BESMED HEALTH BUSINESS CORP.
NO. 5, LANE 116, WU-KONG 2nd RD., WU-KU INDUSTRIAL PARK, TAIPEI TAIWAN
TEL: +886 2 2290 3959 FAX: +886 2 2299 9076 www.besmed.com

K091272

" 510k SUMMARY"

NOV 10 2009

Submitter's Name: ***Besmed Health Business Corp.***
No.5, Lane 116, *Wu-Kong 2nd Road, Wu-Ku Industrial Park, Taipei Hsien, 24890, Taiwan*

Date summary prepared: April 10, 2009

Device Name:

Proprietary Name: BESMED Jet Nebulizer Bottle Set,
Model PN-1128E

Common or Usual Name: Jet Nebulizer
Classification Name: CAF, Class II
21 CFR 868.5630

Indications for Use:

The BESMED Jet Nebulizer Bottle Set is used to administer various aerosol treatments to adult and pediatric patients in both the homecare and hospital settings.
Its use is indicated whenever a physician or healthcare professional administers or prescribes medical aerosol products to a patient using a Small Volume Nebulizer.

Device Description:

The MAXHEALTH Air Nebulizer is intended to spray liquid medications in aerosol fonn into gases that re directly delivered to the patient.

Performance Testing:

1) Nebulizer Characterization Study: USFDA 2lCFR part 58
2) Biocompatibility Test:
• Cytotoxicity study - ISO 10993·5
• Skin irritation study - ISO 10993-10
• Skin sensitization study - ISO 10993·10

Legally marketed device for substantial equivalence comparison:

HSINER Jet Nebulizer, (K052811)

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Comparison Table

Comparison Areas	Predicate Device	New Device
Manufacturer	Hsiner Co., Ltd.	Besmed Health Business Corp.
510K number	K052811	TBA
Device name	Jet Nebulizer	Jet Nebulizer Bottle Set
Model	HS- 31100	PN-1128
Similar:		
Intended for Use	The Jet Nebulizer is used to administer various aerosol treatments to adult and pediatric patients in both the homecare and hospital settings. This device is intended for use only with FDA approved drugs upon the specific direction by a physician. Its use is indicated whenever a physician or healthcare professional administers or prescribes medical aerosol products to a patient using a Small Volume Nebulizer.	SAME
Principle	Aerosolizes liquid into aerosol form by compressing air	SAME
Capacity of medication cup	6 ml	SAME
Particle size	< 5 micron	SAME
Accessories	Mouthpiece – 1 piece T-piece – 1 piece Corrugate tube – 1 piece Air tube – 1 piece	SAME

(continued)

Different:		
Dimension	7.9 x 4.1 (Tall x Diameter cm)	7.8 x 4.5 (Tall x Diameter cm)
Features	Novel appearance, compact structure, cabinet bulk, simple operation, convenient carrying	1. Provide non-oil lubrication single-cylinder piston pump for air pressure 2. Novel appearance, compact structure, cabinet bulk, simple operation, convenient carrying

Differences between the Legally Marketed Predicate Devices:

The BESMED Jet Nebulizer Bottle Set, PN-1128E is viewed as substantially equivalent to the predicate device: HSINER Jet Nebulizer, (K052811)

Except the different specifications, there are no significant differences that affect the safety or effectiveness of the intended device as compared to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

Dr. Ke-Min-Jen
Besmed Health Business
58 Fu-Chiun Street
Hsin Chu City
China (Taiwan) 300

NOV 1 0 2009

Re: K091272
Trade/Device Name: BESMED Jet Nebulizer Bottle Set, PN-1128E
Regulation Number: 21CFR 868.5630
Regulation Name: Nebulizer
Regulatory Class: II
Product Code: CAF
Dated: October 28, 2009
Received: October 28, 2009

Dear Dr. Jen:

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/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,

for

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

Indications for Use

510 (K) Number : K091272

Device Name: BESMED Jet Nebulizer Bottle Set, PN-1128E

Indications for Use:

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Prescription Use √ AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

L Schultheiss

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

510(k) K091272