K091538

510(k) Summary
(As required by 21 CFR 807.92(a))

MAR 2 5 2010

Application Date: 3/15/2010

A. Submitter Information

Wet Nose Technologies, LLC
3750 2nd Avenue
Los Angeles, CA 90018

Establishment Number: 3007521506

Phone Number: 949-481-5713
Fax Number: 949-481-5745

Contact: Jim Barley

Trade Name: Wet Nose Technologies Pressure Release Valve

B. Device Information

Trade/Proprietary Name: Wet Nose Technologies Pressure Release Valve

Common name of device: Pressure Relief Valve

Classification Name: Nonrebreathing Valve

Product Code: CBP

Regulatory Class: II

Classification Number: 868.5870

Reason for 510(k): New Device

C. Predicate Device: Fisher & Paykel BC110 Pressure Manifold

Predicate 510(k) #: K040366
Predicate product code: CBP

D. Device Description

The Pressure Release Valve (PRV) is a custom valve designed specifically for pediatric/infant use within a Continuous Positive Airway Pressure (CPAP), High/Heated Flow Nasal Cannual (HFNC) and other pressure systems. This valve is a safety feature designed to limit the system pressure of the circuit to pressures below the PRV relief pressure range. The device is intended for use with flow rates greater than 0 L/min up to, and including, 15 L/min. The device is placed upstream of the patient in-line with the circuit to protect the patient from excessive inspiratory pressure in event of a downstream occlusion or an increase of system pressure above the relief pressure. Thus, this device may be used to regulate the maximum pressure achievable within a pressure system. Opening the PRV will activate an audible sound to alert Healthcare professionals over pressurization and the possible need for corrective action. The activation pressure 20 cm H2O +/- 4 cm H2O is based on the relief pressure at 8 L/min is 16 is 20 cm H2O and at 15 L/min is 24 cm H2O. The valve reacts instantaneously to an occlusion and automatically resets upon release of the occlusion. The device is disposable, single-patient use and is prescription only.
The Pressure Release Valve connects with the pressure tubing by way of a Wet Nose Technologies 'T6' Adapter.

The Pressure Release Valve and the 'T6' Adapter are sterilized by gamma irradiation and supplied sterile in bag pouch. Fifty bag pouches are packaged in a dispenser box. Each bag pouch and dispenser box is labeled with the contents and the appropriate information per the FDA's Quality System Regulation and Labeling requirements.

E. Statement of Indications for Use

The Wet Nose Technologies (WNT) Pressure Release Valve is intended for use with 'positive pressure' breathing gas delivery systems (e.g., High Flow Nasal Cannula or Bubble CPAP type systems) for pediatric/infants patients utilizing continuous flow systems with flow rates greater than 0 L/min and up to, and including 15 L/min.

The device is intended for use when a disposable, low pressure (20 cm H20 +/- 4 cm H2O activation), audible, non-adjustable pressure relief valve is needed to be placed upstream of the patient in-line with the circuit to protect the patient from excessive inspiratory pressure in event of a downstream occlusion or an increase of system pressure above the relief pressure. Intended to alert the healthcare provider(s) of a need to take corrective action to reduce system pressure, the device emits an audible sound when circuit pressure is above relief pressure.

F. Comparison of Required Technological Characteristics:

Information was submitted to demonstrate that there are no significant differences in technological characteristics between the Wet Nose Technologies Pressure Release Valve and the cited predicate device.

G. Discussion of Nonclinical Tests:

The intended use of the Wet Nose Technologies Pressure Release Valve is identical to that of the cited predicate device. Any differences in technological characteristics were insignificant and do not raise new issues of safety or effectiveness.

Performance testing consisted of the following:

1. Change in relief pressure with flow rate
2. Leak Testing
3. Response time to an occlusion

In addition, testing for compliance to the applicable sections of the following voluntary standards was performed:

4. ANSI/AAMI/ISO 11137 – Sterilization of health care products -- Radiation -- Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices
5. ISO 11607;2003 – Packaging for terminally sterilized medical devices
6. ISO 10993-4:2006 – Biological evaluation of medical devices Part 4: Selection of tests for interactions with blood

H. Discussion of Clinical Tests:

None submitted

I. Conclusions Demonstrating Safety, Effectiveness and Performance:

The WNT Pressure Relief Valves has a pressure activation level of 20 cm H20. The Instructions for Use provide the pressure activation levels by flow rate for the device.

The design of the Pressure Release Valve and the T6 Adapter minimize the chance of user error. The device has been tested and found to meet all product specifications and requirements. Accelerated aging was used to verify the performance of the product over the life of the device.

Instructions for Use detail how to use the devices and the conditions of use. Product labeling clearly shows that the device is for single patient use only.

The WNT Pressure Release Valve and T6 Adapter have been found to be safe and effective for their intended use.

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

Mr. Jim Barley
Director of Regulatory Affairs/Quality Assurance
Wet Nose Technologies, LLC
3750 2nd Avenue
Los Angeles, California 90018

MAR 2 5 2010

Re: K091538
Trade/Device Name: Wet Nose Technologies Pressure Release Valve
Regulation Number: 21CFR 868.5870
Regulation Name: Nonrebreathing Valve
Regulatory Class: II
Product Code: CBP
Dated: March 15, 2010
Received: March 19, 2010

Dear Mr. Barley:

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

510(k) Number (if known):_____

Device Name: Wet Nose Technologies (WNT) Pressure Release Valve

Indications For Use:

The Wet Nose Technologies (WNT) Pressure Release Valve is intended for use with 'positive pressure' breathing gas delivery systems (e.g., High Flow Nasal Cannula or Bubble CPAP type systems) for pediatric/infants patients utilizing continuous flow systems with flow rates greater than 0 L/min and up to, and including 15 L/min. The device is intended for use when a disposable, low pressure (20 cm H20 +/- 4 cm H2O activation), audible, non-adjustable pressure relief valve is needed to be placed upstream of the patient in-line with the circuit to protect the patient from excessive inspiratory pressure in event of a downstream occlusion or an increase of system pressure above the relief pressure. Intended to alert the healthcare provider(s) of a need to take corrective action to reduce system pressure, the device emits an audible sound when circuit pressure is above relief pressure.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/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)

L. Schultheis

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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