K072019

**Non-Confidential Summary of Safety and Effectiveness**



18-Sep-07

Activaero America, Inc.
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**Official Contact:** William Zimlich - CEO

**Proprietary or Trade Name:** AKITA² APIXNEB

NOV - 5 2007

**Common/Usual Name:** Nebulizer systems

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

**Predicate Devices:** I-neb Insight – K052941 – Profile / Respironics
ProDose – K030747 – Profile / Respironics
eFlow™ – K033833 – Pari
AutoNeb – K935693 - Vortran

**Device Description**

The AKITA² APIXNEB nebulizer and the handset together constitute a single patient, 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 AKITA² APIXNEB nebulizer handset.
- A nebulizer handset based upon the PARI e-Flow™, K033833, which uses piezoelectric vibration of a perforated stainless steel membrane (head) for the aerosol generation.
- Single patient use, reusable
- Nebulization only during inhalation phase
- Smart Card series for defined patient breathing patterns

**Indications for Use**

The AKITA² APIXNEB 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 AKITA² APIXNEB 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 as series of performance tests were done.

For substantial equivalence the predicate comparisons included:

- General Attributes
  - Indications for Use
  - Patient Population
  - Environments of use
  - Vortran AutoNeb – K935693, I-neb – K052941and **Pro***dose* AAD System – K030747
- Nebulizer performance
  - Particle characterization
  - Pari – eFlow™ - K033833
- Nebulization during inhalation
  - Vortran AutoNeb – K935693, I-neb – K052941and **Pro***dose* AAD System – K030747
- Delivery based upon breathing patterns
  - I-neb – K052941and **Pro***dose* AAD System – K030747
- Algorithm to program breathing patterns
  - I-neb – K052941and **Pro***dose* AAD System – K030747
  - *in vitro* data - Activaero
- Controlled inhalation flow
  - I-neb – K052941
- Use of programmable disc (Smart cards) for setting nebulization and delivery parameters
  - **Pro***dose* AAD System – K030747 and I-neb – K052941

For safety and effectiveness testing included:

- Performance of the AKITA² APIXNEB system
  - Flow performance
  - Trigger Pressure performance
  - On/Off performance
  - Nebulization Time performance
  - Time lag performance
  - Timing Parameters
  - Life Time test
  - Cleaning performance
  - Smart Card performance
  - Inhalation / Exhalation resistance
- VOC and $PM_{2.5}$ testing
- Electrical safety, EMC, EMI, Mechanical and environmental testing

**Differences Between Other Legally Marketed Predicate Devices**

The AKITA² APIXNEB 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
9200 Corporate Boulevard
Rockville MD 20850

NOV - 5 2007

Activaero America, Incorporated
C/O Mr. Paul Dryden
President
ProMedic, Incorporated
3460 Pointe Creek Court, # 102
Bonita Springs, Florida 34134

Re: K072019
Trade/Device Name: AKITA$^2$ APIXNEB
Regulation Number: 21 CFR 868.5630
Regulation Name: Nebulizer
Regulatory Class: II
Product Code: CAF
Dated: September 18, 2007
Received: September 20, 2007

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.

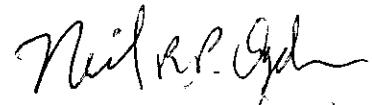
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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) 276-0115. 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. for
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:** K072019 (To be assigned)

**Device Name:** AKITA$^2$ APIXNEB

**Indications for Use:**

The AKITA$^2$ APIXNEB is a nebulizer system that will be used with patients for whom doctors have prescribed medication for nebulization in the home care, nursing home, sub-acute institution, or hospital environment.

The AKITA$^2$ APIXNEB 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: K072019