Withings

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K110872
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" 510(k) Summary for_____" MAY 2 0 2011

Submitter's Name: ***Withings***

Address: *37 bis, rue du General Leclerc, Issy Les Moulineaux Cedex, 92442, FRANCE*

Telephone: 33-1 41 46 04 60

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Manufacturer's Name: **YA HORNG Electronic Co., Ltd.**

Address: *No. 35, Zsha Lun, Jon Zsha Village, Antin Shiang, Tainan, 74555, Taiwan, ROC*

Contact Person: Dr. Jen, Ke-Min

Date Summary Prepared: March 20, 2011

Proprietary Name: *Withings Blood Pressure Monitor, Upper Arm Type: BP-800*

Common Name: BLOOD PRESSURE MONITOR

Classification Name: NON-INVASIVE BLOOD-PRESSURE MEASUREMENT SYSTEM

(per 21CFR section 870.1130)

Device Class: Class II (performance standards)

Specialty: CARDIOVASCULAR

Product code: DXN

Legally Marketed (Predicate) Device :

- YA HORNG Digital Upper Arm Blood Pressure Monitor BP-700, BP-700T, BP-700U, BP-700B, BP-700TB, BP-700UB, and BP-700TUB (K090058)
- KD-931D Fully Automatic Electronic Blood Pressure Monitor (K102631)

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Description of the new device: (Same as the predicate devices)

Withings Blood Pressure Monitor, Upper Arm Type:BP-800 uses the Oscillometric method to measure the blood pressure. The Oscillometric method is adopted clinically to measure the blood pressure recently. It is not needed to use the stethoscope, as in the traditional measuring method, to monitor the Korotkov sound when deciding the systolic or diastolic pressure. The Oscillometric method senses the vibrating signal via the closed air pipe system and utilizes the microcomputer to automatically sense the characteristics of the pulse signal. Through simple calculation, the reading can reflect the accurate real blood pressure, and the systolic pressure is defined as the pressure when the cuff pressure oscillating amplitude begins to increase and the diastolic pressure as the pressure when the cuff pressure oscillating amplitude stops decreasing.

Technological Characteristics of our new device compared to the predicate device:

The technological characteristics of Withings Blood Pressure Monitor, Upper Arm Type:BP-800 is substantially equivalent to YA HORNG Digital Upper Arm Blood Pressure Monitor BP-700, BP-700T, BP-700U, BP-700B, BP-700TB, BP-700UB, and BP-700TUB (K090058); and KD-931D Fully Automatic Electronic Blood Pressure Monitor (K102631). There is the same manufacturer, YA HORNG Electronic Co., Ltd., which FDA owner number is 9040892 for the new device BP-800 and predicate BP-700 series. Especially, there are the same design specifications, the same form and intended to be used in the same manner that means the new devices are same as the predicate devices.

The mainly different are:

1. The new devices are different vision appearance and specifications for the predicate devices.
2. There are different storage temperature, operating temperature, and humidity for the new device and predicate devices.
3. The new device and the predicate devices have the different sizes of the cuff for upper arm.

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4. The new device BP-800 and the predicate device KD-931D can connect to **iPhone**; and the predicate devices BP-700 series are the identical device with the optional functions for the BP-700U, BP-700UB, and BP-700TUB which can connect to the PC, backlight, and the voice function for the general upper arm use.

Thus there are substantially equivalent.

Test Summary:

1. **ELECTRIC SAFETY, EMC and FCC test reports,**

General safety	*IEC/EN 60601-1:2007*	***PASS***
	EN 1060-1:2009, EN 1060-3:2009	***PASS***
EMC conformity	*EN 60601-1-2: 2007*	***PASS***
FCC conformity	*ANSI C63.4: 2008*	***PASS***

2. **WOVEN COTTON SHEETING:**

(Same as the predicate devices: K090058, BP-700 series)

Uses the 510K Blood-Pressure Cuff: YA HORNG Blood-Pressure Cuff (K051539).

3. **PERFORMANCE & CLINICAL TEST**

AAMI / ANSI SP10

***Withings** believes this information and referred document to be sufficient for the FDA to find our proposed device substantially equivalent to the predicate product and other products currently in distribution.*

Dr. Jen, Ke-Min
official correspondent

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

JUL 18 2011

Withings
c/o Dr. Jen Ke-Min
Official Correspondent
ROC Chinese-European Industry Research Society
No. 58 Fu Chiun Street
Hsin Chu City
CHINA (TAIWAN) 30067

Re: K110872
Trade/Device Name: Withings Blood Pressure Monitor
Regulation Number: 21 CFR 870.1130
Regulation Name: Non-invasive Blood Pressure Measurement System
Regulatory Class: II (two)
Product Code: 74 DXN
Dated (Date on orig SE ltr): March 20, 2011
Received (Date on orig SE ltr): March 29, 2011

Dear Dr. Ke-Min:

This letter corrects our substantially equivalent letter of May 20, 2011.

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 (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 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); 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/CDRHOffices/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" (21CFR 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

K110872

Indications for Use

510(k) Number: K

Device Name: Withings Blood Pressure Monitor, Upper Arm Type: BP-800

- *Indications for use:*

The Withings Blood Pressure Monitor, Upper Arm Type: BP-800 is noninvasive blood pressure measurement systems intended to measure the systolic and diastolic blood pressures and pulse rate of an adult individual, over age 18, at home by using a non-invasive technique in which an inflatable cuff is wrapped around the upper arm.
The cuff circumference is limited to be 9'~17' (22cm~42cm) for Upper Arm type.

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)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K110872

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