510(k) Summary

K061760
p1/2

K-jump's Arm Blood Pressure Monitor, Model KP-7600 series.

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared

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AUG 14 2006

Date Prepared: June 16, 2006

Name of Device and Name/Address of Sponsor

Arm Blood Pressure Monitor, Model KP-7600 series
K-jump Health Co., Ltd.
No. 56 Wu Kung 5th Road
Wu Ku Industrial Park
Taipei Hsien, Taiwan
Phone: +886 2 2299 1378 Facsimile: +886 2 2299 1386
Contact person: Danny Wang
Email: danny.wang@kjump.com.tw

Common or Usual Name:	Blood Pressure Monitor
Classification Name:	System, Measurement, Blood Pressure, Non-invasive
Predicate Device:	K-jump Health Co., Ltd. Arm Blood Pressure Monitor Models KP-6821A & KP-6822A series

Intended Use

The Arm BPM is intended to measure the systolic, diastolic, and pulse rate (heart rate) by using an inflating cuff which is wrapped around the upper arm. The device is indicated for use in adults.

Technological Characteristics

The Arm BPM is designed to measure the systolic, diastolic, and pulse rate (heart rate) of an individual. The device consists of an inflatable cuff that is wrapped around the upper arm and held in place with Velcro™, a Dot-matrix LCD display, a semiconductor sensor, an internal air pump, a battery power or ac/dc power source, and keys for operation.

Performance Data

In addition to the conformity standards, ANSI/AAMI SP10:2002 *Manual, Electronic or Automated Sphygmomanometers*, of the predicate device. This Arm BPM also complies with the electrical safety standards 60601-1 *Medical Electrical Equipment- Part 1: General Requirements For Safety* & 60601-1-2:2001 *Medical Electrical Equipment- Part 1-2: General Requirements For Safety- Collateral Standard: Electromagnetic Compatibility- Requirements and Tests.*

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 14 2006

K-Jump Health Co., Ltd.
c/o Mr. Danny Wang
Quality Representative
No. 56 Wu Kung 5th Rd.,
Taipei Hsien, Taiwan 248

Re: K061760
Trade/Device Name: Arm Blood Pressure Monitor, Model KP-7600
Regulation Number: 21 CFR 870.1130
Regulation Name: Non-Invasive Blood Pressure Measurement System
Regulatory Class: Class II
Product Code: DXN
Dated: July 21, 2006
Received: August 1, 2006

Dear Mr. Wang:

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) 276-0120. 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 (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

K061760

Indications for Use Statement

510(k) Number (if known): _____

Device Name:
Arm Blood Pressure Monitor model KP-7600 series

Indications for Use:
The Arm BPM is intended to measure the systolic, diastolic, and pulse rate (heart rate) by using an inflating cuff which is wrapped around the arm. The device is indicated for use in adults.

Prescription Use _____ Over-The Counter Use √
(Per 21 CFR 801 Subpart D) OR (21 CFT 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 K061760