EXHIBIT 1

510(k) SUMMARY

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: K083256

JUN 26 2009

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: October 6, 2008

2. Name of Device:

K-jump Health Co., Ltd. Ultrasonic Nebulizer System, Model KN-9210

3. Common or Usual Name:

Ultrasonic Nebulizer

4. Predicate Device Information:

- K051365, Compressor Nebulizer System, Model KN-9321, K-jump Health Co., Ltd, Taiwan
- K974379, ULTRANEB, Bremed Italia s.r.l., Italy

5. Device Description:

The KN-9210 uses the ultrasound vibration technique in which a piezeoelectric ceramic installed as a generator of ultrasound wave when powered key pressed and system been powered on. The medicine solution on the semi-oval cup can be converted to mist through the water medium which propagated the ultrasound from resonator on the device. Then, a mini fan on the device drives the mist or aerosol through the air flow chamber and mouth piece installed on the top cover to the patient. The patient can use this aerosol for his/her respiratory therapy with two-safety valve installed on the mouthpiece which is standed on the top of drug ampoule.

The device consists of a piezeoelectric ceramic, a fan, a plastic body (including a top cover, a main body, a rear cover, an inlet filter, a filter cover, a nebulization chamber and an air-flow chamber), a medicine cup, a printed circuit board with electronic components, a DC socket, an AC adapter power source (or a rechargeable battery assembly as an optional power source), and a key for ON/OFF operation.

6. Intend Use:

The KN-9210 is intended to be a source of ultrasonic nebulizer which, when driven by its built-in ceramic resonator and fan, nebulizes specific inhalable drugs for inhalation by patient for treatment of respiratory disorders, such as allergies, asthma, cystic fibrosis, COPD, etc. It can be used with adult and pediatric patients.

7. Comparison to Predicate Devices:

The subject device is substantially equivalent to the predicate devices, K#051365, Compressor Nebulizer System, Model KN-9321 on Nebulizer materials and to the K#974379, ULTRANEB Ultrasonic Nebulizer, Bremed Italia s.r.l. on Ultrasonic Nebulizer. These predicate devices were cleared with the same indication for use as K-jump device.

The substantial equivalence chart is provided as follows:

Characteristics	**K-jump Device (Subject Device)**	**Compressor Nebulizer System, Model KN-9321, K#051365, K-jump Health Co., Ltd.**
Main body	ABS Resin, POLYLAC PA-707, Supplier: CHI MEI CORPORATION	ABS Resin, POLYLAC PA-707, Supplier: CHI MEI CORPORATION
Air filter holder	ABS Resin, POLYLAC PA-707, Supplier: CHI MEI	ABS Resin, POLYLAC PA-707, Supplier: CHI MEI

	CORPORATION	CORPORATION
Filter	Polyurethane foam, K329, Supplier: Sanchian	Polyurethane foam, K329, Supplier: Sanchian
Top Cover	Polycardbonate L-1225Y, Supplier: Teijin Chemicals Ltd.	Polypropylene Resin Profax, 6331, Supplier: TAIWAN POLYPROPYLENE CO., LTD.
Nebulization Chamber	Polycardbonate L-1225Y, Supplier: Teijin Chemicals Ltd.	Polypropylene Resin Profax, 6331, Supplier: TAIWAN POLYPROPYLENE CO., LTD.
Air-Flow Chamber	Polycardbonate L-1225Y, Supplier: Teijin Chemicals Ltd.	N/A
Drug Ampoule	Polyehtylene Terphthalate, A-PET, Supplier: Dong Guan Sen Yuan Environmental Plastic Co., Ltd.	Polypropylene Resin Profax, 6331, Supplier: TAIWAN POLYPROPYLENE CO., LTD.
Mouth piece	Polycardbonate L-1225Y, Supplier: Teijin Chemicals Ltd.	Polypropylene Resin Profax, 6331, Supplier: TAIWAN POLYPROPYLENE CO., LTD.
Mask	PVC Compound 65PHR, Supplier:Jieh-Ming Plastics Mfg Co., Ltd.	PVC Compound 65PHR, Supplier:Jieh-Ming Plastics Mfg Co., Ltd.

Characteristics	**K-jump Device (Subject Device)**	**ULTRANEB, Bremed Italia s.r.l., K#974379**
Model No.	KN-9210	ULTRANEB
Nebulization Type	Ultrasonic	Ultrasonic
Dimension	85X56X130mm (3.35"X2.20"X5.12")	83X50X110mm (3.27"X1.97"X4.33")
Weight	0.437 lbs. (198g)	0.463 lbs. (210g)
Electrical Requirements	100-240 V/15VDC (with AC/DC switching adapter)50/60Hz, or 12 VDC Rechargeable battery(optional), or Car connection cable (optional)	100-240 V/15VDC (with AC/DC switching adapter)50/60Hz, or 12 VDC Rechargeable battery(optional), or Car connection cable (optional)
Power consumption	12 watts	12 watts
Power indicator	LED	LED
ON/OFF Switch	Push Button	Push Button
Filter	Inlet	Inlet
Mode of Operation	45min ON/45 min OFF	45min ON/45 min OFF
Safety valve on mouthpiece	Two-valve system	Two-valve system
Particle Size Range	0.5 to 5 microns	0.5 to 5 microns
Capacity	5 ml	5 ml
Mean Flow Rates	0.7 ml/min	0.7 ml/min

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

The following performance testing was conducted:

- The mean Mass Median Aerodynamic Diameter (MMAD), respirable fraction (% mass between 1 and 5 microns), total mass of medication delivered, and respirable mass (mass of drug between 1 and 5 microns) was measured. The nebulized particle size test was conducted in three medicines:
  - Anti-cholinergic bronchodilator: Atrovent;
  - Beta-agonist bronchodilator: Bricanyl;
  - Anit-inflammatory: Pulmicort

- The three commercially available disinfectants recommended by CDC and HICPAC are investigated in Cleaning/Disinfection Test.

- Biocompatibility Testing conducted on the Nebulizer Adult & Pediatric Masks, Mouthpiece and the components which contact the gas path of the patients:
  - Cytotoxicity Test
  - Rabbit Skin Irritation Test
  - Skin Sensitization Test

- Respiratory Devices Branch Required EMC, Electrical, Mechanical and Environmental Testing

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

Not Applicable

10. **Conclusions:**

K-jump Health Co., Ltd. Ultrasonic Nebulizer System, Model KN-9210 has the same intended use and similar characteristics as the predicate devices. Moreover, bench testing contained in this submission demonstrates that any differences in their technological characteristics do not raise any new questions of safety or effectiveness. Thus, the K-jump Health Co., Ltd. Ultrasonic Nebulizer System, Model KN-9210 is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 26 2009

Mr. Jason Cheng
Product Planning Specialist
K-Jump Health Company Limited
No. 56 Wu Kung 5th Road, Wu Ku Industrial Park
Taipei Hsien
China (TAIWAN) 248

Re: K083256
Trade/Device Name: Ultrasonic Nebulizer System, Model KN-9210
Regulation Number: 21 CFR 868.5630
Regulation Name: Nebulizer
Regulatory Class: II
Product Code: CAF
Dated: May 21, 2009
Received: May 22, 2009

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.

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/cdrh/mdr/ 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Susan Runner, D.D.S., M.A.
Acting 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): K083256

Device Name: K-jump Health Co., Ltd. Ultrasonic Nebulizer System, Model KN-9210

Indications for Use:

K-jump Health Co., Ltd. Ultrasonic Nebulizer System includes a DC powered ceramic resonator and a fan that provides a source of mist for home health care use. The device is used with a pneumatic nebulizer to convert certain inhaled drugs into an aerosol form for inhalation by a patient. The device can be used with adult or pediatric patients.

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

510(k) Number: K083256

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)

Concurrence of CDRH, Office of Device Evaluation (ODE)