K063449

510(k) Summary of Safety and Effectiveness

Submitter Information:

Access Point Medical, LLC
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USA

MAR 3 1 2007

USA Contact:

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Device Name:

Trade Name: Deluxe Nebulizer
Common Name: Nebulizer (Direct Patient Interface)
Classification Name: Anesthesia Conduction Kit (Reference, 21CFR, 868.5630, April 1, 2005)

Predicate Devices:

The Deluxe Nebulizer is substantially equivalent to the Medical Depot Power Neb 2™ nebulizer cleared for market under 510(k) K003344. The indication for use for the Deluxe Nebulizer is identical to the Power Neb 2™.

Device Description:

The Deluxe Nebulizer, consist of four components. The nebulizer main unit, air compressor, air filters and nebulizer kit (hand held nebulizer with mouthpiece). The Nebulizer atomizes medicinal liquid into tiny fog droplets by compressing air. Patients inhale the compressed air for optimal internal medicinal delivery.

Intended Use:

The Access Point, LLC Deluxe Nebulizer is intended to provide a source of compressed air for medical purposes for use in home health care. The Deluxe Nebulizer is used in conjunction with a pneumatic nebulizer to produce a fine aerosol mist of medication for respiratory therapy, for both children and adults suffering from respiratory disorders.

Technology Characteristics:

The Deluxe Nebulizer operation is based upon a non-oil lubricating, single-cylinder piston pump for air pressure. It is compact, simple to operate and convenient to carry. As shown in Figure 1 below, air flows through the air filter into the nebulizer's air compressor unit, out the jet outlet and then through the nebulizer.

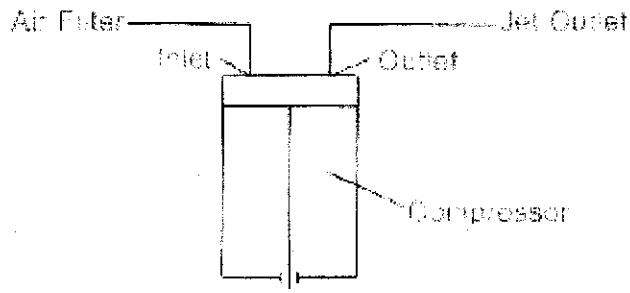


FIGURE 1 – WORKING PRINCIPLE

The Nebulizer (Figure 4) atomizes medicinal liquid into tiny fog droplets by compressing air. Patients inhale the compressed air for optimal internal medicinal delivery.

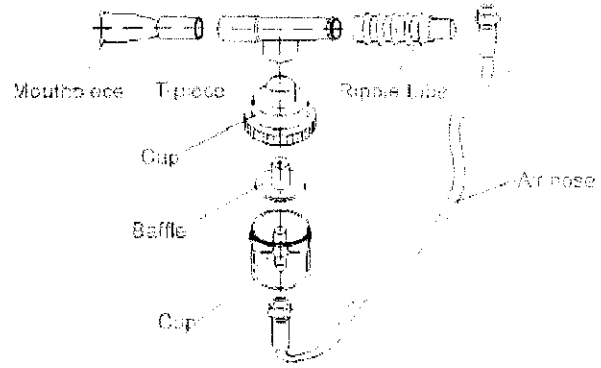


FIGURE 4 – NEBULIZER

Summary of Performance Testing

The Deluxe Nebulizer was designed to conform to the applicable sections of the following recognized consensus standards. The testing included verifying conformance to these standards and the published specifications.

Standard Guidance	Issue Date	Title
IEC 60601-1	1998	Medical Electrical Equipment – Part 1: General Requirements for Safety
IEC 60601-1-2	2001	Medical Electrical Equipment – Part 1-2: General Requirements for Safety – Collateral Standard; Electromagnetic Compatibility – Requirements and Tests (General)
FDA Document Number 784	1993	Reviewer Guidance for Nebulizers, Metered Dose Inhalers, Spacers and Actuators

Conclusion:

The Deluxe Nebulizer is as safe and effective as the predicate devices when used according to the instructions in the directions for use supplied with the devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 0 1 2007

Access Point Medical, L.L.C
C/O Ms. Casey Conroy
Responsible Third Party Official
Underwriters Laboratories, Incorporated
1285 Walt Whitman Road
Melville, New York 11747

Re: K063449
Trade/Device Name: Deluxe Nebulizer™, Nebulizer
Regulation Number: 21 CFR 868.5630
Regulation Name: Nebulizer
Regulatory Class: II
Product Code: CAF
Dated: February 6, 2007
Received: February 9, 2007

Dear Ms. Conroy:

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.

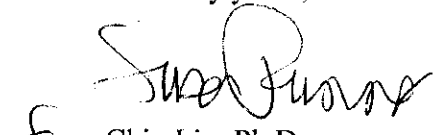
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



for 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

510(k) Number: _____

Device Name: Deluxe Nebulizer™, Nebulizer

Indications for use:

The Access Point, LLC Deluxe Nebulizer is intended to provide a source of compressed air for medical purposes for use in home health care. The Deluxe Nebulizer is used in conjunction with a pneumatic nebulizer to produce a fine aerosol mist of medication for respiratory therapy, for both children and adults suffering from respiratory disorders.

Prescription Use____ **X** _____ OR Over-The-Counter _____
(Per 21 CFR 801.109)

(Please do not write below this line – continue on another page if needed)

Concurrence of CDRH, Office of Device Evaluation

K063449