K051862

AUG 2 3 2005

YAHORNG
Ya Horng CO., LTD.
No. 35, Zsha Lun, Jon Zsha village,
Antin Shiang, Tainan, Taiwan, ROC
Tel: 886-6-5932201 Fax: 886-6-5935870
E-mail: lab@yahorng.com http:// www.yahorng.com

"510(k) Summary"

Submitter's Name:	YA HORNG Electronic Co., Ltd.
Address:	***No. 35, Zaha Lun, Jon Zsha Village, Antin Shiang, 745, Taiwan, ROC***
Telephone:	886-6-5932201
FAX:	886-6-5935870
Contact Person:	Dr. Jen, Ke-Min
Date Summary Prepared:	July 4, 2005
Proprietary Name:	PC Compatible Blood Pressure Monitor AK-4000TU, BP-410U, BP-410R ; Automatic Digital Wrist Blood Pressure Monitor BP-420U, BP-420R
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 :	*AMLUCK AUTOMATIC DIGITAL WRIST BLOOD PRESSURE MONITOR AK-3000 / AK-4000* 510(k) No: K012796

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 2 3 2005

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
CHINA (TAIWAN) 300

Re: K051862
Trade Name: Amluck Ya Horng PC Compatible Blood Pressure Monitor, AK-4000TU, BP-410U,BP-410R; and, Automatic Digital Wrist Blood Pressure Monitor, BP-420U, BP-420R
Regulation Number: 21 CFR 870.1130
Regulation Name: Noninvasive Blood Pressure Measurement System
Regulatory Class: II (two)
Product Code: DXN
Dated: July 4, 2005
Received: July 8, 2005

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); 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 (301) 594-4648. 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 (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

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

Enclosure

YAHORNG
Ya Horng CO., LTD.
No. 35, Zsha Lun, Jon Zsha village,
Antin Shiang, Tainan, Taiwan, ROC
Tel: 886-6-5932201 Fax: 886-6-5935870
E-mail: lab@yahorng.com http:// www.yahorng.com

Indications for Use

510(k) Number: K051862

Device Name: YA HORNG ELECTRONIC CO., LTD.

PC Compatible Blood Pressure Monitor AK-4000TU, BP-410U, BP-410R ;

Automatic Digital Wrist Blood Pressure Monitor BP-420U, BP-420R

- ***Indications for use:***

The YA HORNG PC Compatible Blood Pressure Monitor AK-4000TU, BP-410U, BP-410R; and Automatic Digital Wrist Blood Pressure Monitor BP-420U, BP-420R 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 wrist. The cuff circumference is limited to be 5.3" – 8.5".

- ***Note:***

BP-410R , BP-420R : Data Transmission: Connection to PC using RS232 cable.
AK-4000TU, BP-410U, BP-420U: Data Transmission: Connection to PC using USB cable

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 K051862