K080100

Non-Confidential Summary of Safety and Effectiveness

10-Jan-08

JUN 30 2008

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

Proprietary or Trade Name: Watchhaler

Common/Usual Name: Spacer / Holding chamber

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

Predicate Devices: Trudell AeroChamber Plus Valved Holding Chamber K992917
Trudell AeroChamber Plus aVHC with Flow-Vu IFI K070674
InfaMed Funhaler K042546

Device Description

The Watchhaler is a spacer primarily used in the pediatric population for the inhalation of approved MDIs for the therapy of the upper and lower respiratory system. The design of the device is held in the shape of a colored toy animal to address its users, the children. The device consists of a balloon which is enclosed by a translucent housing. During inhalation the balloon collapses with the speed of deflation controlled by a mechanical valve. The fixed volume of the balloon and the low inhalation flow provided by the valve help to ensure a constant drug delivery.

Indications for Use -- The Watchhaler is a holding chamber intended to administer aerosolized medication with a Metered Dose Inhaler.

Patient Population -- Pediatric – 3 years and older

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

Contraindications -- None

Non-Confidential Summary of Safety and Effectiveness
Page 2 of 2
10-Jan-08

Attribute	Proposed Watchhaler
Indications for Use (all have except pentamidine)	The Watchhaler is a holding chamber intended to administer aerosolized medication with a Metered Dose Inhaler.
Environments of use	Home care, nursing home, sub-acute institutions or hospitals
Patient population	Pediatric (3 years and older)
Single patient, multi-use	Yes
Used with mouthpiece	Yes
Used with most pressurized Metered Dose Inhalers	Yes
Feedback	Visual
Flow control / maximum flow rate	Yes / 15 Lpm
Materials	ISO 10993 tested
Inhalation volume	Maximum 300 ml

Differences Between Other Legally Marketed Predicate Devices

The Watchhaler is viewed as substantially equivalent to the following predicate devices – Trudell AeroChamber Plus Valved Holding Chamber K992917, Trudell AeroChamber Plus aVHC with Flow-Vu IFI K070674, and InfaMed Funhaler K042546

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

JUN 30 2008

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

Re: K080100
Trade/Device Name: Watchhaler
Regulation Number: 21 CFR 868.5630
Regulation Name: Nebulizer
Regulatory Class: II
Product Code: NVP
Dated: June 25, 2008
Received: June 26, 2008

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.
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: K080100 (To be assigned)

Device Name: Watchhaler

Indications for Use:

The Watchhaler is a holding chamber intended to administer aerosolized medication with a Metered Dose Inhaler. For pediatric patients (3 years and older). The environment of use includes home care, nursing homes, sub-acute institutions, and hospitals

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: K080100