K122482

OCT 2 2 2012

TRANSTEK

Section 5 - 510(k) Summary

Date of Summary Preparation: 07/25/2012

1. Submitter's Identifications

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2. Correspondent's Identifications

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3. Name of the Device

Device Classification Name: System, Measurement, Blood-Pressure, Non-invasive
Product Name: Wrist Blood Pressure Monitor
Trade Name: Transtek
Models: TMB-895, TMB-988, TMB-1014, TMB-1117
Classification Panel: Cardiovascular
Common/Usual Name: Automatic Blood Pressure Monitor
Product Code: DXN
Device Classification: Class II
Contraindications: None

4. The Predicate Devices

OMRON, DIGITAL WRIST BLOOD PRESSURE MONITOR,
MODEL HEM-609N,
K042505

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5. Device Description

Transtek Wrist Blood Pressure Monitor, TMB-895, TMB-988, TMB-1014, TMB-1117 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 wrist.

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 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".

Transtek Wrist Blood Pressure Monitor is single-mounted device of the main unit and cuff unit. The preformed cuff unit, which is applicable to wrist circumference approximately between 13.5 and 21.5 cm, includes the inflatable bladder and nylon shell. All four models of the wrist blood pressure monitor use the same size of cuff. The subject devices consist of the microprocessor, the pressure sensor, the operation keys, the pump, the electromagnetic deflation control valve, and the LCD. The subject devices are powered by two AAA alkaline batteries.

The device also compares 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%.

6. Intended Use of Device

Transtek Wrist Blood Pressure Monitor, Models TMB-895, TMB-988, TMB-1014, TMB-1117 are digital monitors 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 – 8 1/2 inches).

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

The Wrist Blood Pressure Monitor compares average blood pressure results to pre-established AHA (American Heart Association) hypertension guideline of 135/85 mmHg.

Transtek Wrist Blood Pressure Monitor, TMB-895, TMB-988, TMB-1014, TMB-1117 models are not intended to be a diagnostic device. Contact your physician if hypertensive values are indicated.

7. Summary of Substantial Equivalence

(Continued on next page)

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Table 1: The difference between Transtek Wrist Blood Pressure Monitors

Feature	TMB-895/TMB-988/TMB-1014/TMB-1117 Performance Data
Power	2*AAA alkaline batteries (3V DC)
Display mode	Digital LCD V.A. TMB-895: 41*44mm TMB-988: 35*40mm TMB-1014: 36*41mm TMB-1117: 31.5*44mm
Measurement method	Oscillographic testing mode
Measurement range	Pressure: 0 to 300mmHg (0 to 40kPa) Pulse value: 40 to 199 times/minute
Accuracy	Pressure: 5℃~40℃ within ±3mmHg 0℃~45℃ (out of 5℃~40℃) within ±5mmHg Pulse value: ±5%
Normal working condition	Temperature: 5℃~40℃ Relative humidity: ≦80%
Storage and transportation condition	Temperature: -20℃~60℃; Relative humidity: 10%~93%
Measurement perimeter of the wrist	About 13.5cm~21.5cm
Main unit weight	Approx. (Excluding the batteries) TMB-895: 150g TMB-988: 95g TMB-1014: 120g TMB-1117: 120g
Main unit dimensions	Approx. (Not including the wrist cuff) TMB-895: 73*70*32mm TMB-988: 68*75*22mm TMB-1014: 80*65*22mm TMB-1117: 68*75*31mm
Degree of protection	Internal type B powered equipment
Air Release	Exhaust valve
Pressure method	Motor pump
Pressure Detection	Semiconductor sensor
Pulse Detection	Semiconductor sensor

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Table 2: The difference between Transtek Wrist Blood Pressure Monitor and Predicate HEM 609N

Feature	TMB-895 /TMB-988 /TMB-1014 /TMB-1117	Predicate: HEM-609N	Comparison
Device name	Wrist Blood Pressure Monitor	Digital Wrist Blood Pressure Monitor	Similar
Indication for use	Measure the blood pressure and heartbeat rate. Irregular heartbeat detection.	Measure the blood pressure and heartbeat rate. Irregular heartbeat detection.	Similar
Components	Main Unit, Cuff, Instruction Manual, 2*AAA batteries, Storage Case and Warranty Card	Main Unit, Cuff, Instruction Manual, 2*AAA batteries, Storage Case and Warranty Card	Similar components and materials
Measurement method	Oscillographic	Oscillographic	Similar
Labeling	Company name and address Specifications Product description Indication for use Contraindications for use Precautions Warnings Safety terms and conditions Safety alert descriptions Safety and performance standards and so on	Company name and address Specifications Product description Indication for use Contraindications for use Precautions Warnings Safety terms and conditions Safety alert descriptions Safety and performance standards and so on	Similar
Energy used	Battery (2*AAA, 3V DC)	Battery (2*AAA, 3V DC)	Similar
Display	Liquid crystal digital display	Liquid crystal digital display	Similar
Main unit dimensions	Approx. (Not including the wrist cuff) TMB-895: 73*70*32mm TMB-988: 68*75*22mm TMB-1014: 80*65*22mm TMB-1117: 68*75*31mm	Approx. (Not including the wrist cuff) 70*54*37mm	Similar
Applicable cuff	Wrap around cuff	Wrap around cuff	Similar
Measurement range	Pressure: 0 to 300 mmHg Pulse value: 40 to 199 beats/min	Pressure: 0 to 299 mmHg Pulse Rate: 40 to 180 beats/min	Similar

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Feature	TMB-895 /TMB-988 /TMB-1014 /TMB-1117	Predicate: HEM-609N	Comparison
Accuracy of pressure indicator	5℃~40℃ within ±3mmHg 0℃~45℃ (out of 5℃~40℃) within ±5mmHg	Within ±3mmHg	Similar
Accuracy of pulse rate	Within ±5% of reading	Within ±5% of reading	Similar
Cuff inflation	Automatic inflation with air pump	Automatic inflation with air pump	Similar
Deflation of pressure	Automatic air release	Automatic rapid deflation	Similar
Operating voltage	3V DC	3V DC	Similar
Measurement perimeter of wrist	13.5cm~21.5cm	13.5cm~21.5cm	Similar
Operation environment	Temperature: 5℃~40℃ Relative humidity: ≤80% Barometric pressure: 86~106 kPa	Temperature: 10℃~40℃ Relative humidity: 30~85% Barometric pressure: 80~105 kPa	Similar
Transport and storage environment	Temperature: -20℃~60℃ Relative humidity: 10%~93%	Temperature: -20℃~60℃ Relative humidity: 10~95%	Similar

8. Conclusions

The subject devices have all similar features of the predicate device HEM-609N. Those subtle differences of performance parameter do not affect the safety and effectiveness of the subject devices.

In other sections of this submission, those performance testing and assessment proved that the subject devices are safe and effective.

Thus, the subject devices are substantially equivalent to the predicate device.

--- End of this section ---

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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

OCT 2 2 2012

Zhongshan Transtek Electronics Co., Ltd.
c/o Mr. Leo Wang
Senior Consultant
No.1 Fanghua Street, Hi-Tech Zone
Chengdu, Sichuan 610041 (China)

Re: K122482
Trade/Device Name: Transtek Wrist Blood Pressure Monitor
Regulation Number: 21 CFR 870.1130
Regulation Name: Non-invasive blood pressure measurement system
Regulatory Class: Class II (two)
Product Code: DXN
Dated: September 22, 2012
Received: September 25, 2012

Dear Mr. Wang:

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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Section 4 - Indications for Use

510(k) Number (if known):

Device Name: Transtek Wrist Blood Pressure Monitor
Model Numbers: TMB-895, TMB-988, TMB-1014, TMB-1117

Indications for Use:

This series of devices are digital monitors 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 – 8 1/2 inches).

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

The Wrist Blood Pressure Monitor compares average blood pressure results to pre-established AHA (American Heart Association) hypertension guideline of 135/85 mmHg.

Transtek Wrist Blood Pressure Monitor, TMB-895, TMB-988, TMB-1014, TMB-1117 models are not intended to be a diagnostic device. Contact your physician if hypertensive values are indicated.

Prescription Use _____ AND/OR Over-The-Counter Use ___X___

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for B Zuckerman

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K122482

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