K014204

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510(k) SUMMARY

K-Jump's Arm Blood Pressure Monitor, Models KP-6821 and KP-6822 series

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

MAR 5 2002

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K-Jump Health Co., Ltd.
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Taiwan
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Date Prepared: November 5, 2001

Name of Device and Name/Address of Sponsor

Arm Blood Pressure Monitor, Model KP-6821 and KP-6822

K-Jump Health Co., Ltd.
No. 56 Wu Kung 5th Road
Wu Ku Industrial Park
Taipei Hsien
Taiwan
Phone: 011 886 2 22991378
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Contact Person: Daniel Tseng

Common or Usual Name	Blood Pressure Monitor
Classification Name	System, Measurement, Blood Pressure, Non-Invasive
Predicate Device	I. A & D Engineering Inc. Arm Blood Pressure Monitor Model UA-779 II. K-Jump Health Co., Ltd. Wristwatch Blood Pressure Monitor Model KP-6120

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 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 arm and held in place with Velcro™, an LCD display, a semiconductor sensor, an internal air pump, a battery power source, and keys for operation.

Performance Data

The Arm BPM complies with EN 60601-1-2 (1993); EN 55011 (1991), IEC 801-2 (1991); IEC 801-3; EN 1060-1 and EN 1060-3 and the AAMI/ANSI SP10A-1996 standard. "Electronic or Automatic Sphygmomanometer."

K-Jump conducted a clinical trial in accordance with the ANSI/AAMI SP10A-1996 "Electronic or Automatic Sphygmomanometer" standard. One hundred patients had their blood pressure and heart rate tested with both an Ausculatory Mercurial Sphygmomanometer and the Arm BPM.

Substantial Equivalence

The Arm BPM is substantially equivalent to the A & D Engineering Inc.'s Arm BPM Model UA-779 and K-Jump's WristWatch BPM Model 6120. The Arm BPM and its predicate device are all noninvasive blood pressure monitors. Both the Arm BPM and A & D's Arm BPM take readings from the Upper Arm using the oscillometric method. The Arm BPM and A & D UA-779 have the same intended use, principles of operation and virtually identical technological characteristics. With the exception of minor variations in pressure measurement ranges, minimum operational relative humidity, minimum storage temperature and memory capacity, the devices are technologically identical. These minor differences do not raise any new issues of safety or effectiveness because both devices comply with the AAMI/ANSI SP10A-1996 standard "Electronic or Automated Sphygmomanometer.". Thus, the Arm BPM is substantially equivalent to the A & D's UA-779 and the WristWatch BPM. Further, the Arm BPM substantial equivalence is demonstrated by conformance to the ANSI/AAMI SP10A-1996 standard.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 5 2002

K-Jump Health Co., Ltd.
c/o Mr. Jonathan S. Kahan, Esq.
Regulatory Counsel
Hogan & Hartson L.L.P.
555 Thirteenth Street, N.W.
Washington, DC 20004

Re: K014204
Trade Name: Arm Blood Pressure Monitor, Models KP-6821, KP-6822
Regulation Number: 21 CFR 870.1130
Regulation Name: Non-Invasive Blood Pressure Measurement System
Regulatory Class: Class II (two)
Product Code: DXN
Dated: December 21, 2001
Received: December 21, 2001

Dear Mr. Kahan:

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 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained 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.
Acting Director
Division of Cardiovascular
and Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Attachment 14

Indications for Use Form

510(k) Number (if known): _____

Device Name: **K-JUMP Health Co., Ltd. Arm Blood Pressure Monitor, Models KP-6821 and KP-6822 series**

Indication for Use:

The K-Jump Arm Blood Pressure Monitor, Model KP-6821 AND KP-6822 are 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.

(PLEASE DO NOT WRITE BELOW THIS LINE---CONTINUE ON ANOTHER PAGE IF NEEDED)

_____ _____ _____ _____

_____Concurrence of CDRH, Office of Device Evaluation (ODE)

Division of Cardiovascular & Respiratory Devices
510(k) N 1/20/14 2014

Prescription Use_____ OR Over-The-Counter Use_____

(Per 21 C.F.R. 801.109)