MAR 2 4 2014

K133125

Withings
Société par actions simplifiées au capital de 2 551 824 euros
Siège social : 20, rue Rouget de Lisle – 92130 ISSY LES MOULINEAUX - FRANCE N°
de SIRET : 504 787 565 RCS NANTERRE
Tél : +33 1 41 46 04 60
Fax : +33 9 56 83 90 32

" 510(k) Summary "

K133125

Submitter's Name:	**Withings**
Address:	20 rue Rouget de Lisle, 92130, Issy Les Moulineaux, 92130, FRANCE
Telephone:	33-1 41 46 04 60
FAX:	33-9 56 83 90 32
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:	September 18, 2013
Proprietary Name:	Withings Blood Pressure Monitor, Upper Arm Type: BP-801
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 :	Withings Blood Pressure Monitor Upper Arm Type: BP-800 (K110872) KD-936 Fully Automatic Electronic Blood Pressure Monitor (K120672)

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Description of significant physical and performance characteristics:

The Withings BP-801 is a blood pressure monitor intended for use in measuring blood pressure and pulse rate in adult patient population with arm circumference ranging from 9 to 17 inches (22 - 42 cm) via an arm cuff.
It is designed and manufactured according to IEC 80601-2-30, Particular requirements for the basic safety and essential performance of automated non-invasive sphygmomanometers.
The operational principle is based on oscillometric and silicon integrates pressure sensor technology it can calculate the systolic and diastolic blood pressure, the measurement results can also be classified by the function of blood pressure classification indicator.
The Withings BP-801 is a blood pressure monitor achieves its function by integrate the device with an iPhone 4S. As it does not include a LCD or other display components, it is necessary for the new device to connect to an iPhone 4S containing a support software to constitute a complete blood pressure measurement system. And the new device connects iPhone 4S through Bluetooth or USB cable.

Indication for Use:

The Withings Blood Pressure Monitor, Upper Arm Type: BP-801 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 to 17 inches (22cm~42cm) for Upper Arm type.

Patient Population: Adults

Environment of Use: Home settings

Device composition:

- A cuff
- An alloy cylinder
- A USB adapter to connect to an iPhone 4S.

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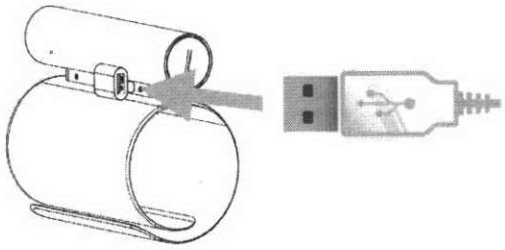

Material description :

Alloy cylinder :		Anodized 6061 aluminum
Cuff tissues	:	Lycra, Velcro loop, Velcro hook, PU leather, bias The patient contacting materials of the cuffs has been tested in accordance with ISO10993-1 and FDA Guidance. The tests included Cytotoxicity, Sensitization, and Intracutaneous Reactivity.

Collateral devices :

An iPhone 4S shall be connected to the NIBP. The user interface which is shown to the patient is available on this collateral device (CD).

Operational process :

a) The patient first connects the NIBP to the CD.
b) The patient hits the START button on the CD.
c) The NIBP performs the measurement.
d) If no error condition is met, the NIBP sends the heart rate, systolic and diastolic pressure results to the CD for display.
e) If an error condition is met, the NIBP sends an error report for the CD, which displays an error message to the user.

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

Withings Blood Pressure Monitor, Upper Arm Type: BP-801 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.

Test Summary:

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

General safety	IEC 60601-1:2005	**PASS**
	EN 1060-1:2002, EN 1060-3:2005	**PASS**
EMC conformity	IEC 60601-1-2: 2007	**PASS**
FCC conformity	ANSI C63.4 & 47	**PASS**

2. **WOVEN COTTON SHEETING:**

(Same as the predicate devices: Withings Blood Pressure Monitor Upper Arm Type: BP-800, K110872)

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

3. **PERFORMANCE & CLINICAL TEST**

The Withings BP-801 is a blood pressure monitor conforms to the following standards:

- ANSI/AAMI/ISO 81060-1:2007 Non-invasive sphygmomanometers - Part 1: Requirements and test methods for non-automated measurement type.
- ANSI/AAMI/ISO 81060-2:2009 Non-invasive sphygmomanometers - Part 2: Clinical validationof automated measurement type.
- ANSI/AAMI/IEC 80601-2-30:2009 Medical electrical equipment - Part 2-30: Particular requirements for the basic safety and essential performance of automated noninvasive sphygmomanometers.

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According to ANSI/AAMI/ISO 81060-1:2007 & ANSI/AAMI/ISO 81060-2:2009 & ANSI/AAMI/IEC 80601-2-30:2009 protocols:

1. The blood pressure values of a test person included in the analysis may not differ from each other by more than 12 mmHg for the systolic and 8 mmHg for test diastolic value (haemodynamic stability)
2. Out of 4 pairs of measured values, the first 2 consecutive pairs of measured values that were conforming with the criteria of the ANSI/AAMI/ISO 81060-1:2007 & ANSI/AAMI/ISO 81060-2:2009 &ANSI/AAMI/IEC 80601-2-30:2009 protocol was included in the analysis.

[Criterion 1]

For systolic and diastolic blood pressures, the mean error of determination, of the 108 individual paired determinations of BP-801 and the reference sphygmomanometer paired for all subjects shall not be greater than 5.0 mmHg, with a standard deviation no greater than 8.0 mmHg.
The total numbers of patients are 108 people and each patient carried with 3 determinations.
The total number of determinations (N= 108*3=324)

[Criterion 1] N=324 (108 subjects of patients * 3 determinations/each subject)			
STANDARD DEVIATION		**Mean Difference of systolic**	
mmHg		mmHg	
Systolic	Diastolic	Systolic	Diastolic
3.70	3.89	-0.242	-0.02

[Criterion 2]

For the systolic and diastolic blood pressures for each of the 108 subjects, the standard deviation of the averaged paired determinations per subject of BP-801 and of the reference sphygmomanometer shall meet the criteria listed in Table 1.
The result is:

* The Mean difference of Sys =-0.2 at the Standard Deviation of 1.86, which is within the criterion 6.95mmHg
* The Mean difference of Dia =-0.02 at the Standard Deviation of 2.13, which is within the criterion 6.95mm

[Criterion 2] M=108 subjects			
STANDARD DEVIATION		**Mean Difference of systolic**	
mmHg		mmHg	
Systolic	Diastolic	Systolic	Diastolic
1.86	2.13	-0.2	-0.02

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

Similarities:

Comparison item	**Proposed device**	**Predicate device**	
Applicant (Manufacturer)	Withings (YA HORNG Electronic Co., Ltd.)	Withings (YA HORNG Electronic Co., Ltd.)	Andon Health Co., Ltd.
Model name	BP-801	BP-800	KD-936
510K number	K133125	K110872	K120672
Intended use	SAME except cuff circumference is limited to 22cm ~ 42cm for Upper Arm type	SAME except cuff circumference is limited to 22cm ~ 42cm for Upper Arm type	The BLOOD PRESSURE MONITOR is a noninvasive blood pressure measurement system 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 22cm ~ 48cm.
Technological characteristics	SAME	SAME	Oscillometric method -- Sounds are heard over the artery when blood pressure is determined by the indirect

(continue)

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Similarities:

Comparison item	Proposed device	Predicate device	
Applicant (Manufacturer)	Withings (YA HORNG Electronic Co., Ltd.)	Withings (YA HORNG Electronic Co., Ltd.)	Andon Health Co., Ltd.
Model name	BP-801	BP-800	KD-026
510K number	K133125	K110872	K120672
Measuring method	SAME	SAME	Oscillometric method
Accuracy	SAME (as BP-800)	Pressure: <200 mmHg ± 3 mmHg or ≧200 mmHg ± 2% Pulse: ±5% of reading value	Pressure: ±3mmHg Pulse: ±5% of reading value
Pressure deflation	SAME	SAME	Automatic linear pressure deflation valve
Pressure release device	SAME	SAME	Automatic solenoid venting valve
Sensor	SAME	SAME	Semiconductor pressure sensor
Accessories	SAME	SAME	Storage case, instruction manual and
Life cycle	SAME	SAME	3 years

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Differences:

Comparison item	Proposed device	Predicate device	
Applicant (Manufacturer)	Withings (YA HORNG Electronic Co., Ltd.)	Withings (YA HORNG Electronic Co., Ltd.)	Andon Health Co., Ltd.
Model name	BP-801	BP-800	KD-936
510K number	K133125	K110872	K120672
Electric power	SAME (as BP-800)	AAA Alkaline battery x 4 pcs (no adapter)	Rechargeable batteries (Li-Ion 400 mAh)
Wireless communication:	Bluetooth V4.0 dual mode (V2.1 + EDR) Frequency Band: 2.402-2.480 GHz	NA	Bluetooth V3.0 + EDR Class 2 SPP Frequency Band: 2.402-2.480 GHz
Display	can display the measurement result on the **iPhone 4S**	SAME (as KD-936)	can display the measurement result on the **iPhone**
Sleeve	SAME (as BP-800)	Arm type: 22cm ~ 42cm	Arm type: 22cm ~ 48cm
Operating temperature & humidity	10 to 40°C, 15 to 90% RH, atmospheric 86Kpa~106kpa, altitude: 2000m	10 ~ 40 ℃ (50 ~ 104 ^{0}F) 15 ~90 % RH	5 ~ 40 °C < 90 %RH
Storage temperature & humidity	25 to 70°C,10 to 95%RH, atmospheric 86Kpa~106kpa, altitude: 2000m	-5 ~ 50 ℃ (23 ~ 122 ^{0}F) 15 ~90 % RH	-20 to 55 °C < 90 %RH

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Conclusion:

The technological characteristics of Withings Blood Pressure Monitor Upper Arm Type: BP-801 is substantially equivalent to Withings Blood Pressure Monitor Upper Arm Type: BP-800 (K110872); and KD-936 Fully Automatic Electronic Blood Pressure Monitor (K120672). There is the same manufacturer, YA HORNG Electronic Co., Ltd., which FDA owner number is 9040892 for the new device BP-801 and predicate BP-800. 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 main differences 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 BP-800 have the same cuff size for upper arm.
4. The new device BP-801 can connect to **iPhone 4S** with **Bluetooth or USB cable;** and the predicate device KD-936 can connect to **iPhone with Bluetooth**; and the predicate devices BP-800 can connect to iPhone with 30 pin cable.

Thus there are substantially equivalent.

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

March 24, 2014

Withings
c/o Dr. Jen, Ke-Min
20 rue Rouget de Lisle, 92130
Issy Les Moulineaux, 92130
FRANCE

Re: K133125
Trade/Device Names: Withings Blood Pressure Monitor BP-801
Regulatory Number: 21 CFR 870.1130
Regulation Name: Noninvasive Blood Pressure Measurement System
Regulatory Class: Class II (Two)
Product Code: DXN
Dated: January 29, 2014
Received: February 5, 2014

Dear Dr. Jen:

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); 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 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" (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

Enclosure

Indications for Use

510(k) Number: K133125

Device Name: Withings Blood Pressure Monitor, Upper Arm Type: BP-801

- *Indications for use:*

The Withings Blood Pressure Monitor, Upper Arm Type: BP-801 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 to 17 inches (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)

Concur

Date: 2014.05.24 [illegible] -04'00'

for Bram Zuckerman