August 19, 2019

Shenzhen Viatom Technology Co., Ltd.
℅ Lucy Yan
Consultant
Shenzhen Joyantech Consulting Co, Ltd.
1122#, International Mayor Communication Center, Baishizhong
Nanshan district, Shenzhen, 518000 Cn

Re: K190207
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
Dated: June 24, 2019
Received: July 15, 2019

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)*
K190207

Device Name
Blood Pressure Monitor

Indications for Use *(Describe)*
The subject device intended to measure the diastolic, systolic blood pressures and pulse rate for adult population in home and hospital facilities by using a non-invasive oscillometric technique with a single upper arm cuff (22-42 cm).
The device detects the appearance of irregular heart beats during measurement and gives a warning signal with readings.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
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."

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	Dec. 26, 2018
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: Lucy@cefda.com Shenzhen Joyantech Consulting Co., Ltd. 1122# ， International Mayor Communication Center, Baishizhong Road 55#, Nanshan District, Shenzhen, Guangdong, P.R.China. Contact person: Mr. Field.Fu E-Mail: field@cefda.com Shenzhen Joyantech Consulting Co., Ltd. 1122# ， International Mayor Communication Center, Baishizhong Road 55#, Nanshan 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	BP1, BP1A
Classification	Classification panel: Cardiovascular

information	Classification name: System, Measurement, Blood-Pressure, Non-Invasive Regulation Number: 870.1130 Device Class: II Product Code: DXN
Type of 510(k) submission	Traditional

3 Predicate Device Information

Sponsor:	Andon Health Co., Ltd.
Device:	KD-391 Semi Automatic Electronic Blood Pressure Monitor
510(K) Number:	K080326

4 Device Descriptions

Viatom Blood Pressure Monitor are designed to measure the systolic and diastolic blood pressure and pulse rate of an individual by using a non-invasive technique in which an inflatable cuff is wrapped around the upper arm. Our method to define systolic and diastolic pressure is similar to the auscultatory method but uses an electronic pressure sensor rather than a stethoscope and mercury manometer. The sensor converts tiny alterations in cuff pressure to electrical signals, by analyzing those signals to define the systolic and diastolic blood pressure and calculating pulse rate, which is a well-known technique in the market called the "oscillometric method".

The main components of the Blood Pressure Monitor are the main unit and cuff unit. The preformed cuff unit, which is applicable to arm circumference approximately between 220 and 420 mm, includes the inflatable bladder 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 rubber bulb, exhaust valve, bluetooth tranismision and cuff. The subject devices are powered by Li-ion Polymer Battery.

The device has irregulae heart beat (IHB) indicator which is defined as a rhythm that is 25% less or 25% more than the average rhythm detected while the monitor is measuring the systolic and diastolic blood pressure.

The subject device includes bluetooth tranismision which can tranfer data to APP installed in smart phone. The APP can display, store and review the measurement data including the systolic and diastolic blood pressure and pulse rate.

5 Intended Use/ Indications for Use

The subject device intended to measure the diastolic, systolic blood

pressures and pulse rate for adult population in home and hospital facilities by using a non-invasive oscillometric technique with a single upper arm cuff (22-42 cm). The device detects the appearance of irregular heart beats during measurement and gives a warning signal with readings.

6 SE Comparisons

Table 1. Substantial Equivalence Comparison

Characteristics	Subject device	Predicate device (K080326)	Remark
Device Name	Ultra-Portable Smart Blood Pressure Monitor	KD-391 Semi Automatic Electronic Blood Pressure Monitor	NA
Device Model	BP1, BP1A	KD-391	NA
Manufacturer	Shenzhen Viatom Technology Co., Ltd.	Andon Health Co., Ltd.	NA
Intended Use/ Indication for Use	The subject device intended to measure the diastolic, systolic blood pressures and pulse rate for adult population in home and hospital facilities by using a non-invasive oscillometric technique with a single upper arm cuff (22-42 cm). The device detects the appearance of irregular heart beats during measurement and gives a warning signal with readings.	KD-391 Semi Automatic Electronic Blood Pressure Monitor is for use by medical professionals or at home and is a non-invasive blood pressure measurement system intended to measure the diastolic and systolic blood pressures and pulse rate of an adult individual by using a non-invasive technique in which an inflatable cuff is wrapped around the upper arm. The cuff circumference is limited to 22cm-48cm.	Similar Note01
Intended Population	adult	adult	same
Intended Anatomical site	upper arm	upper arm	same
Prescription & OTC	OTC	OTC	same
Working Principle	Oscillometric method	Oscillometric method	same
Pump Mode	manual inflation and measurement	manual inflation and measurement	same
Internal Power supply	Rechargeable lithium-polymer battery	4*AA alkaline Batteries	Different Note02
Cuff Size	220mm~420mm	220mm~480mm	Refer to Note01

Measuring range	Pressure: 0 to 300 mmHg	Pressure: (0mmHg~300mmHg)	SE
	Pulse: 40 to 200 beat/minute	Pulse: (40-199) beats/minute	
Accuracy	Pressure: ±3mmHg; Pulse: ±2 bpm	Pressure: ±3mmHg; Pulse ±5%.	Different Note03
Irregular Heartbeat Detection	Yes	Yes	same
Operating Environment	5~40℃	10~40℃	Similar Note04
Storage Environment	-25~70℃	-20~50℃	
Bluetooth transmission	The device has wireless function with bluetooth LE.	No.	Different Note05

Note01: The subject devices have the smaller cuff circumference than predicate device, but the subject devices have been passed the test of ISO81060-2 and IEC 80601-2-30.
Note02: The power supply 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.
Note03: The pulse accuracy is different from the predicate device. The subject device is tested by bench test. The subject device has been verified by the required accuracy. It passed the tests.
Note04: The subject device has a smaller 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.
Note05: The subject device has bluetooth function but the predicated device has no wireless function. FCC test and wireless coexistence about the wireless performance have been validated.

The subject device is as same as predicate device in Working Principle, Intended patient population, intended application site, measuring accuracy. Only their Cuff size, power supply and operating/storage environment are a little bit different (refer to Note01 to Note03) which had been validated by FCC and wireless coexistence. The subject device has a bluetooth function (Note04) which had been validated.

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
- ✧ IEC 60601-1:2005+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: 2010 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: 2013 Medical electrical equipment - Part 2-30: Particular requirements for the basic safety and essential performance of automated non-invasive sphygmomanometers
- ✧ CFR 47 FCC PART 15. Subpart B/C Unintentional Radiators/ Miscellaneous Wireless Commutations Service

8 Brief discussions of clinical tests

- ✧ ISO 81060-2:2013 Non-invasive sphygmomanometers - Part 2: Clinical validation of automated measurement type;

In this clinical investigation, 85 patients (38 males and 47females) 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.

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

9 Other information (such as required by FDA guidance)

No other information.

11 Conclusions

The subject device:

Blood Pressure Monitor, manufactured by Shenzhen Viatom Technology Co., Ltd. is respectively substantially equivalent to the predicate device (KD-391 Semi Automatic Electronic Blood Pressure Monitor) manufactured by Andon Health Co., Ltd. (K080326).