K092245
P1/2

APPENDIX #1

510(K) SUMMARY

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

The assigned 510(k) number is: ____ .

OCT 2 8 2009

1. **Submitter's Identification:**

Company: **HONSUN(NANTONG)CO.,LTD**

Add: Add: No8, Tongxing Road, Nantong Economic & Technological Development Area JIANGSU CHINA
E-mail: david-zhang@lordmed.com

Contact: Mr. David Zheng

Date Summary Prepared: 7TH June 2009

2 **Trade or Proprietary Device Name:**

Aneroid Sphygmomanometer with Stethoscope, Model LD-100

Common or Usual Name:

Blood Pressure Kit (Blood Pressure Cuff)

Classification Name:

Cuff, Blood Pressure

Panel: Cardiovascular

3. **Legally Marketed Predicate Device:**

Aneroid Sphygmomanometer with Stethoscope, k060871 WENZHOU LONGWAN

MEDICAL INSTRUMENT COMPANY

4. **Device Description:**

The Aneroid Sphygmomanometer with Stethoscope is a non-invasive blood pressure measurement system for monitoring blood pressure levels. This Non-automated Sphygmomanometer uses an occluding cuff, an aneroid

Add: No8, Tongxing Road, Nantong Economic & Technological Development Area JIANGSU CHINA
Tel:(00)86-0513-85986718- * 614 Fax:(00)86-0513—85986716

Sphygmomanometer 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
5. Carrying case

The Aneroid Sphygmomanometer 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.

5. Intended Use:

The Aneroid Sphygmomanometer with Stethoscope is a non-automated, mechanical blood pressure monitor that is used for the indirect measurement (non-invasive) and display of arterial blood pressure. It can be used by professionals as well as trained individual users over age 18 at hospitals or at home to monitor both systolic and diastolic pressure. The device is for use in OTC.

6. Statement of Compliance to FDA Recognized Consensus Standards:

The Aneroid Sphygmomanometer with Stethoscope, **Model LD-100**, has been tested to and conforms with ANSI/AAMI AAMI / ANSI SP10:2002/A2:2006 Standard for Non-automated Sphygmomanometers.

7. Conclusion:

HONSUN(NANTONG)CO.,LTD. concludes that the subject Aneroid Sphygmomanometer with Stethoscope, Model LD-100, is as safe and effective as the predicate, Aneroid Sphygmomanometer with Stethoscope, based on conformance to **AAMI / ANSI SP10:2002/A2:2006**, "Standard for Manual, electronic, or automated sphygmomanometers. Test results as well as non-clinical mechanical testing performed.

Add: Add: No8, Tongxing Road, Nantong Economic & Technological Development Area JIANGSU CHINA
Tel:(00)86-0513-85986718- * 614 Fax:(00)86-0513—85986716

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

OCT 2 8 2009

Honsun (Nantong) Co., Ltd.
c/o Mr. David Zhang
Official Correspondent
No8, Tongxing Road
Nantong Economic & Technological Development Area
Nantong, Jiangsu 226000
CHINA

Re: K092245
Trade/Device Name: Aneroid Sphygmomanometer with Stethoscope, Model LD-100
Regulatory Number: 21 CFR 870.1120
Regulation Name: Blood Pressure Cuff
Regulatory Class: II (two)
Product Code: DXQ
Dated: September 15, 2009
Received: October 1, 2009

Dear Mr. Zhang:

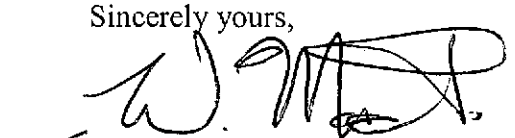
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 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 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 (301) 594-4646. 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 (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



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

Enclosure

Exhibit B

510(k) Number (if known):

Device Name: Aneroid Sphygmomanometer with Stethoscope
Model LD-100

Indications For Use:

The Aneroid Sphygmomanometer with Stethoscope is a non-automated, mechanical blood pressure monitor that is used for the indirect measurement (non-invasive) and display of arterial blood pressure It can be used by professionals as well as trained individual users over age 18 at hospitals or at home to monitor both systolic and diastolic pressure. The device is for use in OTC .

Prescription Use _____
(Per 21 CFR 801 Subpart D)

Over-The Counter Use_x
(21 CFR 807 Subpart C)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K092245

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

Concurrence of CDRH, Office of Device Evaluation (ODE)