K032492
1 of 3

SEP - 9 2003

510(k) Summary

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

Mr. C.M. Daniel Tseng
K-jump Health Co., Ltd.
No. 56 Wu Kung 5th Road
Wu Ku Industrial Park
Taipei Hsien
Taiwan
Phone: + 886 2 22991378
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Date Prepared: August 11, 2003

Name of Device

Wristwatch Blood Pressure Monitor Model KP-7000

Name/Address of Sponsor

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

Common or Usual Name

Wrist Blood Pressure Monitor

Classification Name

Class II § 870.1130; System, Measurement, Blood Pressure, Non-Invasive

Predicate Device

I. K-jump Health Co., Ltd.'s Wristwatch BPM Blood Pressure Monitor Model KP-6120.
II. MicroLife's Wrist Watch Blood Pressure Monitor Model BP-3BU1-3.

Intended Use/Indications for Use

The device is intended to measure the systolic and diastolic blood pressure and pulse rate (heart rate) by using an inflating cuff. The device is indicated for use with adults.

Technological Characteristics

The device is an electronic blood pressure monitor. The device consists of an inflating cuff, a LCD display, a bellows sensor, an internal air pump, a leakage valve, an exhaust valve, a battery power resource, and keys for operation.

Performance Data

The Wristwatch Blood Pressure Monitor Model KP-7000 complies with the following FDA-recognized consensus standards, to the extent that these standards are applicable to this device:

- AAMI/ANSI SP10 (1992 / A1:1996);
- IEC 60601-1-1 (2000); and
- IEC 60601-1-2 (2002).

The KP-7000 also complies with the following additional standards:

- EN61000-4-2 (1995); and
- EN61000-4-3 (2002).

In accordance with AAMI/ANSI SP10, a clinical trial also was performed to verify the accuracy of in-vivo measurement. The results demonstrate that the KP-7000 accurately measures the patient's blood pressure and pulse rate.

Substantial Equivalence

The KP-7000 has the same intended use and indications for use as K-Jump's Wristwatch Blood Pressure Monitor Model KP-6120 and MicroLife's Model BP-3BU1. The KP-7000 has the same technological characteristics as the the KP6120 except: (1) that the KP-7000 uses a bellows sensor; (2) the KP-7000 has a lower maximum storage temperature; and (3) the KP-7000 displays blood pressure

and heart rate on the same screen simultaneously rather than on subsequent, alternating screens. Microlife's Model BP-3BU1 also uses a bellows sensor and has the same maximum storage temperature as the KP-7000. Thus, the minor differences between the KP-7000 and the predicate devices are not new technological characteristics for wrist watch blood pressure monitors. The modification of the device's LCD display was made for user convenience. Therefore, these minor technological differences do not raise any new questions of safety or effectiveness. Accordingly, the KP-7000 is substantially equivalent to its predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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K-Jump Health Co., Ltd
c/o Mr. Jonathan S. Kahan
Hogan & Hartson L.L.P.
555 Thirteen Street, N.W.
Washington, D.C. 20004-1109

Re: K032492
Trade Name: Wristwatch Blood Pressure Monitor Model KP-7000
Regulation Number: 21 CFR 870.1130
Regulation Name: Non-invasive blood pressure monitor
Regulatory Class: Class II (two)
Product Code: DXN
Dated: August 12, 2003
Received: August 12, 2003

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.

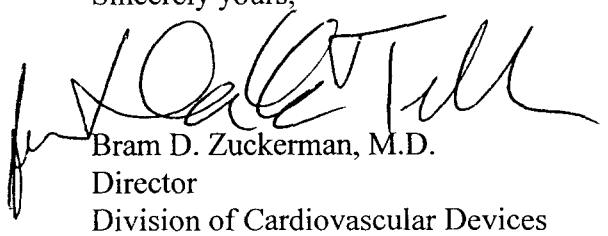
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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), please contact the Office of Compliance at (301) 594-4646. 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,



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

Enclosure

Indications for Use Statement

510(k) Number (if Known): K032492

Device Name: Wristwatch Blood Pressure Monitor Model KP-7000

Indication for Use:

The KP-7000 is intended to measure the systolic and diastolic blood pressure and pulse rate (heart rate) by using an inflating cuff which is wrapped around the wrist. It 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)

Prescription Use _____ OR Over-The-Counter Use X
(Per 21 C.F.R. 801.109) (Optional Format 1-2-96)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K032492