December 17, 2018

Visiomed Technology Co., Ltd.
% Filed Fu
Consultant
Shenzhen Joyantech Consulting Co., Ltd
1122#, International Mayor Communication Center,
Baishizhong Road 55#
Nanshan District, Shenzhen, 518000 CN

Re: K172965
Trade/Device Name: Handheld Vital Signs Monitoring System, Model: BW-X07HD
Regulation Number: 21 CFR 870.2300
Regulation Name: Cardiac Monitor (Including Cardiotachometer and Rate Alarm)
Regulatory Class: Class II
Product Code: MWI, DRT, DXN, DQA, FLL
Dated: January 2, 2018
Received: January 19, 2018

Dear Filed Fu:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/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 -S5

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K172965

Device Name
Handheld VitalSigns Monitoring System, Model: BW-X07HD

Indications for Use *(Describe)*
The BW-X07HD Handheld VitalSigns Monitoring System is intended to be used in hospital, clinic, homecare, home and other medical settings where patient care is offered by qualified healthcare personnel who can use the device to monitor the patient's physical indexes, including ECG, SpO2, NIBP and TEMP as well as the pulse rate.
For measuring ECG, SpO2 the intended patient population is adult, for measuring NIBP the intended patient population is both adult and pediatric aged more than 3 years old, whereas for measuring TEMP the intended patient population is all types of people including newborn, pediatric and adult.
The device is used to collect, store, and transmit general patient health information and patient vital signs data between the patient and a health care professional.

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.

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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	2017-12-24
Manufacturer information	Submitter's Name: **Visiomed Technology Co.,Ltd** Address: **2 Floor of No.1 Building, Jia An Technological Industial Park, 67 Distric,** **Bao An, Shenzhen,** **Guangdong,** **China** Contact person: Chen XiaoFeng TEL: 0755-29481701-103 FAX: 0755-29481705 E-Mail: jay@visiomed-tech.com
Submission Correspondent	Contact person: Mr. Field.Fu E-Mail: cefda13485@163.com Shenzhen Joyantech Consulting Co., Ltd. 1122#，International Mayor Communication Center, Baishizhong Road 55#, Nanshan District, Shenzhen, Guangdong, China
Establishment registration number	3012429388

2. Device Information

Type of 510(k) submission:	Traditional
Trade Name:	Handheld VitalSigns Monitoring System
Model:	BW-X07HD
Classification name:	Monitor, Physiological, Patient(With Arrhythmia Detection Or Alarms)
Review Panel:	Cardiovascular
Product Code:	Product Code: MWI Subsequent Product Codes: DRT, DXN, DQA, FLL
Device Class:	2
Regulation Number:	870.2300

3. Predicate Device Information

Sponsor:	Sotera Wireless, Inc.
Device:	ViSi Mobile Monitoring System
510(K) Number:	K150361

4. Device Description

The BW-X07HD Handheld VitalSigns Monitoring System is a handheld, smart and wireless connected medical device. The device can be easily used by healthcare professional personnel, ordinary users or patients, to monitor multiple physiological indexes, including TEMP, ECG, NIBP and SpO2 as well as the pulse rate. Medical data can be stored locally and can be sent through WiFi, 3G or 4G network.

The device incorporates an embedded system and an Android application. The embedded system integrates the Temp module, the ECG, NIBP, SpO2 module and the wireless module together. The device allows users to communicate through an HD video conferencing system but cannot be used as phone (only IP connection, Micro SIM card for data transmission).

5. Intended Use/Indications for Use

The BW-X07HD Handheld VitalSigns Monitoring System is intended to be used in hospital, clinic, homecare, home and other medical settings where patient care is offered by qualified healthcare personnel who can use the device to monitor the patient's physical indexes, including ECG, SpO2, NIBP and TEMP as well as the pulse rate.

For measuring ECG, SPO2 the intended patient population is adult, for measuring SpO2 the intended patient population is adult, for measuring NIBP the intended patient population is both adult and pediatric aged more than 3 years old, whereas for measuring TEMP the intended patient population is all types of people including newborn, pediatric and adult.

The device is used to collect, store, and transmit general patient health information and patient vital signs data between the patient and a health care professional.

6. SE Comparison

Item	Subject Device BW-X07HD	Predicate Device K150361	Remark
Intended Use/Indication for Use	The BW-X07HD Handheld VitalSigns Monitoring System is intended to be used in hospital, clinic, homecare, home and other medical settings where patient care is offered by qualified healthcare personnel who can use the device to monitor the patient's physical indexes, including ECG, SpO2, NIBP and TEMP as well as the pulse rate. For measuring ECG, SpO2 the intended patient population is adult, for measuring SpO2 the intended patient population is adult, for measuring NIBP the intended patient population is both adult and pediatric aged more than 3 years old, whereas for measuring TEMP the intended patient population is all types of people including newborn, pediatric and adult. The device is used to collect, store, and transmit general patient health information and	The ViSi Mobile Monitoring System is intended for use by clinicians and medically qualified personnel for single or multi-parameter vital signs monitoring of adult patients (18 years or older). It is indicated for ECG (3 or 5 lead-wire), respiration rate (RESP), heart rate (HR), noninvasive blood pressure (NIBP), continuous noninvasive blood pressure (cNIBP), noninvasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO2), pulse rate (PR), and skin temperature (TEMP) in hospital-based facilities; including, general medical-surgical floors, intermediate care floors, and emergency departments. The ViSi Mobile Monitoring System may be used as standalone devices or networked to	Similar (Note 01)

Item	Subject Device BW-X07HD		Predicate Device K150361	Remark
	patient vital signs data between the patient and a health care professional.		ViSi Mobile Remote Viewers through wireless 802.11 communications.	
Product Code	MWI, DRT, DXN, FLL, DQA		MWI, DRT, DXN, FLL, DQA	Same
Patient population	The intended patient population for measuring Temp is all types of people including newborn, pediatric and adult, whereas, for measuring NIBP is both pediatric and adult, for measuring ECG is adult and SpO2 is adult.		Adults ≥ 18 years	Different (Note 02)
Usage Environment	home and hospital		Hospital-based facility including emergency departments, general medical-surgical and intermediate care floors.	Similar (Note 03)
Power Supply				
Internal supply	**Type**	Rechargeable Li-polymer battery	Rechargeable Li-polymer battery	Similar (Note 04)
	Capacity	3.7V/2500mAh	3.7 V/2000 mAh	
	Performance capacity	4 hours	> 12 hours	
AC-DC Power supply	**Line Voltage**	100Vac to 240Vac	100Vac to 240Vac	SE
	Current	less than 0.5A rms. at 90Vac input and maximum load	/	
	Frequency	50Hz or 60Hz	50Hz or 60Hz	
ECG Function				
Measuring Mode		5 Electrodes,7-Lead ECG	3-wire: II	SE
			5-wire: I, II, III, AVL, AVR, AVF, V	
DC offset Voltage Range		±300mV	±300mV	
Differential Voltage Measurement Range		±5mV	±5mV	
Resolution		1bpm	1bpm	Same
NIBP Function:				
Blood Pressure	**Principle of Operation**	oscillation		Same
	Measurement Range	Adult & Pediatric: 0-295mmHg (0-39.3kPa)	Systolic Range: 60 to 240 mmHg	Similar (Note 05)
			Diastolic Range: 40 to 160 mmHg	
	Accuracy	±3mmHg (±0.4kPa)	Mean error of less than ± 5 mmHg and a std. dev. of ≤ 8 mmHg	
	Pressure Resolution	1mmHg	1mmHg	
Pulse Rate	**Measuring Range**	40 bpm to 180 bpm	30 to 240 BPM	
	Accuracy	±3 bpm	±3 BPM	
	Resolution	1 bpm	1 BPM	
SpO2 Function				
Principle of Operation		Lambert Beer Law		Same
SpO2	**Measurement Range**	0~100%	49 to 100%	Similar (Note 06)

Item	Subject Device BW-X07HD		Predicate Device K150361	Remark
	Accuracy	Adult ±2 % (70% to 100% SpO2), Undefined (0 to 69% SpO2);	≤ 2% from 70-100% (no motion) Unspecified from 49-69%	
	Resolution	1%	1%	
Pulse Rate	**Measuring Range**	25 bpm to 250 bpm	30 to 240 BPM	
	Accuracy	±3 bpm	≤ 3 BPM	
	Resolution	1 bpm	1 BPM	
Temperature Function				
Principle of Operation	Infrared red			Same
Measurement Range	Body temperature: 32.0°C~43.0°C / 89°F ~109.4°F Room temperature： 0°C~50°C / 32°F~122°F Surface temperature： 0°C~90°C / 32°F~194°F		0□ ~ 19.9□(32□~ 67.9□) ±0.3□(±0.5□) 20□ ~ 24.9□(68□~ 76.9□) ±0.3□(±0.5□) 25□ ~ 35.9□(77□~ 96.7□) ±0.2□(±0.3□) 36□ ~ 39.9□(96.8□~ 103.9□) ±0.1□(±0.2□) 40□ ~41.9□(104□~ 107.5□) ±0.2□(±0.3□) 42□ ~ 50.0□(107.6□~ 122□) ±0.3□(±0.5□)	Similar (Note 07)
Accuracy (not including sensor)	+/- 0.2°C (35°C-42°C) / +/- 0.2°F (95°F-107.6°F) in body temperature +/-0.3°C (32°C-34.9°C, 42.1°C-43°C) / +/- 0.3°F (89.6°F-93.2°F, 107.6°F-109.4°F) in body temperature. +/- 0.2°C (22°C-40°C) / +/- 0.2°F (71,6°F-104°F); Others +/-2°C / +/-2°F in surface temperature.			
Resolution	0.1°C / 0.1°F		0.1°C / 0.1°F	
Average Time Constant	1~2s		< 6 min (25□~37□(77□~98.6□))	

Note 01:
In the Intended Use/Indication for Use, the measuring function range (measuring ECG, TEMP, SPO2, NIBP) of the Subject Device is smaller than the predicated device which is measuring ECG, RESP, TEMP, SPO2 and NIBP.
The use environment of the subject device is broader than the predicated device. The concern from environment difference lay on the user conditions such as operation temperature, humidity, water-proof and electromagnetic compatibility items, etc. But the subject device was tested according to IEC 60601-1-2, IEC 606061-1-11 and the other standards, and all the testing results are PASS.
The use population of the subject device is broader than the predicated device, but the clinical test of NIBP was provided including both adult participants and pediatric participants aged more than 3 years old and the clinical test of TEMP was provided including all types of people including newborn, pediatric and adult from the different use population.
The wireless data transmission is different from the predicate device. The subject device uses WIFI, 3G and Bluetooth. All the performances including wireless EMC, wireless coexistence and cybersecurity has evaluated.
All concerns from the differences were resolved. There were raise no safety and effective issues from the differences.

Note 02: The patient population of subject device is broader than the range of the Predicate Device. But the subject device has passed the clinical validation for the relative population. The clinical test of NIBP was provided including both adult participants and pediatric participants aged more than 3 years old and the clinical test of TEMP was provided including all types of people including newborn, pediatric and adult. The clinical tests are passed.

Note 03: As the Note 01, the usage environment of subject device is broader than the predicate device. The concern from environment difference lay on the user conditions such as operation temperature, humidity, water-proof and electromagnetic compatibility items, etc. The subject device was tested according to IEC 60601-1-2, IEC 606061-1-11 and the other standards, and all the testing results are PASS, the concerns mentioned previously were resolved.

Note 04: The specification of Li-polymer battery is a little different between subject device especailly for the capacity. But the subject device has complied with IEC62133 requirements.

Note 05: The NIBP parameter is a little different between subject device and predicate device. But the subject device has complied with the latest standard IEC 80601-2-30, ISO 81060-2 clinical test.

Note 06: The SpO2 parameter is a little different between subject device and predicate device. But the subject device has complied with the latest standard IEC 60601-2-61 and the clinical test according to the FDA guidance.

Note 07: The Temp parameter is a little different between subject device and predicate device. But the subject device has complied with the latest standard IEC 60601-2-56 and the clinical test.

7. Nonclinical Tests

The subject device conforms to the following standards:
✧IEC 60601-1:2005+A1:2012: Medical Electrical Equipment - Part 1: General Requirements For Basic Safety And Essential Performance
✧IEC 60601-1-2:2007 Medical Electrical Equipment - Part 1-2: General Requirements For Basic Safety And Essential Performance - Collateral Standard: Electromagnetic Compatibility - Requirements And Tests.
✧ISO 10993-5:2009 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 60601-2-49:2011 Medical electrical equipment - Part 2-49: Particular requirements for the basic safety and essential performance of multifunction patient monitoring equipment
✧IEC 60601-2-27:2011 Medical Electrical Equipment - Part 2-27: Particular Requirements For The Basic Safety And Essential Performance Of Electrocardiographic Monitoring Equipment
✧IEC 80601-2-30: 2013 Medical Electrical Equipment - Part 2-30: Particular Requirements For The Basic Safety And Essential Performance Of Automated Noninvasive Sphygmomanometers
✧ISO 81060-2:2013 Non-Invasive Sphygmomanometers - Part 2: Clinical Validation Of Automated Measurement Type
✧ISO 80601-2-61:2011 Medical Electrical Equipment - Part 2-61: Particular Requirements For Basic Safety And Essential Performance Of Pulse Oximeter Equipment
✧ISO 80601-2-56: 2009 Medical electrical equipment - Part 2-56: Particular requirements for basic safety and essential performance of clinical thermometers for body temperature measurement

8. Clinical Tests

In this submission, the clinical reports of NIBP, Oximeter and Thermometer were provided.
The clinical results of Oximeter Part of subject device meet the requirement as described in *ISO 80601-2-61:2011.* Besides, no AE or side-effect occurs during the clinical investigation.
The clinical results of NIBP part of subject device meet the requirement as described in *ISO 81060-2:2013.* Besides, no AE or side-effect occurs during the clinical investigation.
The clinical results of Thermometer Part of the subject device meet the requirement as described in *ISO 80601-2-56:2009*. Besides, no AE or side-effect occurs during the clinical investigation.

9. Other information (such as required by FDA guidance)

No other information.

10. Conclusions

The subject device: Handheld VitalSigns Monitoring System, BW-X07HD is substantially equivalent to the predicate device: ViSi Mobile Monitoring System manufactured by Sotera Wireless, Inc.