TRANSTEK

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Section 5 - 510(k) Summary

Date of Summary Preparation: 11/30/2012

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: TRANSTEK Blood Pressure Monitor
Trade Name: TRANSTEK
Models: LS802-E
Classification Panel: Cardiovascular
Common/Usual Name: Automatic Blood Pressure Monitor
Product Code: DXN
Device Classification: Class II
Contraindications: None.

4. The Predicate Devices

TRANSTEK, Blood Pressure Monitor, Model LS-802, K120058

5. Device Description

Transtek Blood Pressure Monitor, LS802-E is 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.

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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 Blood Pressure Monitor is single-mounted devices of the main unit and cuff unit. ABS is used to outer housing of the main unit. The preformed cuff unit, which is applicable to arm circumference approximately between 22cm and 42 cm, includes the inflatable bladder and nylon shell. The device consists of the microprocessor, the pressure sensor, the operation keys, the pump, the electromagnetic deflation control valve and the LCD. The subject device is powered by four AA alkaline batteries or by a DC 6V 400mA adapter.

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%.

Transtek Blood Pressure Monitor LS802-E embeds a Wireless network connections module that allows it to connect to nearby receiving end (such as specific equipment that named Bridge) which is connected to the Internet. Once measurement is over, the LCD of device displays results. And the device will start to send out data. The Bridge receive / storage, and transmission data to Internet server. Thus users can receive, and display/storage, measurement data from LS802-E unit through their end devices (e.g. PC, cellular, tablet) that connected Internet.

6. Intended Use of Device

Transtek Blood Pressure Monitor LS802-E is a digital monitor intended for use in measuring blood pressure and heartbeat rate in adult patient population with arm circumference ranging from 22 cm to 42 cm (about 9 - 17 inches).
This device detects the appearance of irregular heartbeats during measurement and gives a warning signal with readings.
The Blood Pressure Monitor compares average blood pressure results to pre-established AHA (American Heart Association) hypertension guideline of 135/85 mmHg.
Transtek Blood Pressure Monitor, LS802-E is not intended to be a diagnostic device. Contact your physician if hypertensive values are indicated.

7. Design Control Activities and Performance Tests 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 difference does not raise any new questions of safety and effectiveness.

LS802-E conforms to the following standards:

ISO14971, Risk management to medical devices

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AAMI/ANSI SP10, Safety and performance characteristics
IEC60601-1, Electrical safety; IEC60601-1-2, Electromagnetic compatibility
ISO10993, Biological evaluation of medical devices
FCC Part 15, EMI tests of FCC Radiation & RF rules and regulations

Explanation: The new wireless function does not affect blood pressure monitor measurement function. Therefore we have not done the Clinical test.

8. Summary of Substantial Equivalence

8.1 Differences between proposed device and the predicate device

The only significant function difference between the two devices is that LS802-E add-on a wireless data communication, what user option, which can transmit measurement results to those end devices that connected Internet. The other one modification is that Cuff's surface materials changed.

8.2 Discussion

The Transtek Blood Pressure Monitor LS802-E has identical indication for use, fundamental scientific technology, Cuff type, energy type, dimensional specifications, environmental specifications, performance specifications, and similar Cuff surface material, software/firmware, functions, labeling to the predicate device.

The only function difference between LS802-E and the predicate device is that the modified device provides user an optional wireless data transmission. It is an add-on function that is entirely independent from the blood pressure monitor measurement function, which does not reply on the wireless connection to carry out a blood pressure measurement and heartbeat rate analysis and display its results. Thus the wireless data transmission function does not affect the safety and effectiveness of the blood pressure monitor function.

All required design control activities have been implemented and all applicable performance tests have been done according with demands of FDA guidance document "Non-Invasive Blood Pressure (NIBP) Monitor Guidance" FDA March 10, 1997. We found that the modified device does not create new significant risk.

9. Conclusions

The Transtek Blood Pressure Monitor LS802-E is substantially equivalent to the predicate device LS-802 by having the identical indication for use, identical technologies, similar Cuff surface materials, and an add-on function which does not impact the safety and effectiveness of the device.

--- End of this section ---

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

March 1, 2013

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

Re: K123780
Trade/Device Name: Transtek Blood Pressure Monitor Model LS802-E
Regulation Number: 21 CFR 870.1130
Regulation Name: Noninvasive Blood Pressure Measurement System
Regulatory Class: Class II
Product Code: DXN
Dated: January 30, 2013
Received: January 30, 2013

Dear Mr. Leo 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,

Owen P. Faris -S

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

Enclosure

TRANSTEK

Section 4 - Indications for Use

510(k) Number (if known): K123780

Device Name:

Transtek Blood Pressure Monitor
Models: LS802-E

Indications for Use:

Transtek Blood Pressure Monitor LS802-E is a digital monitor intended for use in measuring blood pressure and heartbeat rate in adult patient population with arm circumference ranging from 22 cm to 42 cm (about 9 - 17 inches).

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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)

Owen P. Faris -S