K118713

SEP 12 2011

Section 5

510(K) Summary

Preparation Date:	Sept 8, 2011
Applicant/Sponsor:	Airways Development LLC 209 North 14th Street Kenilworth, NJ 07033
Contact Person:	Wayne W. Disanza President Phone: 908-931-1333 Fax: 908-931-0034
Trade name:	WaterPAP™ Valve
Common Name:	Positive Airway Pressure Valve, Bubble CPAP, PEEP Valve
Classification Name:	Attachment, Breathing, Positive End Expiratory Pressure 21 CFR §868.5965
Product Code:	BYE
Device Class:	II
Predicate Device:	Babi*Plus Bubble PAP Valve A Plus Medical (Manufacturer) 510(k) Number: K090317

Device Description:

The WaterPAP Valve is an infant positive end expiratory pressure device used to increase end lung pressure above atmospheric in constant flow conditions.

Indications for Use:

The WaterPAP Valve is a single patient use positive end expiratory pressure valve for use with infant patients weighing < 10 kg in hospital environments to increase end lung pressure above atmospheric in constant flow conditions.

Comparison of Technological Characteristics:

The WaterPAP Valve is substantially equivalent in indications for use, environment of use, patient population, and function to the Babi*Plus Bubble PAP Valve identified as the predicate device. The WaterPAP Valve and the Babi*Plus Bubble PAP Valve use the same method of submerging a continuous flow gas conduit under water to generate pressure. Comparative performance testing (simulated use) confirmed the substantial equivalence of the WaterPAP Valve with the Babi*Plus device at flow rates of 4 to 12 liters per minute. Additional bench testing resulted in comparative test results.

Nonclinical Tests:
Performance testing comparing the WaterPAP vs. Babi*Plus PAP Valves during simulated use was conducted. Testing was performed with each valve utilizing a simulated respiratory test circuit. A full range of flow and pressure combinations (flow rates 4-12 L/min and pressures 1-10 cm H_20) were tested using both PAP generating valves. Results indicated both PAP valves performed in a similar manner within established specifications of ± 1cm H_20 with comparable test data.

Testing was also performed to determine the rate of water level change during simulated use. Continuous flow of heated humidified gas was bubbled through the valves at minimum – mid and maximum flow/pressure combinations for 4 hours. Results indicated the WaterPAP and Babi*Plus Valves accumulate an equivalent amount of water and therefore the Positive Airway Pressures changes in both valves are essentially equivalent.

Testing was performed to document how increasing flow rates can generate unintended increases in PAP pressures delivered to the patient. The results demonstrate that the WaterPAP and Babi.Plus valves both generate increased pressures with increase flow rates. The gauge pressures of both PAP Valves are predominantly above the depth settings and verify the need for clinicians to use the valve's depth settings as a reference and always rely on the pressure gauge for actual PAP pressures.

Testing was performed to compare the resistance to flow through the underwater air diffusers. The testing was performed with the valves dry at a full range of flow rates. The results showed that the WaterPAP Valve had slightly higher resistance across the full range of flow rates; however the resistance to flow in both devices is well below a level that could have a negative impact during their intended use.

Substantial Equivalence:
The WaterPAP™ Valve is substantially equivalent to Babi*Plus Bubble PAP Valve with respect to indications, environment of use, patient population, technological characteristics, and principle of operation. Based upon bench testing and comparison of the technological characteristics of both devices, the WaterPAP Valve device is substantially equivalent to the Babi*Plus Bubble PAP Valve device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Airways Development LLC
C/O Mr. Richard Larkin
President
R.J. Larkin Consultants, LLC
P.O. Box 558
Cedar Knolls, New Jersey 07927

SEP 12 2011

Re: K110713
Trade/Device Name: WaterPAP™ Valve (Positive Airway Pressure Valve)
Regulation Number: 21 CFR 868.5965
Regulation Name: Positive End Expiratory Pressure Breathing Attachment
Regulatory Class: II
Product Code: BYE
Dated: August 30, 2011
Received: August 31, 2011

Dear Mr. Larkin:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Anthony D. Watson, B.S., M.S., M.B.A.
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 (if known): _____

Device Name: **WaterPAP™ Valve (Positive Airway Pressure Valve)**

Indications for Use:

The WaterPAP Valve is a single patient use positive end expiratory pressure valve for use with infant patients weighing < 10 kg in hospital environments to increase end lung pressure above atmospheric in constant flow conditions.

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: K110713