MAY 13 1999

K991484

Allegiance

Allegiance Healthcare Corporation
1500 Waukegan Road
McGaw Park, Illinois 60085-6787
847.473.1500
FAX: 847.785.2461

SMDA REQUIREMENTS

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS
Airlife® Bubble Humidifiers

Manufacturer:	Allegiance Healthcare Corporation 1660 Iowa Avenue Riverside, CA 92507
Regulatory Affairs Contact:	Sharon Robbins 1500 Waukegan Road MPWM McGaw Park, IL 60085
Telephone:	(847) 785-3311
Date Summary Prepared:	March, 1999
Common Name:	Airlife® Bubble Humidifiers
Classification:	Class II per 21CFR § 868.5450
Predicate Device:	Airlife® Bubble Humidifiers.
Description:	The Airllife Bubble Humidifiers are comprised of polypropylene bottles with caps which are comprised of high impact polystyrene. These humidifiers are filled with sterile water and connected to an oxygen source to add moisture to, and sometimes to warm, the breathing gases for administration to a patient.

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SMDA REQUIREMENTS (continued)

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS
Airlife® Bubble Humidifiers

Intended Use:

Humidifiers are defined as a device that is intended to add moisture to, and sometimes to warm, the breathing gases for administration to a patient

Substantial Equivalence:

The Airlife® Bubble Humidifiers are substantially equivalent to the Airlife® Bubble Humidifiers in that:

- the intended use is the same
- the performance attributes are the similar

Summary of testing:

All materials used in the fabrication of the Airlife® Humidifiers were evaluated through biological qualification safety tests as outlined in ISO 10993 Part-1 "Biological Evaluation of Medical Devices". The biocompatibility tests performed were cytotoxicity, skin irritation and sensitization (guinea pig maximization). These materials also were tested in accordance with industry recognized test methods and were found to be acceptable for the intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 13 1999

Ms. Sharon Robbins
Allegiance Healthcare Corporation
1500 Waukegan Road
McGaw Park, IL 60085-6787

Re: K991484
Airlife® Bubble Humidifiers
Regulatory Class: II (two)
Product Code: 73 BTT
Dated: April 26, 1999
Received: April 28, 1999

Dear Ms. Robbins:

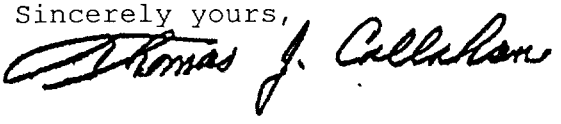
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification"(21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers 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,



Thomas J. Callahan, Ph.D.
Director
Division of Cardiovascular,
Respiratory, and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Allegiance

Allegiance Healthcare Corporation
1500 Waukegan Road
McGaw Park, Illinois 60085-6787
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FAX: 847.785.2461

510(k) Number (if known): Unknown

Device Name: Airlife® Bubble Humidifiers

Indications For Use: Humidifiers are defined as a device that is intended to add moisture to, and sometimes to warm, the breathing gases for administration to a patient.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ or Over-The Counter Use ____
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Cardiovascular, Respiratory, and Neurological Devices
510(k) Number K991484