JUL 0 2 2014

510(k) Summary

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

Date: May 27, 2014

1. Submitter:

Name: SUZHOU JJ METER CO., LTD.

Add: No.156 Xuqing Rd, Xushuguan Town, Suzhou New District, P.R. China

Tel: 0086-512-66168979

Fax: 0086-512-66168979

2. Contact Person:

Long Yang (COO.)

Shenzhen Hlongmed Biotech Co., Ltd.

R1508, East Building, Yihai Plaza, Chuangye Road, Nanshan District,Shenzhen, P.R. China

Tel: 0086-755-86664986

Fax: 0086-755-86664933

E-mail: yanglong@hlongmed.com

3. Device Information:

Trade name:	Sphygmomanometer
Model:	JHT-1110, JHT-1500, JHT-1611
Common name:	Blood Pressure Cuff
Classification name:	Blood Pressure Cuff
Review Panel:	Cardiovascular
Product Code:	DXQ
Regulation Class:	II
Regulation Number:	870.1120

4. Predicate Device Information:

Company Name: Wenzhou Bokang instruments Co., Ltd.

Device Name: Aneroid Sphygmomanometer BK2002

510(k) number: K043286.

5. Device Description:

The device comprises tubing attached to a soft inelastic sleeve with an integrated inflatable bladder that is wrapped around the patient's limb and secured by hook and loop closure . The device tubing is connected to a non-invasive sphygmomanometer.

6. Indication For Use:

The device is intended to be used by medical professionals or in the home for the measurement of systolic and diastolic pressure on adults. The device is intended to be

manually attached to a patient and manually inflated along with a manual method for detecting Korotkoff sounds.

7. Technological Characteristics:

The JJ METER's Sphygmomanometer(model: JHT-1110, JHT-1500, JHT-1611) are virtually the same as Bokang's Aneroid Sphygmomanometer BK2002.

8. Safety and Performance Data:

The JJ METER's Sphygmomanometer(model: JHT-1110, JHT-1500, JHT-1611) have been tested conform to the ISO 81060-1:2007 Non-invasive sphygmomanometers - Part 1: Requirements and test methods for non-automated measurement type, and ISO 10993-5 and ISO 10993-10.

9. Conclusions:

In accordance with the Federal Food, Drug and Cosmetic Act, 21 CFR Part 807 and based on the information provided in this pre-market notification, SUZHOU JJ METER CO., LTD concludes that the Sphygmomanometer(models JHT-1110, JHT-1500, JHT-1611) are safe and effective, and substantially equivalent to the predicate device described herein.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

July 2, 2014

Suzhou Jj Meter Co., Ltd.
c/o Ms. Long Yang
Official Correspondent
R1508, East Bldg, Yihai Plaza
Chuangye Rd. Nanshan District
Shenzhen, Guangdong, 518054 CH

Re: K141392
Trade/Device Name: Sphygmomanometer (Models JHT-1110, JHT-1500, JHT-1611)
Regulation Number: 21 CFR 870.1120
Regulation Name: Blood Pressure Cuff
Regulatory Class: Class II
Product Code: DXQ
Dated: May 20, 2014
Received: May 27, 2014

Dear Ms. Yang:

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 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.

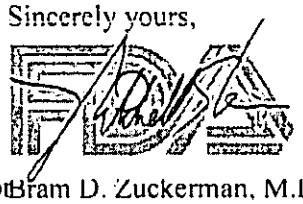
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801 IVD and Part 809); 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 IVD and Part 809), please contact 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. 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,



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

Enclosure

510(k) Number (if known): __K141392_____

Device Name: __ Sphygmomanometer (Model: JHT-1110, JHT-1500, JHT-1611) ____

Indications For Use:

The device is intended to be used by medical professionals or in the home for the measurement of systolic and diastolic pressure on adults. The device is intended to be manually attached to a patient and manually inflated along with a manual method for detecting Korotkoff sounds.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Date: 2014.07.02 14:34:45 -04'00'

Prescription Use ____ OR **Over-The-Counter Use** __ X_
(Per 21 CFR 801.109)