NOV 21 2002

510(k) Summary

K022916

K-JUMP'S MODELS KP-6210 AND KP-6211

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

Daniel C.M. Tseng
K-jump Health Co., Ltd.
No. 56 Wu Kung 5th Road
Wu Ku Industrial Park
Taipei Hsien, Taiwan 248
Phone: + 886 2 22991378
Facsimile: + 886 2 22991386

Contact Person: T.T. Lin, Director

Date Prepared: September 2, 2002

Name of Device and Name/Address of Sponsor

Blood Pressure Monitor SmartlogiC models KP-6210 and KP-6211

K-jump Health Co., Ltd.
No. 56 Wu Kung 5th Road
Wu Ku Industrial Park
Taipei Hsien, Taiwan 248
Phone: + 886 2 22991378
Facsimile: + 886 2 22991386

Common or Usual Name

Blood Pressure Monitor

Classification Name

System, Measurement, Blood Pressure, Non-Invasive

Predicate Devices

I. K-jump Health Co., Ltd.
Wristwatch BPM model KP-6120

II. Rossmax International Co., Ltd.
SmartInflate CardioPro model 1000i and model 3000i

Intended Use

The K-jump's SmartlogiC models KP-6210 and KP-6211 are intended to be used for the measurement of the systolic, diastolic, and pulse rate (heart rate) by using an inflating cuff that is wrapped around the wrist. The devices are indicated for use in adults.

Technological Characteristics

The devices are electronic blood pressure monitors with LCD displays. The devices were designed to measure the blood pressure of the systolic, diastolic, and pulse rate by using an inflating cuff. K-jump's models KP-6210 and KP-6211 have the same intended use and fundamental scientific technology as the previously cleared model KP-6120. The primary changes are: (1) the systolic, diastolic blood pressure, and pulse rate are measured during deflation of the cuff in cleared model KP-6120 and during inflation of the cuff in new models KP-6211 and KP-6210; (2) all of the readings are displayed on subsequent screens of the LCD display in cleared model KP-6120 and on one LCD screen in new models KP-6211 and KP-6210; and (3) small differences in their blood pressure measurement ranges, operational temperature and humidity, storage temperature and humidity, and number of memories.

Performance Data

The Blood Pressure Monitor SmartlogiC models KP-6210 and KP-6211 comply with EN 60601-1-2 (1993); CISPR11 (1993) Class B; IEC 801-2 (1991); IEC 801-3 (1984); and the AAMI/ANSI SP10A-1996.

Substantial Equivalence

The devices are substantially equivalent to K-jump's Wristwatch Blood Pressure Monitor model KP-6120 and Rossmax SmartInflate CardioPro model 1000i and model 3000i. The Blood Pressure Monitor SmartlogiC models KP-6210 and KP-6211 have the same intended use and similar indications and principles of operation. With the exception of small differences in their blood pressure measurement ranges, operational temperature and humidity, storage temperature and humidity, and number of memories, models KP-6211 and KP-6210 are technologically identical to their predicate devices, K-jump's Wristwatch Blood Pressure Monitor model KP-6120 and Rossmax SmartInflate CardioPro model 1000i and model 3000i. The minor technological differences do not raise any new issues of safety or effectiveness. Models KP-6120, KP-6210, and KP-6211 all share the same intended use and operate using the same fundamental technology.

Furthermore, the devices comply with the AAMI/ANSI SP10A-1996 standard in its entirety. Thus models KP-6210 and KP-6211 are substantially equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 21 2002

K-jump Health Co., Ltd.
c/o Mr. Jonathan S. Kahan, Esq.
Regulatory Counsel
Hogan & Hartson L.L.P.
555 Thirteenth St., N.W.
Washington, DC 20004-1109

Re: K022916
Trade Name: Blood Pressure Monitor SmartlogiC Models KP-6210 and KP-6211
Regulation Number: 21 CFR 870.1130
Regulation Name: Non-invasive Blood Pressure Measurement System
Regulatory Class: Class II (two)
Product Code: DXN
Dated: October 24, 2002
Received: October 24, 2002

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.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Form

510(k) Number (if known): K022916

Device Name: **Blood Pressure Monitor SmartlogiC models KP-6210 and KP-6211**

Indications for Use:

The Blood Pressure Monitor SmartlogiC models KP-6210 and KP-6211 are intended to measure the blood pressure of the systolic, diastolic, and pulse rate by using an inflating cuff. The devices are 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) Number K022916

Prescription Use _____ OR Over-The-Counter Use ✓
(Per 21 C.F.R. § 801.109)

(Optional Format 1-2-96)