DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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October 14, 2016

Guangdong Transtek Medical Electronics Co., Ltd
Ada Zhang
Product Certification Supervisor
Zone B, No.105, Dongli Road, Torch Development District
Zhongshan, Guandong, China 528437

Re: K161886
Trade/Device Name: TRANSTEK Blood Pressure Monitor amd Welch Allyn Blood Pressure Device, Models: TMB-1591-A, RPM-BP100SBP and H-BP100SBP
Regulation Number: 21 CFR 870.1130
Regulation Name: Noninvasive Blood Pressure Measurement System
Regulatory Class: Class II
Product Code: DXN
Dated: August 5, 2016
Received: August 5, 2016

Dear Ada Zhang:

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,

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)*
K161886

Device Name
Transtek Blood Pressure Monitor, Welch Allyn Blood Pressure Device
Models: TMB-1591-A, RPM-BP100SBP and H-BP100SBP

Indications for Use *(Describe)*
Transtek Blood Pressure Monitor TMB-1591-A, Welch Allyn Blood Pressure Device RPM-BP100SBP and H-BP100SBP are digital monitors intended for use in measuring blood pressure and heartbeat rate in adult patient population with arm circumference ranging from 15 cm to 54 cm (about 6-21 inches).
These devices detect the appearance of irregular heartbeats during measurement and give a warning signal with readings.

Contraindications:
This device is contraindicated for any person who is connected to a wearable or implantable electronic device or instrument, such as a pacemaker or defibrillator.
These device are 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.

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510(k) Summary

Date of Summary Preparation: 10/13/2016

1. Submitter's Identifications

Submitter's Name: Guangdong Transtek Medical Electronics Co., Ltd
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Contact Person: Ada Zhang
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2. Name of the Device

Device Classification Name: System, Measurement, Blood-Pressure, Non-invasive
Product Name: TRANSTEK Blood Pressure Monitor, Welch Allyn Blood Pressure Device
Trade Name: TRANSTEK, Welch Allyn
Models: TMB-1591-A, RPM-BP100SBP, H-BP100SBP
Classification Panel: Cardiovascular
Common/Usual Name: Arm Blood Pressure Monitor
Product Code: DXN
Device Classification: Class Ⅱ

3. The Predicate Devices

TRANSTEK, Blood Pressure Monitor, Model TMB-1018-BT, K131395

4. Device Description

Transtek Blood Pressure Monitor TMB-1591-A, Welch Allyn Blood Pressure Device RPM-BP100SBP and H-BP100SBP are designed to measure the systolic and diastolic blood pressure and heartbeat rate of an individual by using a non-invasive technique in which an inflatable cuff is wrapped around the arm. The three devices are the same except brand name, model number and the layout of labeling.

Measurement method to define systolic and diastolic pressure is similar to the ausculatory 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 heartbeat rate, which is a well-known technique in the market called the “Oscillometric method”.

These devices also compare the longest and the shortest time intervals of detected pulse waves to mean time interval and displays a warning signal with the reading to indicate the detection of irregular heartbeat when the difference of the time intervals is over 25%.

These devices include the main unit and cuff unit. The main unit consists of the microprocessor, the pressure sensor, the operation keys, the pump, the electromagnetic deflation control valve and the LCD. ABS is used to outer housing of the main unit. The three preformed cuff units, which are applicable to arm circumference between 15-24cm, 22-42cm and 40-54cm to meet different population’s need. The subject device is powered by four AA alkaline batteries or by a DC 6V 1AA adapter.

These devices embed a Bluetooth module that allows it to connect with nearby BT receiving terminal (such as iphone, ipad). Once measurement is over, the LCD of device displays results. And the device will start to transmit data to the pair-up BT terminal automatically. Thus users can display, manage and storage measurement data more easily.

5. Intended Use of Device

Transtek Blood Pressure Monitor TMB-1591-A, Welch Allyn Blood Pressure Device RPM-BP100SBP and H-BP100SBP are digital monitors intended for use in measuring blood pressure and heartbeat rate in adult patient population with arm circumference ranging from 15 cm to 54 cm (about 6-21 inches).

These devices detect the appearance of irregular heartbeats during measurement and give a warning signal with readings.

Contraindications:

This device is contraindicated for any person who is connected to a wearable or implantable electronic device or instrument, such as a pacemaker or defibrillator.

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

6. Discussion of performance tests in design verification and design validation

We conducted design verification and design validation activities to demonstrate that these proposed device met all design specifications as are Substantially Equivalent to the predicate device. The result

show that TMB-1591-A, RPM-BP100SBP and H- BP100SBP conform to the following standards:

a. Safety Test:

- AAMI/ANSI ES60601-1:2005+A1:2012, Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-11:2010, Medical electrical equipment-Part 1-11: General Requirement for basic safety and essential performance – Collateral Standard: Requirements for medical electrical systems used in the home healthcare environment

b. EMC Test:

IEC 60601-1-2 Edition 3:2007-03, Medical Electrical Equipment - Part 1-2: General requirements for safety - collateral standard: Electromagnetic compatibility - Requirements and Tests

c. **Performance and Reliability test:**

IEC 80601-2-30 Edition1.1 2013-07 Medical electrical equipment-Part 2-30: Particular requirements for the basic safety and essential performance of automated non-invasive sphygmomanometers.

d. **FCC Test:**

FCC 47 CFR Part 15, Subpart B

e. **Biocompatibility Test:**

- ISO 10993-1:2009, Biological evaluation of medical devices- Part 1: Evaluation and testing within a risk management process
- ISO 10993-5:2009, Biological evaluation of medical devices-Part 5: Tests for In Vitro cytotoxicity
- ISO 10993-10:2010, Third Edition Biological evaluation of medical devices-Part 10: Tests for irritation and skin sensitization

f. **Risk Assessment:** ISO 14971:2007 Second Edition, Medical devices - Application of risk management to medical devices

g. **Software Verification and Validation:**

-IEC 62304 Ed.1.0 (2006), Medical device software - Software life cycle processes,

h. **Usability Validation:**

-IEC 62366-1:2007+A1:2014 Medical devices - Application of usability engineering to medical devices

-IEC 60601-1-6 Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability

i. **Wireless coexistence**

Radio-Frequency Wireless Technology in Medical Devices

j. **Clinical Validation**

AAMI/ANSI/ISO 81060-2:2013 Non-invasive sphygmomanometers - Part 2: Clinical validation of automated measurement type.

7. Summary of Substantial Equivalence

Transtek Blood Pressure Monitor TMB-1591-A, Welch Allyn Blood Pressure Device RPM-BP100SBP and H-BP100SBP have identical technology, energy type, cuff surface material and similar intended use, performance specifications, software/firmware and functions to the predicate device.

The only significant difference between these proposed devices and the predicate device is that these proposed devices add two other intended cuffs which are applicable for population with arm circumference 15-24cm and 40-54cm. The additional cuffs size are appropriate to the claimed intended arm circumference per IEC 80601-2-30. The material of two additional cuffs is the same with original cuff. Thus there is no biocompatibility problem. The clinical performance and accuracy of these proposed devices have been demonstrated that meet the requirements of AAMI/ANSI/ISO 81060-2:2013. Thus the difference does not raise any new questions of safety and effectiveness.

8. Conclusions

Transtek Blood Pressure Monitor TMB-1591-A, Welch Allyn Blood Pressure Device RPM-BP100SBP and H-BP100SBP are substantially equivalent to the predicate device TMB-1018-BT by having the identical technologies and similar intended use. Two added cuffs does not impact the safety and effectiveness of these proposed devices.

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