JUL 2 2 2005

EXHIBIT #1

510(K) SUMMARY

This summary of 5l0(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA l990 and 21 CFR §807.92.

The assigned 5l0(k) number is: K051365

1. **Submitter's Identification:**

K-jump Health Co., Ltd.
No. 56 Wu Kung 5th Road
Wu Ku Industrial Park
Taipei Hsien
Taiwan
Tel: 011 886 2 22991378
Fax: 011 886 2 22331386

Date Summary Prepared: May 24, 2005

2. **Name of the Device:**

K-jump Health Co., Ltd. Compressor Nebulizer System, Model KN-9321.

Common or Usual Name:

Nebulizer Compressor with Nebulizer

3. **Predicate Device Information:**

K#031908, Med2000 SpA Nebulizer Compressors, Models P1 and P2, with Nebulizer, Med200 SpA, Padengne Sul Garda, Italy

4. **Device Description:**

The K–jump Health Co, Ltd. Compressor Nebulizer System, Model KN -9321, consists of a nebulizer and a DC powered piston-type compressor that generates compressed air. Small, light-weight and designed for convenience, the The K–jump Health Co, Ltd. Portable Nebulizer System, Model KN -9321 offers the user a choice of running off of AC power via a universal adapter or DC power via an optional 12 volt auto adapter, or an optional rechargeable battery pack. The device consists mainly of a motor drive piston compressor, a printed circuit board

and a switch. The circuit board does not incorporate a microprocessor but serves as a means to prevent double feed of power. The circuit board is not a part of the charging circuit for the battery pack.

Specifically, the device is made up of a DC pump assembly, a plastic body (including a top cover, a mina body, a rear cover, an inlet filter, a filter cover, an outlet filter and a cushion), a drug ampoule assembly (including a drug ampoule, a cap and a micronization cone), 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. The DC pump assembly consists of a motor, a motor housing, a cam, a bearing, a crank, a cylinder, two valves and a base for ampoule.

The nebulizer, which employs a venturi effect to convert the medication into a fine aerosol mist, is used either snapped directly onto the compressor outlet barb or with an optional extension tube. Providing a connection between the compressor outlet barb and the nebulizer bottom, the optional extension tube allows the user to place the compressor on a sturdy surface and to simply hold onto the nebulizer. The nebulizer is designed for single patient use and is reusable. The nebulizer with or without its tubing adapter is designed specifically for use only with the The K–jump Health Co, Ltd. Portable Nebulizer System, Model KN -9321. Use of the nebulizer, tubing or compressor with other compressors, nebulizer or tubing may product incorrect flow resulting in improper treatment.

The K–jump Health Co, Ltd. Compressor Nebulizer System, Model KN -9321 will be sold with a carrying bag, AC adapter (power supply) with power cord, the optional tubing with connectors, 5 packs of filters, one mouth-piece, one set of drug ampoule assembly and a user manual. Optional accessories which will be offered with this device are the car connection cable and re-chargeable battery pack.

5. Intended Use:

The K-jump Health Co., Ltd. Compressor Nebulizer System, Model KN-9321, includes a DC powered air compressor that provides a source of compressed air for home health care use. The compressor 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.

K–jump Health Co, Ltd. Compressor Nebulizer System, Model KN -9321, is a pneumatic nebulizer which, when driven by its built-in air compressor, nebulizes specific inhalable drugs for inhalation by a patient for treatment of respiratory disorders such as allergies, asthma, cystic fibrosis, COPD, etc. It can used with adult or pediatric patients.

6. Comparison to Predicate Devices:

The K–jump Health Co, Ltd. Compressor Nebulizer System, Model KN -9321, is substantially equivalent to the Med2000 Model, P1, P2 with Andyflow Nebulizer, K031908, Med2000 SpA. This predicate device was cleared with similar indications for use as our proposed subject device indications for use.

The substantial equivalence chart is provided as follows:

Table 1: Nebuilzer Compressor Comparison Chart

Characteristics	K-jump Device (Subject Device)	Med2000 Nebulizer Compressor with Andyflow Nebulizer K#031908
Model No.	KN-9321	P1
Compressor Type	Piston	Piston
Dimension	84.5X43.5X125mm(3.3"X1.7"X4.9")	153X120X60mm(6.0"X4.7""X2.4")
Weight	0.8 lbs. (345g)	1.1 lbs.
Electrical Requirements	100-240 VAC/15VDC (with AC/DC switching adapter)50/60Hz, or 12 VDC Rechargeable battery(optional), or Car connection cable (optional)	115 VAC/16VDC(with AC/DC adapter) 60Hz
Power consumption	12 watts	23 watts
Maximum compressor pressure	30 psig (with close system)	29 psig
Average Flow Rate	4.5 lpm@12 psi	6.0 lpm@14.7 psi
Power indicator	LED	No
ON/OFF Switch	Push Button	Rocker
Filter	Inlet and Outlet	Inlet only
Mode of Operation	20 min ON/40 min OFF	20 min ON/40 min OFF
Safety valve on mouthpiece	Two-valve system	Holes only

Table 2, below outlines similarities and differences between our nebulizer and the predicate device, as follows:

Table 2: Nebulizer Comparison Chart

Nebulizer Components	Med2000 SpA Andy Flow Model A1/C (K#031908)	K-jump Subject Device
Cup (lower nebulizer part)	Polypropylene Moplen RP34ON	Polypropylene Resin Profax, 6331
Top (Upper nebulizer part)	Polypropylene Moplen RP 34ON Colorant: PRISMA PE BLU 51955	Polypropylene Resin Profax, 6331 Colorant: No
Insert (Nozzle)	Polypropylene Moplen RP 34ON Colorant: MACOWAX Yellow CWK685	Polypropylene Resin Profax, 6331 Colorant: Blue 14043
Particle Size Range	0.5 to 5 microns	Same
Capacity	6 ml.	7 ml.
Mean Flow Rates	3.07 L/min	3.05 L/min

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

The following performance testing was conducted:

Aerosol Dose, Particle Size, Emitted Particulate and Volatile Organic Compound (VOC) Analysis under all combinations of the following:

- Aerosol and Flow Rate Testing
- Predicate Device Performance Comparison, using Cascade Impactor Method with Three Drugs (Albuterol Sulfate, Ipratropium Bromide and Cromolyn Sodium)
- Simulated Lifetime Performance Testing with Albuterol Sulfate
- Emitted Particulate and VOC Testing, the results conformed to EPA requirements of the PM 10 and PM 2.5 Standard
- Flow Rate Characterization Testing
- Biocompatibility Testing conducted on the Nebulizer Adult & Pediatric Masks, Ampoule, Micronization Cone, Ampoule Cap, Mouthpiece and Mask Adapter

- Cytotoxicity-ISO Elution Test (MEM Extract)
- Maximization Test for Delayed Hypersensitivity ISO)
- Subacute Repeated Dose Toxicity Study in Mice
- Salmonella Typhimurium Reverse Mutation Assay: Ames Test
- Intramuscular Implant Test (ISO)

-Biocompatibility Testing with Mouthpiece

1. Cell Growth Analysis via BCA-Staining
2. Irritation Test (Intracutaneous Reactivity)
3. Test for delayed –type hypersensitivity (Guinea-Pig Maximisation Test)

-Biocompatibility Testing with Mask

4. Cell Growth Analysis via BCA-Staining
5. Irritation Test (Intracutaneous Reactivity)
6. Test for delayed-type hypersensitivity (Guinea-Pig Maximisation Test)

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

8. Discussion of Clinical Tests Performed:

Not applicable

9. Conclusions:

K-jump Health Co., Ltd. Compressor Nebulizer System, Model KN-9321 has the same intended use and similar characteristics as the predicate device. Moreover, bench testing contained in this submission demonstrates that any difference in their technological characteristics do not raise any new questions of safety or effectiveness. Thus, the K-jump Health Co., Ltd. Compressor Nebulizer System, Model KN-9321 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

JUL 2 2 2005

K-Jump Health Company, Incorporated
c/o Susan D. Goldstein-Falk
MDI Consultants, Incorporated
55 Northern Blvd., Suite 200
Great Neck, New York 11021

Re: K051365
Trade/Device Name: Compressor Nebulizer System, Model KN-9321
Regulation Number: 21 CFR 868.5630
Regulation Name: Nebulizer
Regulatory Class: II
Product Code: CAF
Dated: May 24, 2005
Received: May 25, 2005

Dear Ms. Goldstein-Falk:

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) 276-0120. 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/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

Exhibit B

510(k) Number (if known): _____

Device Name: K–jump Health Co, Ltd. Compressor Nebulizer System, Model KN -9321

Indications For Use:

K–jump Health Co, Ltd. Compressor Nebulizer System includes a DC powered air compressor that provides a source of compressed air for home health care use. The compressor 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.

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

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

_____ _____ _____ _____ _____ _____

Concurrence of CDRH, Office of Device Evaluation (ODE)

Ann Gleeham

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

510(k) Number: K051365