K090730

510(k) Summary
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8-Sep-09

NOV 13 2009

Activaero America, Inc.
P.O. Box 351
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Official Contact: William Zimlich - CEO

Proprietary or Trade Name: AKITA JET

Common/Usual Name: Nebulizer systems

Classification Name: Nebulizer (Direct Patient Interface)
CAF – 868.5630

Predicate Devices: AKITA² APIXNEB - K072019 – Activaero
LC Sprint nebulizer – K060399 – PARI
AutoNeb – K935693 - Vortran

Device Description
The AKITA JET nebulizer and the AKITA JET nebulizer handset together constitute a multi-use, electronic nebulizer system designed to aerosolize liquid medications. The system includes and features:

- An electrically powered compressor which provides an air flow to the AKITA JET nebulizer handset.
- A nebulizer handset based upon the PARI LC Sprint, K060399
- Single patient, multi-use in the home setting
- Multiple patient, multi-use in the hospital and clinical settings
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- Nebulization only during inhalation phase
- Smart Card series for defined patient breathing patterns

Indications for Use
The AKITA JET is a nebulizer system that will be used with patients for whom doctors have prescribed medication (except pentamidine) for nebulization in the home care, nursing home, sub-acute institution, or hospital environment.

Patient Population
The AKITA JET is intended for patients 3 years and older who can coordinate breathing.

Environment of Use
Home care, nursing home, sub-acute institution, or hospital

Contraindications
None

To demonstrate substantial equivalence as well as safety and effectiveness a series of performance tests were done.

The predicate comparison is broken into several categories:

- General Attributes
  - Indications for Use
  - Patient Population
  - Environments of use
- Nebulizer performance
  - Particle characterization
  - PARI LC Sprint Reusable Nebulizer - K060399
- Delivery during inhalation
  - Activaero AKITA² APIXNEB K072019, Vortran AutoNeb – K935693
- Delivery based upon breathing patterns
  - Activaero AKITA² APIXNEB K072019
- Algorithm to program breathing patterns
  - Activaero AKITA² APIXNEB K072019
- Controlled inhalation flow
  - Activaero AKITA² APIXNEB K072019
- Use of programmable Smart Cards for setting inspiration and nebulization time
  - Activaero AKITA² APIXNEB K072019

For safety and effectiveness testing included:

- Performance of the AKITA JET system via Cascade Impactor testing
- VOC, $PM_{2.5}$ and Ozone testing
- Electrical safety, EMC, EMI, Mechanical and environmental testing

Differences Between Other Legally Marketed Predicate Devices

The AKITA JET system is viewed as substantially equivalent to the predicates.

There are no significant differences that affect the safety or effectiveness of the intended device as compared to the predicate devices.

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

Activaero America, Incorporated
C/O Mr. Paul E. Dryden
President
ProMedic, Incorporated
24301 Woodsage Drive
Bonita Springs, Florida 34134-2958

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Re: K090730
Trade/Device Name: Akita Jet
Regulation Number: 21 CFR 868.5630
Regulation Name: Nebulizer
Regulatory Class: II
Product Code: CAF
Dated: November 6, 2009
Received: November 9, 2009

Dear Mr. Dryden:

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,

for

Susan Runner, D.D.S., M.A.
Acting Division 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 Statement

510(k) Number: K090730 (To be assigned)

Device Name: AKITA JET

Indications for Use:

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Patient Population
The AKITA JET is intended for patients 3 years and older who can coordinate breathing.

Prescription Use XX (Part 21 CFR 801 Subpart D) **or** **Over-the-counter use __** (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)

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

510(k) Number: K090730