ATTACHMENT 4 APR 2 1 2005

510(k) Summary K043531

K-jump's Arm Blood Pressure Monitor, Models KP-6821A, KP-6822A series.

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

Daniel Tseng
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

Date Prepared: December 9, 2004

Name of Device and Name/Address of Sponsor

Arm Blood Pressure Monitor, Models KP-6821A and KP-6822A

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: Daniel Tseng

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-6821, KP-6822

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 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 of the predicate device, this Arm BPM also complies with EN60601-1 (LVD test).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 21 2005

K-Jump Health Co., Ltd.
c/o Mr. Daniel Tseng
President and CEO
No.56 Wu Kung 5th Road
Wu Ku Industrial Park
TaiPei Hsien
TAIWAN

Re: K043531
Trade Name: Arm Blood Pressure Monitor, Models, KP-6821A and KP-6822A
Regulation Number: 21 CFR 870.1130
Regulation Name: Blood Pressure Monitor
Regulatory Class: Class II
Product Code: DXN
Dated: December 09, 2004
Received: December 21, 2004

Dear Mr. Tseng:

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

Sincerely yours,

Donna R. Lochner

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

Enclosure

ATTACHMENT 2

Indications for Use Statement

510(k) Number (if known): K043531

Device Name:
Arm Blood Pressure Monitor models KP-6821A, KP-6822A

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 upper arm. The device is indicated for use in adults.

Prescription Use _____ Over-The Counter Use ___V___
(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)

Mina R. Vachuska
(Division Sign-Off)
Division of Cardiovascular Devices

Concurrence of CDRH, Office of Device Evaluation (ODE)

510(k) Number K043531