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510(k) Summary

This 510(k) Summary of 510(k) safety and effectiveness information is being submitted in accordance with requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) Number: _____

1. Date of Submission: December 20, 2012

2. Sponsor

   Shenzhen Pango Electronic Co., Ltd
   No.25, 1st Industrial Park, Fenghuang Road,
   Xikeng, Henggang, Longgang District
   Shenzhen, Guangdong, 518115, China

   Establishment Registration Number: 3006792041

   Contact Person: MS. Xiaoyun Yang
   Position: Vice General Manager
   Tel: +86-755-33825988
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3. Submission Correspondent
   Ms. Diana Hong & Mr. Lee Fu
   Mid-Link Consulting Co., Ltd
   P.O. Box 237-023, Shanghai, 200237, China
   Tel: +86-21-22815850
   Fax: 240-238-7587
   Email: info@mid-link.net

4. Proposed Device Identification

   Proposed Device Name: Electronic Blood Pressure Monitor;

Proposed Device Model: PG-800A Series, including: PG-800AD, PG-800A-1, PG-800AD-1,

PG-800A3, PG-800A4, PG-800A4D, PG-800A5, PG-800A5D, PG-800A6, PG-800A6D, PG-800A6-1, PG-800A6-2, PG-800A7, PG-800A7D, PG-800A9, PG-800A8, PG-800A11, PG-800A12, PG-800A15

Classification Name: System, measurement, blood-pressure, non-invasive;
Common Name: Electronic Blood Pressure Monitor;
Classification: 2
Product Code: DXN;
Regulation Number: 21 CFR 870.1130;
Review Panel: Cardiovascular;

Intended Use Statement:
PG-800A Series Electronic Blood Pressure Monitor is intended to measure the systolic and diastolic blood pressure as well as the pulse rate of adult person via non-invasive oscillometric technique in which an inflatable cuff is wrapped around the wrist. It can be used at medical facilities or at home. The intended wrist circumference is 13.5-19.5 cm.

5. Predicate Device Identification

510(k) Number: K102920
Product Name: Electronic Blood Pressure Monitor, PG-800A
Manufacturer: Shenzhen Pango Electronic Co., Ltd

6. Device Description

The proposed device, PG-800A Series Electronic Blood Pressure Monitor, is a battery driven automatic on-invasive blood pressure monitor. It can automatically complete the inflation, deflation and measurement, which can measure systolic and diastolic blood pressure as well as the pulse rate of adult person at wrist within its claimed range and accuracy via the oscillometric technique. User can select the unit of the measurement: mmHg or KPa.

All the models included in this submission follow the same software, same measurement principle and same specifications. The main differences are appearance and data storage. These two differences will not affect the safety and effectiveness of the device.

7. Non-Clinical Test Conclusion

Bench tests were conducted to verify that the proposed device met all design specifications as was Substantially Equivalent (SE) to the predicate device. The test results demonstrated that the proposed

device complies with the following standards:

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IEC 60601-1:2005, 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.
AAMI SP10:2002/(R)2008 & A1:2003, Manual, electronic or automated sphygmomanometers.

8. Substantially Equivalent

Table III-1 Substantially Equivalent Comparison

ITEM	PG-800A Series Electronic Blood Pressure Monitor	Electronic Blood Pressure Monitor PG-800A, K102920
Product Code	DXN	Same
Regulation No.	21 CFR 870.1130	Same
Class	II	Same
Intended Use	PG-800A Series Electronic Blood Pressure Monitor is intended to measure the systolic and diastolic blood pressure as well as the pulse rate of adult person via non-invasive oscillometric technique in which an inflatable cuff is wrapped around the wrist. It can be used at medical facilities or at home. The intended wrist circumference is 13.5-19.5 cm.	Same
Measurement Type	Wrist	Same
Patient Population	Adult	Same
Measurement Item	SYS, DYS, Pulse Rate	Same
Principle	Oscillometric	Same
BP Range	30 ~ 280 mmHg	Same
BP Accuracy	±3 mmHg	Same
PR Range	40-199 bpm	Same
Cuff Size	30.8 cm (length) x 8 cm (width)	Same
Power Supply	two AAA or LR03 batteries	Same
Software Level Concern	Moderate	Same

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The proposed device, PG-800A Series Electronic Blood Pressure Monitor, is determined to be Substantially Equivalent (SE) to the predicate device, Electronic Blood Pressure Monitor PG-800A (k102920), in respect of safety and effectiveness.

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

June 14, 2013

Shenzhen Pango Electronic Co., Ltd.
c/o Mr. Jeff D. Rongero
Senior Project Engineer
Underwriters Laboratories, Inc.
12 Laboratory Drive
Research Triangle Park, NC 27709

Re: K131569
Trade/Device Name: Electronic Blood Pressure Monitor, PG-800A Series
Regulatory Number: 21 CFR 870.1130
Regulation Name: Non-invasive Blood Pressure Measurement System
Regulatory Class: II (two)
Product Code: DXN
Dated: May 24, 2013
Received: May 30, 2013

Dear Mr. Rongero:

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

K131569

Indications for Use

510(k) Number:

Device Name: Electronic Blood Pressure Monitor

Models: PG-800A Series, including: PG-800AD, PG-800A-1, PG-800AD-1, PG-800A3, PG-800A4, PG-800A4D, PG-800A5, PG-800A5D, PG-800A6, PG-800A6D, PG-800A6-1, PG-800A6-2, PG-800A7, PG-800A7D, PG-800A9, PG-800A8, PG-800A11, PG-800A12, PG-800A15

Indications for Use:

The PG-800A Series Electronic Blood Pressure Monitor is intended to measure the systolic and diastolic blood pressure as well as the pulse rate of adult person via non-invasive oscillometric technique in which an inflatable cuff is wrapped around the wrist.

It can be used at medical facilities or at home.

The intended wrist circumference is 13.5-19.5 cm.

☐PRESCRIPTION USE
(Part 21 CFR 801 Subpart D)

☒OVER-THE-COUNTER USE
(21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Owen P. Faris -S
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