

SEP 24 2012

**510(k) Summary**

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

Date: July 14, 2012

1. Company and Correspondent making the submission:

	Company	Correspondent
Name	Hangzhou Reli-On Co., Ltd	IRC/ Charles Mack
Address	#204, 3Xin Chang Road, Gongshu District, Hangzhou City, Zhejiang Province, CHINA	77325 Joyce Way Echo, Oregon 97826
Phone	+86-571-28036398	931-625-4938
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Contact	Ms. Yu Manhua / General Manager	Charles Mack/Principal Engineer
Internet	charliemack@irc-us.com	charliemack@irc-us.com

2. Device :

Trade/proprietary name: Blood pressure monitor with  
stethoscope, Model HBPK-A

Common Name : Blood Pressure Cuff

Classification Name : Blood Pressure Cuff

3. Predicate Device :

The predicate device is:

Wenzhou Kindcare Import & Export Co., Ltd  
K081951  
Aneroid Sphygmomanometer, Model KT-A01

Recognized Consensus Standards:

The following standard was used to demonstrate compliance to FDA recognized consensus standards:

- SP10:2002/(R) 2008 & ANSI/AAMI SP10:2002/A1:2003/( Manual, electronic or automated sphygmomanometers

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4. Classifications Names & Citations :

21CFR 870.1120, DXQ, Blood Pressure Cuff, Class 2

5. Description :

Blood pressure monitor with stethoscope, Model HBPK-A is a non-invasive blood pressure measurement system for monitoring blood pressure levels. This Non-automated Sphygmomanometer uses an occluding cuff, an aneroid manometer to measure pressure, and a stethoscope for detecting Korotkoff sounds.

The Aneroid Sphygmomanometer with Stethoscope contains:

1. Adjustable D-ring Cuff (Adult Size)
2. Stethoscope (Attaches to the cuff)
3. Non-stop rotary pin, 300 mmHg gauge
4. Instruction booklet and record
4. Carrying case

The Blood pressure monitor with stethoscope enables the user to monitor the pressure of flowing blood that is exerted against the arteries at highest (systolic or contraction) and lowest (diastolic or relaxation) pressure. To operate, the user places the attached stethoscope on the inner arm above the bend in the elbow, to detect the pulse of the brachial artery. After inflation of the cuff, the user does auditory monitoring with the stethoscope to evaluate systolic and diastolic pressure. The two values are usually recorded as a ratio of the two measurements: systolic over diastolic.

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6. Indications for use :

The Blood pressure monitor with stethoscope, Model HBPK-A is a non-automated, aneroid blood pressure monitor that is used for the indirect measurement (noninvasive) and display of arterial blood pressure. It can be used by professionals as well as trained individual users at hospital or at home to monitor both systolic and diastolic pressure. This device is sold with an adult D-ring cuff and suitable for use on adult.

7. Technical Characteristics:

The submitted Hangzhou Rei-On device is exactly like the predicate. This is a simple manually operated aneroid blood pressure monitor with a bulb for inflation of a bladder which fits around the user or patient's arm. A stethoscope is used to hear the Korotkoff sounds.

8. Safety and Performance Data Summary:

Testing was performed in accordance with the Recognized Consensus standards, noted under Item 3, and also testing to Biological Compatibility Standards (ISO 10993-5, ISO 10993-10). The device successfully passed all the requirements within these standards.

9. Conclusions:

In accordance with the Federal Food, Drug and Cosmetic Act, 21 CFR Part 807 and based on the information provided in this premarket notification Hangzhou Reli-On Co., Ltd, concludes that Blood pressure monitor with stethoscope, Model HBPK-A is safe and effective as proven by compliance to consensus standards.

END

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

SEP 24 2012

Hangzhou Reli-On Co., Ltd.  
c/o Mr. Charlie Mack  
Principal Engineer  
IRC  
77325 Joyce Way  
Echo, OR 97826

Re: K122259  
Trade/Device Name: Blood Pressure Monitor with Stethoscope, Model HBPK-A  
Regulatory Number: 21 CFR 870.1120  
Regulation Name: Blood-Pressure Cuff  
Regulatory Class: II (two)  
Product Code: 74 DXQ  
Dated: September 13, 2012  
Received: September 18, 2012

Dear Mr. Mack:

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

Page 2 - Mr. Charlie Mack

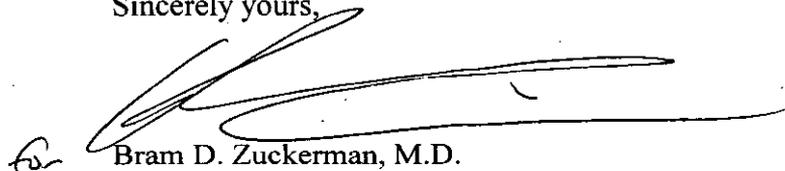
found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

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/CDRHOices/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" (21 CFR 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

**Indications for Use**

510(k) Number (if known): \_\_\_\_\_

Device Name: Blood pressure monitor with stethoscope, Model HBPK-A

Indications for Use:

The Blood pressure monitor with stethoscope, Model HBPK-A is a non-automated, aneroid blood pressure monitor that is used for the indirect measurement (noninvasive) and display of arterial blood pressure. It can be used by professionals as well as trained individual users at hospital or at home to monitor both systolic and diastolic pressure. This device is sold with an adult D-ring cuff and suitable for use on adult.

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 OF  
NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)



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**(Division Sign-Off)**  
**Division of Cardiovascular Devices**

510(k) Number K122259