single-channel ECG rhythms and gives some suggested symptoms such as regular beat, irregular beat, low HR and high HR. The ECG part of the device is for Rx only, and the blood pressure part is for OTC.	The device is indented to measure blood pressure only, electrocardiogram (ECG) only or blood pressure and ECG simultaneously. The device is a digital monitor intended for use in measuring blood pressure and pulse rate in adult population. The device is intended to record, store, and transfer single-channel electrocardiogram (ECG) rhythms. The device also displays ECG rhythms and detects the presence of atrial fibrillation, bradycardia, tachycardia and normal sinus rhythm (when prescribed or used under the care of a physician). the device is intended for use by healthcare professionals, patients with known or suspected heart conditions, and health-conscious, and health-conscious individuals. The device has not been tested and it is not intended for pediatric use.	Similar Note01
Intended Population	Adult	Adult	Same
Intended Anatomical site	BP measurement: Upper arm ECG Recording: Right hand to left hand (Lead I), right hand to left abdomen (Lead II)	BP measurement: Upper arm ECG Recording: Right hand to left hand (Lead I)	Different Note02
Contraindications/Warnings/ Precautions	This device is contraindicated for use in ambulatory environments. This device is contraindicated for use on aircraft.	Added contraindications (n=2) against use in ambulatory environments and aircraft.	SE
Environment of Use	Home Use Healthcare facilities	Home Use	Different Note03
Single Use	No.	No.	Same
Sterility	Non sterile	Non sterile	Same
Label Information	Labeled for both OTC (Home Use) and Rx (Prescription Use)	Labeled for both OTC (Home Use) and Rx (Prescription Use)	Same

Working Principle	Blood Pressure measurement: Oscillometric method ECG recording: The device collects the ECG data through the potential difference of the body surface based on the ECG electrode, and obtains ECG data after being amplified and filtered, then displays through the screen.	Blood Pressure measurement: Oscillometric method ECG recording: User completes circuit with skin contact and hardware transmits audio signal to MCP to convert and display ECG.	Similar Note04
Pressure Sensor	Semiconductor pressure sensor	Semiconductor pressure sensor	Same
Internal Power supply	Rechargeable lithium-polymer battery	4*AA alkaline Batteries	Different Note05
Cuff Size	22-42cm	17-22cm 22-42cm	Different Note 06
Measuring range	Pressure: 0 to 300mmHg	Pressure: 0mmHg~300mmHg	Different Note 07
	Pulse: 40 to 200 beat/minute	Pulse: 40-199 beats/minute	
	Heart rate: 30 to 250 /min	Heart rate: 30 to 300 beats/minute	
Accuracy	Pressure: ±3mmHg Pulse: 2 bpm HR: ±2 bpm or 2%, whichever is greater;	Pressure: Within ±3mmHg or 2% of reading; Pulse: Within 5% of HR reading	Different Note 08
Irregular Heart beat	Irregular beat, High HR, Low HR were displayed in the LCD.	Possible Atrial Fibrillation (or AFib), Tachycardia, Tachycardia, Unreadable or Unclassified were analyse by APP.	Different Note 09
Operating Environment	5℃~45℃ 10% to 95% RH	10℃~40℃ 15% to 90% RH	Different Note 10
Storage Environment	-25℃~60℃ 10% to 95% RH	-20℃~60℃ 10% to 95% RH	
Bluetooth transmission	The device has wireless Bluetooth LE transmission.	BP measurement: Bluetooth ECG recording: Ultrasonic Acoustics acquired by phone	Different Note 11
Body Movement Detection	No.	Yes, for BP measurement	Different Note 12
Data Acquisition for ECG recording:	The device displays ECG rhythms and detects the presence of regular beat and irregular beat (Irregular beat, High HR, Low HR).	The device displays ECG rhythms and detects the presence of atrial fibrillation, bradycardia, tachycardia and normal sinus rhythm.	Different Note09
Frequency Response	0.67 to 40 Hz	0.67 - 40Hz	Same
ECG channels	Single Channel	Single Channel	Same
CMRR	>60 dB	>60 dB	Same
Input Impedance	≥10MΩ, 10Hz	≥10MΩ, 10Hz	Same
Memory	BP measurement:	BP measurement:	Different

Capacity	100 BP readings can be stored in the internal memory. ECG recording: 10 records 30s ECG data	90 BP readings can be stored in the internal memory. ECG recording: Essentially unlimited due to real-time transmission to MCP memory (size of ECG file is miniscule – kilobytes compared to device memory capacity – gigabytes)	Note13
Display	BP measurement: LCD (Liquid Crystal Display) displays; systolic blood pressure diastolic blood pressure pulse rate ECG recording: ECG rhythm Heart Rate Regular beat Irregular beat High HR Low HR	BP measurement: LCD (Liquid Crystal Display) displays; current cuff pressure systolic blood pressure diastolic blood pressure pulse rate error messages ECG recording: APP display ECG rhythm ECG detectors (Normal / Possible Atrial Fibrillation / Bradycardia / Tachycardia Unclassified / Unreadable) Past ECG recording in the memory Some other user convenient information	Different Note14
Materials	Patient contact materials of the cuff have been tested in accordance with ISO 10993 tested in accordance with accordance with ISO 10993 and FDA guidance	Patient contact materials of the cuff have been tested in accordance with ISO 10993 tested in accordance with accordance with ISO 10993 and FDA guidance	Same

Note01: The subject devices have the smaller clinic use range than predicate device. The predicate device is indented to measure blood pressure only, electrocardiogram (ECG) only or blood pressure and ECG simultaneously. But the subject devices can not be indented to measure blood pressure and ECG simultaneously. Moreover, the subject device can detect regular beat, irregular beat High HR and Low HR but can not identify the presence of atrial fibrillation, bradycardia, tachycardia and normal sinus rhythm as the predicate device. The subject device may produce very less risk of fault diagnosis. The subject devices have been passed the test of bench test, ISO 81060-2, IEC 80601-2-30 and IEC 60601-2-47.

Note02: The Intended Anatomical site of the subject device is different from the predicated device on the ECG measurement. The subject device can measure ECG by Lead I and Lead II, but the predicated device only used Lead I. The subject devices have been passed the test of IEC 60601-2-47. Moreover, All the performance of ECG function (Lead I and Lead II) were validated and the results is Pass.

Note03: The Environment of Use of the subject device is different from the predicated device on the ECG measurement. The subject device can be used not only in home but also in healthcare facilities. The accuracy is validated and passed. The high-frequency-use performance of the product life and cleaning /disinfection is evaluated and passed, the device can meet the requirements of healthcare facilities.

Note04: The ECG display principle of the subject device is different from the predicate device. The subject device is integrated of the ECG circuit and display the ECG rhythm on the LCD. But the predicate device transmits audio signal to MCP then display in the smartphone. The subject device may reduce the risk of data transmission error attacked by auto noise interfere. It passed the test of IEC 60601-2-47.

Note05: The power supply of the subject device is different from the predicate device. The subject device is powered by rechargeable lithium-polymer battery which can be charged. The rechargeable lithium-polymer battery has been verified by the IEC62133 standard. It passed the tests.

Note06: The subject devices have the smaller cuff circumference than predicate device, but the subject devices have been passed the test of ISO 81060-2 and IEC 80601-2-30.

Note07: The HR measuring range is different from the predicate device. The subject device is tested by bench test. The subject device has been verified by the required accuracy.

Note08: The pulse accuracy and the HR accuracy are different from the predicate device. The subject device is tested by bench test. The subject device has been verified by the required accuracy.

Note09: The subject device can detect regular beat, irregular beat High HR Low HR but can not identify the presence of atrial fibrillation, bradycardia, tachycardia and normal sinus rhythm as the predicate device which may produce very less risk of fault diagnosis. The subject devices have been passed the test of ISO 81060-2, IEC 80601-2-30 and IEC 60601-2-47. The ECG performance of the subject device is tested by bench test including the irregular beat High HR and Low HR and has been verified by the required accuracy.

Note10: The subject device has a wider measuring range of operating temperature and larger measuring range of storage temperature than predicate device, but the subject devices have been validated all the full claimed range according to the IEC 60601-1, IEC 80601-2-30, IEC 60601-2-47 and IEC 60601-1-11.

Note11: For data transmission, the subject device has bluetooth function but the predicated device uses auto signal to transmit ECG data. FCC test and wireless coexistence especially the cybersecurity evaluation about the wireless performance have been validated.

Note12: The subject device has no body movement detection function but the clinical function is accurate enough and passed the ISO 81060-2.

Note13: The memory capacity is different from the predicate device. The subject device has been verified the capacity in product software verification and validation. It passed the tests.

Note14: The display is different from the predicate device. The subject device has been verified the display in product software verification and validation. It passed the tests.

The subject device is as same as predicate device in basic function (blood pressure and ECG measurement), intended patient population, measuring pressure accuracy. Only the intended clinic use(refer to Note01), intended application site(refer to Note02), use environment (refer to Note03), the work principle (only on the data transmission refer to Note04), power supply(refer to Note05), the cuff size(refer to Note06), the HR measuring range (refer to Note07), the pulse accuracy (refer to Note08), Irregular Heartbeat(refer to Note09), operating/storage environment(refer to Note10), the wireless

transmission(refer to Note11), the body movement detection(refer to Note12), the ECG rhythm identification(refer to Note09), the memory capacity(refer to Note13) and the display contents(refer to Note14) are different which had been validated. However, the differences would not raise any safety or effectiveness issue based on tests in this submission.
Thus, the subject device is Substantially Equivalent (SE) to the predicate device which is legally marketed in US.

7 Brief discussions of the non-clinical tests

The subject device conforms to the following guidances and standards:

- ✧ Non-Invasive Blood Pressure (NIBP) Monitor Guidance
- ✧ ANSI AAMI ES60601-1:2005+A1:2012 Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance;
- ✧ IEC 60601-1-2:2014 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 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;
- ✧ ISO 10993-5: 2009 /(R)2014 Biological evaluation of medical devices – Part 5: Tests for In Vitro cytotoxicity;
- ✧ ISO 10993-10: 2010 Biological evaluation of medical devices – Part 10: Tests for irritation and skin sensitization;
- ✧ IEC 80601-2-30: 2018 Medical electrical equipment - Part 2-30: Particular requirements for the basic safety and essential performance of automated non-invasive sphygmomanometers
- ✧ IEC 80601-2-47: 2012 Medical electrical equipment – Part 2-47: Particular requirements for the basic safety and essential performance of ambulatory electrocardiographic systems
- ✧ 47 CFR FCC PART 15. Subpart C Unintentional Radiators/ Miscellaneous Wireless Commutations Service

8 Brief discussions of clinical tests

- ✧ ISO 81060-2:2018 Non-invasive sphygmomanometers - Part 2: Clinical validation of automated measurement type;

In the blood pressure clinical investigation, 85 patients (39 males and 46 females) participated in the clinical study. Same arm sequential method was adopted during the clinical testing. The manual Mercury Sphygmomanometer was used as a reference

device. All the subjects were volunteer to take part in the clinical study, all the subjects completed the clinical study without any AE or side-effect.

In the ECG clinical investigation, 35 patients (24 males and 11 females) participated in the clinical study. Comprising with the cleared device was adopted during the clinical testing. All the subjects were volunteer to take part in the clinical study, the participants completed the clinical study without any AE or side-effect.

The results showed the accuracy of the blood pressure monitor is within acceptable scope specified in ISO 81060-2 and ECG rhythm.

9 Other information (such as required by FDA guidance)

No other information.

10 Conclusions

The subject device:

Blood Pressure Monitor, manufactured by Shenzhen Viatom Technology Co., Ltd. is respectively substantially equivalent to the predicate device (Omron Model BP7900 Blood Pressure Monitor + EKG) manufactured by Omron Healthcare, Inc. (K182579).