



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Center - WO66-G609  
Silver Spring, MD 20993-0002

December 16, 2015

Sky Innovation Technology (Shanghai) Limited  
% Charles Shen  
Official Correspondent  
Manton Business And Technology Services  
37 Winding Ridge  
Oakland, New Jersey 07436

Re: K150908

Trade/Device Name: XM-01 Electronic Automatic Blood Pressure Monitor  
Regulation Number: 21 CFR 870.1130  
Regulation Name: Noninvasive Blood Pressure Measurement System  
Regulatory Class: Class II  
Product Code: DXN  
Dated: October 28, 2015  
Received: October 30, 2015

Dear Charles Shen:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Bram D. Zuckerman", is written over a large, light gray watermark of the FDA logo.

for Bram D. Zuckerman, M.D.

Director

Division of Cardiovascular Devices

Office of Device Evaluation

Center for Devices and Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known)

K150908

Device Name

XM-01 Automatic Electronic Blood Pressure Monitor

Indications for Use (Describe)

XM-01 Automatic Electronic Blood Pressure Monitor is a home use digital monitor intended for use in measuring blood pressure and pulse rate in adult patient population with wrist circumference ranging from 13.5 cm to 19.5 cm.

The device is not intended to be a diagnostic device. Contact your physician if hypertensive values are indicated.

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.\***

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## Section 5: 510(k) Summary:

This summary of 510k safety and effectiveness information is being submitted  
In accordance with the requirements of 21CFR 807.92

### 5.1 Submitter & Foreign Manufacture Identification

Sky Innovation Technology (Shanghai) Limited  
9th Floor Hechuan Building, 2016 Yishan Rd, Minhang District, Shanghai Postal code:  
201103, China  
Tel: (086) 400-9999-523  
Submitter's FDA Registration Number: N/A

### 5.2 Contact Person

Charles Shen  
Manton Business and Technology Services  
37 Winding Rdg, Oakland, NJ 07436  
Tel: 608-217-9358  
Email: cyshen@aol.com

### 5.3 Date of Summary: April 1, 2015

### 5.4 Device Name:

<b>Proprietary Name:</b>	XM-01 Automatic Electronic Blood Pressure Monitor
<b>Common Name:</b>	Blood Pressure Monitor
<b>Classification Name:</b>	System, Measurement, Blood-Pressure, Non-invasive
<b>Device Classification:</b>	II
<b>Regulation Number:</b>	21 CFR 870.1130
<b>Panel: General</b>	Cardiovascular
<b>Product Code:</b>	DXN

### 5.5 Predicate Device Information:

- (1) K123669, "Transtek Wrist Blood Pressure Monitor", manufactured by  
"Zhongshan Transtek Electronics Co., Ltd."

### 5.6 Device Description:

XM-01 Automatic Electronic Blood Pressure Monitor is 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 wrist. This is a home use device.

Measurement 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 nmometer. With a sensor, the microprocessor converts tiny alterations in cuff pressure to electrical signals, and analyze those signals to define the systolic and diastolic blood pressure and calculating heartbeat rate, which is a well-known technique in the market called the "Oscillometric method". The sensor also detect pulse rate at the same time.

XM-01 Automatic Electronic Blood Pressure Monitor achieves its function **by** integrating a single-mounted device hardware to a mobile application software, which is downloadable to a mobile device such as Apple or Android phone. As the hardware itself does not include a **LCD** or other display components, it is necessary for the device hardware to communicate with mobile devices containing the supporting software to constitute a complete blood pressure measurement system. This communication is realized through an embedded Bluetooth module.

The single-mounted device hardware is composed of the main unit and cuff unit. The cuff unit, which is applicable to wrist circumference approximately between 13.5 *and* 19.5 cm, includes the inflatable bladder and nylon/cotton/PVC shell. The main unit consists of the microprocessor, pressure sensor, pump, the electromagnetic deflation control valve and the battery. The subject device is powered by a 3.7V/400mAH lithium battery. The battery can be re-charged by either a DC5V 500mA charger or a USB cable.

The mobile application, downloadable to mobile devices such as Apple IOS or Android phone, receives measurement results from the single mounted device. The mobile App allows the test results to be displayed on the mobile devices (such as cell phone) for user review. It also transmits the data to the database in remote server for storage and future retrieval.

### **5.7 Indications for Use:**

XM-01 Automatic Electronic Blood Pressure Monitor is a home use digital monitor intended for use in measuring blood pressure and pulse rate in adult patient population with wrist circumference ranging from 13.5 cm to 19.5 cm.

The device is not intended to be a diagnostic device. Contact your physician if hypertensive values are indicated.

### **5.8 Design Control and Performance Testing Summary:**

Design control activities for this modification were performed and bench tests have been done. Those performance tests, risk management, and design verification tests provide demonstration that the device does not raise any new questions of safety and effectiveness.

XM-01 Automatic Electronic Blood Pressure Monitor conforms to the following standards:

- **ISO 14971**, Risk management to medical device
- **ISO 81060-2**, Non-invasive sphygmomanometers -- Part 2: Clinical investigation of automated measurement type
- **ISO 80601-2-30**, Medical electrical equipment -- Part 2-30: Particular requirements for basic safety and essential performance of automated non-invasive sphygmomanometers
- **IEC60601-1**, Electrical safety;
- **IEC6060 1-1-2**, Electromagnetic compatibility
- **FCC Part 15**, EMI tests of FCC Radiation & RF rules and regulations
- **ISO 10993-1**, Biological evaluation of medical devices -- Part 1: Evaluation and testing within a risk management process

XM-01 Automatic Electronic Blood Pressure Monitor conforms to the following guidance document:

- FDA guidance document Non-Invasive Blood Pressure (NIBP) Monitor Guidance (March, 1997).

**5.9 Technological Comparison with Predicate Device**

The following table shows similarities and differences of use, mechanism, design, and labeling between our device and the predicate devices.

**Table 5.1: Comparison of Intended Use, Mechanism, Labeling, and Design**

Description	Subject Device	Predicate Device (K123669)	Comparison
Indication for Use	<p>XM-01 Automatic Electronic Blood Pressure Monitor is a home use digital monitor intended for use in measuring blood pressure and pulse rate in adult patient population with wrist circumference ranging from 13.5 cm to 19.5 cm.</p> <p>The device is not intended to be a diagnostic device. Contact your physician if hypertensive values are indicated.</p>	<p>Transtek Wrist Blood Pressure Monitor TMB-1014-BT is a digital monitor intended for use in measuring blood pressure and heartbeat rate in adult patient population with wrist circumference ranging from 13.5 cm to 21.5 cm (about 5 1/4-S8 1/2 inches).</p> <p>This device detects the appearance of irregular heartbeats during measurement and gives a warning signal with readings.</p> <p>The Wrist Blood Pressure Monitor compares average blood pressure results to pre-established AHA (American Heart Association) hypertension guideline of 135/85 mm Hg.</p> <p>Transtek Wrist Blood Pressure Monitor, TMB-1014-BT is not intended to be a</p>	Similar

		diagnostic device. Contact your physician if hypertensive values are indicated.	
Component	Main Unit, Cuff, Battery	Main Unit, Cuff, Battery	Similar
Measurement Method	Oscillographic	Oscillographic	Same
User Control	User controls measurement from mobile devices through mobile application software	User controls measurement from LCD screen on hardware	Minor difference
Labelling	Company Name and Address, Specifications, Product Descriptions, Indications for Use, Contraindication for Use, Precautions, Warnings, Safety Terms and Conditions, Safety Alert Description, Safety and Performance Standards, etc.	Company Name and Address, Specifications, Product Descriptions, Indications for Use, Contraindication for Use, Precautions, Warnings, Safety Terms and Conditions, Safety Alert Description, Safety and Performance Standards, etc.	Same
Power Source	Rechargeable Lithium Battery	Battery	Similar
Cuff	Wrist wrap around	Wrist wrap around	Same
Display	Remote display on mobile devices	Local liquid crystal digital display, and remote display on mobile devices	Similar
Wireless Mode	Bluetooth	Bluetooth	Same
Data Storage	On mobile devices and on server	Mobile devices	Similar

Our device is essentially identical to the predicate device in terms of indications for use, design, mechanism, and labeling between subject device and the predicate device. The several minor differences do not affect the safety and effectiveness of the device

### 5.10 Substantial Equivalence Conclusion

It has been shown in this 510(k) submission that XM-01 Automatic Electronic Blood Pressure Monitor and its predicate devices have the identical indications for use, design, mechanism, labeling, and similar performance.

The difference between the XM-01 Automatic Electronic Blood Pressure Monitor and their predicate device do not raise any question regarding its safety and effectiveness.

XM-01 Automatic Electronic Blood Pressure Monitor, as designed and manufactured, are as safe and effective as its predicate device, and therefore is substantially equivalent as its predicate device.