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SHENZHEN KINGYIELD TECHNOLOGY CO., LTD.
BP201 Wrist Blood Pressure Monitor
Annex35 510K Summary

510(k) Summary

OCT 27 2008

1. **Submitter's Name:** Mr. Dacheng Gong, Manager

SHENZHEN KINGYIELD TECHNOLOGY CO., LTD.

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Date of Summary: Jan. 12 2007

2. **Trade Name:** BP201 Wrist Blood Pressure Monitor

3. **Classification Name**

Non-invasive Blood Pressure Measurement System.

Regulation Number: 21 CFR 870.1130

Class: II

4. Product Code: DXN

5. Classification Panel: Cardiovascular

6. Predicate Device: IEM-609N Digital Blood Pressure Monitor with Intelligence marketed by Omron Healthcare INC.

K 042505 (Predicate)

7. Device Description:

BP201 Wrist Blood Pressure Monitor is a fully automatic non-invasive blood pressure monitor which measures systolic and diastolic blood pressure and heart rate of adult population using the oscillometric method by inflating an inflatable cuff on the wrist.

The Intended use:

BP201 Wrist Blood Pressure Monitor is intended to be used to measure blood pressure (systolic and diastolic) and heart rate from the wrist by using the oscillometric method.

The device is intended for using in only adult population, not applied to the other populations such as neonatal baby.

It can not be used while the wrist (arm) has bleeding or wound to avoid the blood flowing from the wound in pressurizing.

8. Performance and Technological Characteristics :

8.1 Performance Summary

In terms of operating specification, Safety & EMC requirements, the

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device conform to applicable standards including ANSI/AAMI SPI0:2002, BS EN1060-4: 2004, IEC60601-1:1998+A1:1991+A2:1995 IEC 60601-1-2:2001/A1:2004. A comparison study with a device that uses auscultatory method used by trained observers was performed to validate the performance of BP201. The comparison study demonstrated that the clinical repeatability of BP201 is statistically and clinically acceptable.

8.2 Technological Characteristics

BP201 Wrist Blood Pressure Monitor uses an inflated cuff which is wrapped around the wrist .The cuff is inflated by a built-in air pump. The systolic and diastolic blood pressures are determined by Oscillometric method. The inflation rate is controlled by MCU at a constant rate 2~5mmHg/second. The user can release the cuff to stop measuring by pressing the “START/STOP” button at any time while measuring. The measuring result is displayed in LCD.

9. Substantial equivalence discussion

9.1. About the non-clinical tests

BP201 Digital Wrist Blood Pressure Monitor has the same intended use, the same technological characteristics as the predicate device HEM-609N, such as Measurement localization, Measuring parameters, Measurement range, Measurement Accuracy, Inflation, Deflation, Measurable

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circumference of wrist, Power source, Battery life, Operate environment, Preservation environment.

The main differences are the physical size, shape and weight, and there is no any new issue of safety and effectiveness.

So the non-clinical performance information demonstrates the equivalence of the non-clinical performance.

In a word, BP201 is equivalent to the predicate device for the non-clinical performance.

9.2. About the clinical tests

The device complies with the ANSI/AAMI SP10:2002 standard and BS EN1060-4: 2004 in its entirety. Thus BP201 & the predicate device HEM-609N are substantially equivalent.

10. Conclusion

BP201 Wrist Blood Pressure Monitor has the same intended use, the same technological characteristics as the predicate device HEM-609N. Moreover, non-clinical testing & clinical testing contained in this submission demonstrated that any difference in their technological characteristics does not raise any new issues of safety and effectiveness. In a word, BP201 is substantial equivalent to the predicate device HEM-609N.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 27 2008

Shenzhen Kingyfield Technology Co., Ltd.
c/o TUV Rheinland of North America, Inc.
Mr. Tamas Borsai
Division Manager, Medical Division
12 Commerce Rd.
Newton, CT 06470

Re: K083043
Trade/Device Name: BP201 Wrist Blood Pressure Monitor
Regulation Number: 21 CFR 870.1130
Regulation Name: Noninvasive Blood Pressure Measurement System
Regulatory Class: Class II (two)
Product Code: DXN
Dated: October 10, 2008
Received: October 14, 2008

Dear Mr. Borsai:

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 such 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

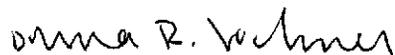
Page 2 – Mr. Tamas Borsai

all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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 (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



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

Enclosure

SHENZHEN KINGYIELD TECHNOLOGY CO., LTD.
BP201 Wrist Blood Pressure Monitor
Anné37 Indication for Use Statement

Indications for Use Statement

510(k) Number (if known): K083043

Device Name: BP201 Wrist Blood Pressure Monitor

Indications For Use:

It can be used as medical assistant instrument at home or in medical center for adult population for measuring systolic and diastolic blood pressure and heart rate.

The device is intended for use in only adult population, not applied to the other populations such as neonatal baby.

It can not be used while the wrist (arm) has bleeding or wound to avoid the blood flowing from the wound in pressurizing.

Prescription Use _____ AND/OR Over-The-Counter Use (Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Diana R. Johnson
(Division Sign-Off)
Division of Cardiovascular Devices

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