K051539
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AUG 5 - 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

3. SUMMARY OF SAFETY AND EFFECTIVENESS

(According to 21 CFR 807.92)

DATE OF SUBMISSION:	May 22, 2005
SUBMITTER:	General Manager, Mr. HSU, SHENG HSIUNG YA HORNG ELECTRONIC CO., LTD. No 35, Zsha Lun Jon Zsha Village, Antin Shiang, Tainan, CHINA (TAIWAN) 745 TEL: 886-6-5932201 FAX: 886-6-5935870
ESTABLISHMENT REGISTRATION NO:	3001147827
OFFICIAL CONTACT:	Dr. JEN, KE-MIN ROC CHINESE-EUROPEAN INDUSTRIAL RESEARCH SOCIETY NO 58, FU-CHIUN ST. HSIN-CHU CITY, CHINA (TAIWAN) 30067 TEL: 886-3-5208829 FAX:886-3-5209783
TRADE NAME:	TRICOT BLOOD PRESSURE CUFF
COMMON/USUAL NAME:	BLOOD PRESSURE CUFF
CLASSIFICATION NAME:	CUFF, BLOOD PRESSURE (CFR870.1120)
CLASSIFICATION PANEL:	CARDIOVASCULAR
PREDICATED DEVICE:	KTJ-20C GOLDEN HORSE MEDICAL EQUIPMENT (K010686)
INTENDED USE:	The TRICOT blood pressure cuff is used in conjunction with non-invasive blood pressure measurement systems by personnel properly trained. The device is non-sterile and is intended as a reusable multi-patient device for measuring one's blood pressure. It is available in child through large adult sizes

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Ya Horng Electronic Co.,Ltd.
c/o Dr. Jen Ke-Min
Official Correspondent
No.35, Zsha Lun, Jon Zsha Village
Antin Shiang, Tainan,
China Taiwan, 745

Re: K051539
Trade Name: Ya Horng Blood- Pressure Cuff, Tricot
Regulation Number: CFR 870.1120
Regulation Name: Blood Pressure Cuff
Regulatory Class: Class II (two)
Product Code: DXQ
Dated: June 6, 2005
Received: June 10, 2005

Dear Dr. Ke-Min:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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 (240) 276-0295. 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/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

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2. INDICATIONS FOR USE STATEMENT

Indications for Use

510(k) Number: ~~TBA~~ K051539

Device Name: YA HORNG ELECTRONIC CO., LTD.
BLOOD-PRESSURE CUFF, TRICOT

INTENDED USE

The TRICOT blood pressure cuff is used in conjunction with non-invasive blood pressure measurement systems by personnel properly trained. The device is non-sterile and is intended as a reusable multi-patient device for measuring one's blood pressure. It is available in child through large adult sizes.

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 K051539