K041963 OCT 20 2004

AMERICAN BANTEX CORPORATION

1815 Rollins Road
Burlingame, California
(650) 697 - 3545
(650) 697 - 3596
Tracy S. Best, Regulatory Affairs Consultant
Preparation Date: July 10, 2004

Summary of Safety and Effectiveness for the:

Trade Name:	American Bantex Humidifier
Common Name:	Bubble Humidifier, Dry
Classification Name:	Respiratory gas humidifier, 21 CFR 868.5450, 73BTT, Direct Patient Interface – Class II

Legally Marketed Predicate Devices for Substantial Equivalence:

*K991484 – Airlife Bubble Humidifier, Allegiance Healthcare Corporation

Rationale for SE: The Airlife Bubble Humidifier is a Class II device that is intended to moisten the breathing gases that are delivered directly to the patient for breathing. This predicate device, along with the submitted device operate similarly by having the patient breathing gases pass through distilled water or sterile water in a refillable plastic jar. Both devices are reusable for not more than 30 days. These are made from acrylic and polypropylene plastics and are intended for single patient use. The material types used in this and in the predicate devices are identical. The materials have previously been tested and accepted for biocompatibility and are widely accepted as industry material standards. Both the submitted device, and the predicate are latex free.

Description of Submitted Device:

The American Bantex Humidifier is device that provides humidity in a non-heated pathway. The American Bantex Humidifier works with most all Oxygen Concentrators or to an oxygen source used in homes, doctors' office, hospital or institutional environments. The inlet uses an easy-to-grab winged styled nut that universally adapts to most all gas connections. The outlet is a push-on standard medical tubing connector with a tapered end. The American Bantex Humidifier is equipped with either a 3 or 6-PSI safety valve that will alarm if there is a kink or blockage in the delivery system.

Intended Uses of the American Bantex Humidifier:

The American Bantex Humidifier is intended for use with Oxygen Concentrators in a patients home, physicians office or hospital / institutional environment. The humidifier increases the moisture content of the airstream gases for administration to the patient.

005

K041963

Technological Characteristics and Substantial Equivalence:

Table 1b: Comparison of American Bantex Humidifier to the predicate Airlife Bubble Humidifier.

Component:	American Bantex Humidifier	Airlife Bubble Humidifier
Humidifier Bottle:	Clear polypropylene	Clear polypropylene
Lid:	ABS	ABS
Check valve and lid:	Brass / ABS	Brass / ABS
Filter tube / bulb:	PVC / PVC	PVC / ABS
510(k) Approval	This submission	K991484

The characteristics, method of operation, accessory use and single patient use are equivalent to that of the predicate device. Both have a double helix threaded jar that is impact resistant and seals easily.

Conclusion:

The successful testing demonstrated the device consistently performed within its design parameters, is as safe and effective, and performs as well as, or better than, the predicate device.

010

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 2 0 2004

American Bantex Corporation
C/O Mr. Tracy S. Best
Regulatory Affairs Consultant
994 North Main Street
Bountiful, Utah 84010

Re: K041963
Trade/Device Name: American Bantex Humidifier
Regulation Number: 21 CFR 868.5450
Regulation Name: Respiratory Gas Humidifier
Regulatory Class: II
Product Code: BTT
Dated: October 4, 2004
Received: October 7, 2004

Dear Mr. Best:

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/dsma/dsmamain.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

510(k) Number (if known): K041963

Device Name: AMERICAN BANTEX HUMIDIFIER

Indications for Use:

The American Bantex Humidifier is intended for use with oxygen concentrators or gas sources in a patients home, physicians office or hospital / institutional environment. The humidifier increases the moisture content of the airstream gases for administration directly to the patient.

Single patient use only

Non-sterile

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (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 K041963

011