K090058

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YAHORNG
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APR 22 2009

"510(k) Summary"

Submitter's Name: YA HORNG Electronic Co., Ltd.

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

Telephone: 886-6-5932201

FAX: 886-6-5935870

Contact Person: Dr. Jen, Ke-Min

Date Summary Prepared: March 1, 2008

Proprietary Name: Digital Upper Arm Blood Pressure Monitor
BP-700, BP-700T, BP-700U, BP-700B, BP-700TB, BP-700UB, BP-700TUB

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-100J, BP-110J; and Digital Wrist Blood Pressure Monitor BP-500, BP-510*

510(k) No: K072860

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

YA HORNG Digital Upper Arm Blood Pressure Monitor BP-700, BP-700T, BP-700U, BP-700B, BP-700TB, BP-700UB, and BP-700TUB use 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 YA HORNG Digital Upper Arm Blood Pressure Monitor BP-700, BP-700T, BP-700U, BP-700B, BP-700TB, BP-700UB, and BP-700TUB are substantially equivalent to YA HORNG Digital Upper Arm Blood Pressure Monitor BP-100J, BP-110J; and Digital Wrist Blood Pressure Monitor BP-500, BP-510 (K072860). There is the same Owner, YA HORNG Electronic Co., Ltd., which FDA owner number is 9040892. 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 memory capacity for the predicate devices.

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2. The new devices just for the general upper arm use and the predicate devices are either for the general upper arm or wrist use.
3. The subject devices BP-700 series are the identical device with the optional functions including connects 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	*EN 60601-1:1990+A1+A2+A11+A12+A13*	***PASS***
	EN 1060-1:1995, EN 1060-3:1997	***PASS***
EMC conformity	*EN 60601-1-2: 1993*	***PASS***
FCC conformity	*ANSI C63.4: 2003*	***PASS***

2. **WOVEN COTTON SHEETING:** (Same as the predicate devices)

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

3. **PERFORMANCE & CLINICAL TEST**
   AAMI / ANSI SP10

YA HORNG Co. Ltd. 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
YA HORNG Electronic Co., Ltd.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 22 2009

Ya Horng Electronic Co., Ltd.
c/o Dr. Jen, Ke-Min
ROC Chinese-European Industrial Research Society
No. 58, Fu-Chiun St.
Hsin-Chu City, 30067
Taiwan, ROC

Re: K090058
Trade/Device Name: Ya Horng Digital Upper Arm Blood Pressure Monitor, Models BP-700, BP-700T, BP-700U, BP-700B, BP-700TB, BP-700UB and BP-700TUB.
Regulation Number: 21 CFR 870.1130
Regulation Name: Noninvasive Blood Pressure Measurement System
Regulatory Class: Class II (Two)
Product Code: DXN
Dated: April 10, 2009
Received: April 16, 2009

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 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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. 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 contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at 240-276-3464. For more information regarding the reporting of adverse events, please go to http://www.fda.gov/cdrh/mdr/.

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

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Indications for Use

510(k) Number: ~~K08067T~~ K090058

Device Name: YA HORNG ELECTRONIC CO., LTD.
Digital Upper Arm Blood Pressure Monitor BP-700, BP-700T, BP-700U, BP-700B, BP-700TB, BP-700UB, BP-700TUB

- ***Indications for use:***

The YA HORNG Digital Upper Arm Blood Pressure Monitor BP-700, BP-700T, BP-700U, BP-700B, BP-700TB, BP-700UB, BP-700TUB are 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 9.0" ~ 13.0" for Arm type.

※ Optional model: BP-700U, BP-700UB, and BP-700TUB, software in the PC for record archiving and printing purposes only.

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) 4/21/09
Division of Cardiovascular Devices

510(k) Number K090058