EXHIBIT 1

510(k) SUMMARY

APR - 9 2010

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: K092335

1. Submitter's Identification:

K-jump Health Co., Ltd.
No. 56 Wu Kung 5th Road
Wu Ku Industrial Park
Taipei Hsien, 248, Taiwan
Tel: +886-2-22991378
Fax: +886-2-22331386

Contact: Mr. Jason Cheng
Date Summary Prepared: July 31, 2009

2. Name of Device:

K-jump Health Co., Ltd. Peak Flow Meter, Model KN-9710

3. Common or Usual Name:

Peak Flow Meter [21 CFR 868.1860]

4. Predicate Device Information:

- K010009, Peak Flow Meter, Model KoKo Peak KP and KP+, PDS Health Products, Inc., U.S.A
- K040723, Peak Flow Meter with PEF and FEV1, Model PF-100, Microlife Intellectual Property GmbH, Switzerland

5. Device Description:

The Peak Flow Meter, KN-9710, uses hot wire on the thin film inside the air flow measurement tube. The hot wire will electrically heat up to a constant temperature. As air flow passes through the air flow measuring tube, the wires cool off, requiring extra electrical energy to heat up to the the constant temperature. The air flow sensor will instantly feed back a voltage to maintain temperature. And the proper proportion and evaluation of the peak flow rate and volume will be determined. The KN-9710 is a compact, small and light-weight designed portable handheld device that electronically measures the Peak Expiratory Flow (PEF) as will as the Forced Expiratory Volume in the first second of expiration (FEV1).

6. Intend Use:

The KN-9710 is intended for monitoring expiratory-breath function at home under direction of a physician or licensed health care professional. It measures the peak expiratory flow (PEF) and timed forced expiratory volumes for 1 second (FEV1) through its mouthpiece. This device can be used from 6-year-old children to adult patients for monitoring and managing of chronic respiratory conditions, especially asthma and COPD.

7. Comparison to Predicate Devices:

The subject device is substantially equivalent to the predicate devices, K010009, Model KoKo Peak KP and KP+. The substantial equivalence chart is provided as follows:

Characteristics	K-jump Device (Subject Device)	KoKo KP+, PDS Healthcare Product, USA, K#010009	PF-100 Microlife K#040723
Model No.	KN-9710	KoKo KP+	PF-100
Measurement method	Hot wire on the thin film	Cantilever beam	Rotating wing wheel
Maximum recorded flow rate	900 l/min	999 l/min	900 l/min
Maximum recorded volume	9.0 Liter	9.99 Liter	9.99 Liter
Volume measuring accuracy	±5% or ±0.1 L	±3.5% or ±0.1 L	±5% or ±0.1 L
Flow measuring accuracy	±10% or ±20 l/min	±5% or ±20 l/min	±10 or ±20 l/min
Test duration	1 to 2 seconds	1 to 2 seconds	1 to 2 seconds

Correction Factors	Altitude	None	None
# of Results stored	240 Tests	64 Tests	240 Tests
Storage medium	Non-volatile EEPROM	Non-volatile EEPROM	Non-volatile EEPROM
Time/Date	Real-time clock	Real-time clock	Real-time clock
User warnings			
Low battery	Yes	Yes	Yes
Memory low	No	No	No
Memory full	No	No	No
Alarm type	Yes	Yes	Yes
Color zones	3 zones (green, yellow, red)	3 zones (green, yellow, red)	Manually recorded in seperative "traffic light scheme"
Device configuration	Use device key	Use device display	Use device key
Display	LCD display	LCD display	LCD display
Power source	Two 1.5V AA batteries	Two 1.5 silver oxide batteries	Two 1.5 AAA batteries
Dimension	144X131X33mm	120X50X20mm	144X77X48mm
Weight	198g	82g	150g
Operating condition	10℃ ~40℃ (Altitude 0-1400m) 15℃ ~25℃ (Altitude 1400-3000m) 10% ~85% RH, non-condensing	10℃ ~ 38℃ 0% ~100% RH, non-condensing	10℃ ~ 40℃ 10% ~85% RH, non-condensing
Storage condition	-5℃ ~ 50℃ 10% ~85% RH, non-condensing	-20℃ ~ 60℃	-5℃ ~ 50℃ 10% ~ 90% RH, Non-condensing

8. <u>Discussion of Non-Clinical Tests Performed for Determination of Substantial Equivalence are as follows:</u>

The following performance testing was conducted:

- The KN-9710 electronic peak flow meter was tested at an independent laboratory, LDS Hospital (Salt Lake City, UT), using a precision waveform generator. The peak expiratoy (PEF) and forced expiratory volume in one second (FEV1) measurement from the KN-9710 were compared against the generated values. Both PEF and FEV1 values were well within the required ATS (ATS 1994 update) accuracy specification using the 24 standard waveforms and the 26 flow-time waveforms. Interdevice and intradevice variability testing demonstrated the KN-9710 to comply with all variability requirements. Our evaluation showed the KN-9710 met ATS (ATS 1994 update) monitoring device

recommendations for accuracy and precision in the measurement of PEF and FEV1.

- The recognized consensus standards for safety of medical electrical equipment: IEC 60601-1 for safety and IEC 60601-1-2 for electromagnetic compatibility are complied.

- The biocompability of KN-9710 is tested according to the guidance #G95-1. The cytotoxicity, skin sensitization and skin irritation test reports showed KN-9710 complied with the biological evaluation standard ISO 10993-1.

9. Discussion of Clinical Tests Performed:

Not Applicable. Determination of substantial equivalence is not based on assessment of clinical data.

10. Conclusions:

K-jump Health Co., Ltd. Peak Flow Meter, Model KN-9710, 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 device claims to meet the American Thoracic society (ATS 1994 update) recommendations. Performance test at LDS Hospital demonstrates the the KN-9710 meets the ATS (ATS 1994 update) standard recommendations.

From the above information we conclude the the subject device, KN-9710, is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

APR - 9 2010

Mr. Jason Cheng
Regulatory Affairs
K-jump Health Company, Limited
No. 56, Wu Kung 5th Road
Wu Ku Industrial Park
Taipei Hsien, 248
TAIWAN

Re: K092335
Trade/Device Name: K-jump Health Co., Ltd. Peak Flow Meter, Model KN-9710
Regulation Number: 21 CFR 868.1860
Regulation Name: Peak-Flow Meter for Spirometry
Regulatory Class: II
Product Code: BZH
Dated: April 2, 2010
Received: April 2, 2010

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,

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

EXHIBIT B

Indications for Use Statement

510(k) Number (if known): K092335

Device Name: K-jump Health Co., Ltd. Peak Flow Meter, Model KN-9710

Indications for Use:

K–jump Health Co, Ltd. Peak Flow Meter, Model KN-9710, is intended for monitoring expiratory-breath function at home under direction of a physician or licensed health care professional. It measures the peak expiratory flow (PEF) and timed forced expiratory volumes over 1 second (FEV1). This device can be used from 6-year-old children to adult patients for monitoring and managing of chronic respiratory conditions, especially asthma and COPD.

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

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

510(k) Number: K092335