JUN 21 2007

EXHIBIT 11

510(k) Summary

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 22991378
Facsimile: + 886 2 22991386

Date Prepared: Feb. 14, 2007

Name of Device and Name/Address of Sponsor

Digital Forehead Thermometer, Model KD-2200

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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Contact Person : Danny Wang

Common or Usual Name	Clinic Thermometer
Classification Name	Class II §880.2910 Clinical Electronic Thermometer
Predicate Device	Up-grade Forehead Thermometer, K#032362, Medisim Ltd.

Intended Use/Indications for Use

The devices are intended to measure the human body

temperature using the forehead as measurement site. It can be used with adult or pediatric patients.

Technology Characteristics

The Digital Forehead Thermometer, Model KD -2200, consists of a probe with thermister sensor and stainless steel plate, a PC board with ASIC circuits, a LCD display, a plastic main body, an ON/OFF power key, a buzzer and two AAA type batteries for the determination of human body temperature. The tip of probe is made with a thermister sensor and stainless steel plate which may sense the temperature changing. The electronic signal was transferred to ASIC circuit on PC board through sensor of probe. The LCD displays the predictive temperature or last temperature recorded and warning information during measurement.

Performance Data

The Digital Forehead Thermometer, Model KD-2200 complies with the ASTM E1112-00(Reapproved 2006) "Electronic Thermometer for Intermittent Determination of Patient Temperature" standard, EN 60601-1-2 (2001) and EN 60601-1(1997).

Substantial Equivalence

The device is substantially equivalent to Up-grade Forehead Thermometer, K#032362. The device is share the same intended use an indication for use with the exception of small differences in their temperature measurement ranges, minimum operational temperature and humidity, minimum storage temperature and humidity, both devices are technologically identical.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Danny Wang
Quality Representative
K-jump Health Company, Limited
No. 56 Wu Kung 5th Road
Wu Ku Industrial Park, Taipei Hsien
TAIWAN 248

JUN 21 2007

Re: K070491
Trade/Device Name: Digital Forehead Thermometer, Model KD-2200
Regulation Number: 21 CFR 880.2910
Regulation Name: Clinical Electronic Thermoter
Regulatory Class: II
Product Code: FLL
Dated: June 15, 2007
Received: June 18, 2007

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) 276-0115. 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,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K070491

EXHIBIT A

Indications for Use

510(k) Number (if Known):_____

Device Name: Digital Forehead Thermometer, Model KD-2200

Indication for Use:

The Digital Forehead Thermometer, Model KD-2200 is intended to measure the human body temperature using the forehead as measurement site. It can be used with adult or pediatric patients.

(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**_____√_____
(Per 21 C.F.R. 801.109)

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(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K070491