K102988 1/1

NOV - 9 2010

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Sec. III 510(k) Summary

This 510(k) Summary is prepared per the request of 21 CFR 807.92. The Assigned 510(k) Number is: _____

Date	20 JUL 2010
Sponsor	**Shenzhen Pango Electronic Co., Ltd** No.25, 1st Industrial Park, Fenghuang Road, Xikeng Village, Henggang Town, Longgang District, Shenzhen, Guangdong, 518115, China Contact Person: Ms. Xiaoyun Yang, Vice General Manager T: +86-755-33825988 | F: +86-755-33825989 | E: sales@pan-go.com
Submission Correspondent	MS. Diana Hong / MR. Lee Fu Shanghai Mid-Link Consulting Co., Ltd P.O.BOX 237-023, Shanghai, 200237, China
Proposed Device	**Electronic Blood Pressure Monitor, PG-800B**
Classification	System, Measurement, Blood-pressure, Non-invasive | DXN | 21 CFR 870.1130 | Class II
Intended Use	PG-800B 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 upper arm. It can be used at medical facilities or at home. The intended arm circumference is 22-32 cm.
Device Description	The proposed device, PG-800B Electronic Blood Pressure Monitor, is a battery driven automatic non-invasive blood pressure monitor. It can measure systolic and diastolic blood pressure as well as the pulse rate of adult person at arm within its claimed range and accuracy via the oscillometric technique. The device has the data storage function. It has an bar indicating function, which can indicate the WHO (World Health Organization) Blood Pressure Classification of the measured blood pressure by referencing Diastolic Blood Pressure issued at Journal of Hypertension 1999. Vol 17, No.2.
Testing	Electric Safety per IEC 60601-1:1988+A1:1991+A2:1995 / EMC per IEC 60601-1-2:2001+A1:2004 Performance and Clinical Verification Test per ANSI/AAMI SP10:2002+A1:2003+A2:2006 Biocompatibility per ISO 10993-5:2006 / ISO 10993-10:2002+AMD:2006
Predicate Device	KD-595 Blood Pressure Monitor as cleared in K070828.
SE Conclusion	The proposed device, PG-800A Electronic Blood Pressure Monitor, measures the blood pressure via same principle, oscillometric, at the same site, upper arm, as the predicate device. Both of them are driven by batteries. The proposed device, PG-800B Electronic Blood Pressure Monitor, is claimed to be Substantially Equivalent (SE) to the predicate device, KD595 Blood Pressure Monitor as cleared in K070828, in aspect of safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

Shenzhen Pango Electronic Co., Ltd.
c/o Mr. Ned Devine
Third Party reviewer
Underwriters Laboratories, Inc.
333 Pfingsten Rd.
Northbrook, IL 60062

NOV - 9 2010

Re: K102988
Trade/Device Name: Electronic Blood Pressure Monitor, PG-800B
Regulation Number: 21 CFR 870.1130
Regulation Name: Non invasive Blood Pressure Measurement System
Regulatory Class: Class II (two)
Product Code: DXN
Dated: October 22, 2010
Received: October 28, 2010

Dear Mr. Devine:

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.

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,

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

Enclosure

K102988 1/1

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Sec. II Indication for Use Statement

510(k) Number: K102988

Device Name: PG-800B Electronic Blood Pressure Monitor

NOV - 9 2010

Indications for Use:

PG-800B 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 upper arm.

It can be used at medical facilities or at home.

The intended arm circumference is 22-32 cm.

Prescription Use _____ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use ___X___ (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)

Donna B. McNamara

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K102988