K060871

510(k) Summary

JUN - 9 2006

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

Date: February 18, 2006

1. Company and Correspondent making the submission:

Name – Wenzhou Longwan Medical Instrument Company
Address – 8 Jinjiang Road, Longwan Fuping Development Area, Longwan section, Wenzhou, Zhejiang, P. R. China
Telephone/Fax – (86-577) 88868068
Contact – Mr. Birrell Xiang / Manager
Email – wetd@mail.wzptt.zj.cn

2. Device:

Proprietary Name – AS101
Common Name – Blood Pressure Cuff
Classification Name – Aneroid Sphygmomanometer

3. Validation of Performance:

Testing was performed in accordance with AAMI/ANSI SP10: 2002 & AAMI/ANSI SP10: 2002/A1: 2003.

4. Labeling: Labeling of the AS101 Aneroid Sphygmomanometer complies with AA MI/ANSI SP10, Section 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 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
4. 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 at hospitals or at home to monitor both systolic and diastolic pressure.

6. Statement of Compliance to FDA Recognized Consensus Standards:

The Aneroid Sphygmomanometer with Stethoscope, Model AS101, has been tested to and conforms to ANSI/AAMI SP-10: 2003 Standard for Non-automated Sphygmomanometers.

7. **Conclusions:**

In accordance with the Federal Food, Drug and Cosmetic Act, 21 CFR Part 807, based on the information provided in this premarket notification Wenzhou Longwan Medical Instrument Company concludes that the AS101 Aneroid Sphygmomanometer is safe and effective and complies to the testing validations defined in AAMI/ANSI SP10 standard.

8. Wenzhou Longwan Medical Instrument Company will update and include in this summary any other information deemed necessary by the FDA.

END

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN - 9 2006

Wenzhou Longwan Medical Instrument Company
c/o Charlie Mack
President
International Regulatory Consultants
340 Shady Grove Road
Flintville, TN 37335

Re: K060871
Trade Name: AS101 Blood Pressure Cuff
Regulation Number: 21 CFR 870.1120
Regulation Name: Blood Pressure Cuff
Regulatory Class: II (two)
Product Code: DXQ
Dated: May 21, 2006
Received: May 30, 2006

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.

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 (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

Indications for Use

510(k) Number (if known): K060871

Device Name: Aneroid Sphygmomanometer

Indications for Use:

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Prescription Use_____ AND/OR Over-The-Counter Use_____√_____

(Part 21 CFR 801 Subpart D) (Part 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)

(Division Sign-Off)
Division of Cardiovascular Devices
510(k) Number K060871