EXHIBIT 1

510(k) SUMMARY

FEB 25 2011

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

The assigned 510(k) number is: K102947

1. Submitter's Identification:

K-jump Health Co., Ltd.
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Wu Ku Industrial Park
Taipei Hsien, 248, Taiwan
Tel: +886-2-22991378
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Contact: Mr. Jason Cheng
Date Summary Prepared: September 30, 2010

2. Name of Device:

Non-Contact Infrared Thermometer, Model KI-8280

Regulation Number: 21 CFR 880.2910
Regulation Name: Thermometer, Electronic, Clinical
Regulatory Class: II
Product Code: FLL

3. Predicate Device Information:

- K080759, ThermoFlash LX-26, JXB Co., Ltd., Guangzhou, China

4. Device Description:

The Non-Contact Infrared Thermometer, Model KI-8280, uses infrared sensor

(thermopile) to detect the radiated infrared energy emitted by the objects, solid, liquid or gas. The intensity of the emitted energy depends on the temperature of the object and the infrared sensor can recognize it to transfer to the proper electronic signal. The electronic signal can be processed in the subject device to convert to the temperature reading. Therefore, the subject device is able to measure the temperature of a person by the energy the person emits. The predicate device, JXB Thermoflash, use the same detection principle to measure the patient's temperature.

The subject device also use the focusing design to collect the infrared emitted from nearby area of object surface. This mechanism make the subject device have the ability to detect the object surface temperature in the distance of 3-8cm. The subject device intended to detect the temperature of patients. The temperature is converted to the oral temperature. The temperature reading shown in the device display after measuring is the patient's oral temperature.

The compact, small and light-weight design, the K–jump Health Co, Ltd. Non-Contact Infrared Thermometer, Model KI-8280, enables to provide safe and reliable results and offers a very good clinical accuracy for human body temperature measurement.

5. Intend Use:

The non-contact infrared thermometer, Model KI-8280, can measure body temperature for infants and adults without contact to human body. It can be used by consumers in household environment and doctor in clinic as reference.

6. Comparison to Predicate Devices:

The subject device is substantially equivalent to the predicate devices, K080759, ThermoFlash LX-26. The substantial equivalence chart is provided as follows:

Characteristics	K-jump Device (Subject Device)	ThermoFlash LX-26 JXB Co., Ltd. K#080759
Measurement method	Infrared radiation detection	Infrared radiation detection
Measuring Range	Forehead Mode: 32.2℃~43.3℃(90.0°F~109.9°F) Surface Mode:	In body mode: 32°C – 42.9°C (90°F – 109°F) In Surface Temp mode: 0°C ~

	0.0℃~100.0℃(32℉~212℉)	60°C (32°F to 140°F)
Display Resolution	0.1℃ (0.1℉)	0.1℃ (0.1℉)
C/F Switchable	Yes	Yes
Measuring accuracy	Forehead Mode: ±0.2℃(0.4℉) Surface Mode: ±1℃(1.8℉)	±0.2℃(0.4℉) range from 36 -39.0℃ (93.2-102.2℉) ±0.3℃(0.5℉) range from 34 ~ 35.9℃(93.2~96.6℉) & 39 ~ 42.5℃(102.2~108.5℉)
Display	LCD display	LCD display
Measurement Distance	3 - 8 cm	5 – 8 cm
Key	Two button (On/Off, Memory)	Four button (measuring, Menu, Setting*2)
Memory	10 sets	32 sets
Power source	Two 1.5V AAA batteries	Two 1.5V AA batteries
Low battery Indication	Replace the battery if the low battery indication appears	Replace the battery if the low battery indication appears
Waterproof	No	No
Dimension	138X90X45 mm	196x150x50 mm
Weight	125g (including batteries)	220g
Operating condition	10℃ ~40℃ (50.0 ~ 104℉), < 95% RH, non-condensing	10℃ ~ 40℃ < 85% RH

7. **Discussion of Non-Clinical Tests Performed for Determination of Substantial Equivalence are as follows:**

The following performance testing was conducted:

- The Non-Contact Infrared Thermometer, KI-8280, is complied with voluntary standards includes ASTM E1965 and EN 12470-5.
- The recognized consensus standards for safety of medical electrical equipment: IEC 60601-1 with amendments for safety and IEC 60601-1-2 for electromagnetic compatibility are complied.
- Guidance documents included the "FDA Guidance on the Content of Premarket Notification 510(k) submissions for Clinical Electronic Thermometers".

8. **Discussion of Clinical Tests Performed:**

The clinical performance test protocol and data analysis is followed the requirements the ASTM E 1965. The test report shows the patient's temperature readings difference between digital thermometer and the subject device, KI-8280, are within acceptable range. It can conclude that the Non-Contact Infrared Thermometer, KI-8280, is acceptable to measure patient's temperature

9. Conclusions:

Non-Contact Infrared Thermometer, Model KI-8280, has the same intended use and similar characteristics as the predicate device. Moreover, the subject device demonstrates product safety by successful completion of testing to the IEC60601-1 standard and electromagnetic standard, IEC 60601-1-2. The performance test demonstrates the KI-8280 meets the ASTM E1965 and EN 12470-5 standards and concludes that any differences in their characteristics do not rise any safety and effectivness issues.

From the above information we conclude the the subject device, KI-8280, is substantially equivalent to the predicate devices, ThermoFalsh LX-26.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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FEB 25 2011

Re: K102947
Trade/Device Name: Non-Contact Infrared Thermometer, Model KI-8280
Regulation Number: 21 CFR 880.2910
Regulation Name: Thermometer, Electronic, Clinical
Regulatory Class: II
Product Code: FLL
Dated: February 16, 2011
Received: February 18, 2011

Dear Mr. Cheng:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

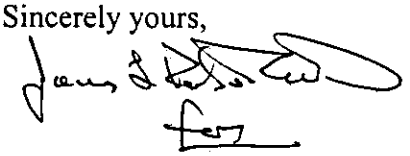
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



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Enclosure

EXHIBIT B

Indications for Use Statement

510(k) Number (if known): K102947

Device Name: Non-Contact Infrared Thermometer, Model KI-8280

Indications for Use:

Non-Contact Infrared Thermometer, Model KI-8280, can measure body temperature for infants and adults without contact to human body. It can be used by consumers in household environment and doctor in clinic as reference.

Prescription Use _____ (Per 21 CFR 801 Subpart D) OR Over-The Counter Use ___x___ (21 CFT 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

2/25/11

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K102947