K951944

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510 (K) SUMMARY
NASAL CANNULA FOR CONTINUOUS POSITIVE AIRWAY PRESSURE
[redacted]-AN (73) CLASS: II
BZD

1. Submitted by:

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Contact Person:

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Date: Sept. 9, 1996

Device name: Nasalflair

2. Predicate device:

Puritan Bennett
Single Patient Use Nasal CPAP
AN-[redacted]-SE Class II (K900164)
BZD Adams Circuit

3. Description of Nasalflair:

Nasalflair is a device that fits into patient's nares in a way that makes a substantially airtight seal, which facilitates the delivery of nasal Continuous Positive Airway Pressure (nCPAP) therapy. The device has two cannulae that fit into the patient's nares. Surrounding the tip of each cannulae are cuffs that inflate to create a seal around the cannulae just inside the nares. The cuffs are inflated through an aperture in the cannulae wall with the same air and pressure the patient is breathing. Pressure inside the inflated cuffs is equal to the pressure in the airway, thereby providing an adequate airtight seal. The cuffed cannula tips are elliptical, and swivel for maximum patient comfort. They snap onto and off of the J pieces to facilitate cleaning and economical replacement. The J pieces have a tab to hold a stabilizing strap. They also have a fixed orifice to provide a vent for exhalation. The J pieces curve back up over the nose to the forehead area where they connect to a Y piece. A corrugated tube connects the Y piece to the flow generator.

Prescribed positive pressure is produced and regulated by the flow generator. Gas flow travels from the flow generator through a 22mm I.D. corrugated tube that connects to the Nasalflair wye piece which splits the flow and sends it through two flexible 15mm I.D tubes, each connects to a J shaped piece having cuffed cannulae that fit into patient's nares directing the air flow into the nasal passage, oral pharynx, trachea, and into the lungs.

The Y piece is attached to a soft nylon lined foam pad that rests on the patient's forehead and is held in place with adjustable hook/loop straps. Different types of head gear may be used depending on individual patient preference.

4. Intended use:

The Airways Nasalflair is intended for use as a therapeutic device under the direction of qualified medical personnel. Nasalflair is used by patients who have been prescribed nCPAP as a treatment for Sleep Apnea. Nasalflair may be used with CPAP and BiPAP™ flow generators capable of generating 20 ± 2 cmH20 pressure via a 22mm I.D. main flow air supply tube.

5. Statement of Comparison to Predicate Device:

The Airways Nasalflair is substantially equivalent to the Puritan Bennett Adams Circuit with Nasal Pillows. Both devices are nCPAP patient interfaces used with CPAP and BiPAP™ flow generators capable of generating 20 ± cmH20 pressure via a 22mm I.D. main flow air supply tube. Both devices use similar head gear to hold the device over the patient's face engaging and sealing the nasal airway during sleep. Adams Circuit head gear may be used with Nasalflair and vice versa. Both devices produce a substantially airtight fit at the nares opening to produce CPAP. Nasalflair makes an airtight seal with an inflatable cuff on the inner wall of the nares. The Adams Circuit makes an airtight seal with mechanical pressure against the opening of the nares. Nasalflair and Adams Circuit provide nCPAP pressure and flow characteristics that are substantially equivalent.

6. Safety and Effectiveness:

SAFETY:

Performance testing, (with consideration to flow and pressure) through Nasalflair and Adams Circuit were completed and compared. While flow performance standards have not been established for devices of this type, it is important the device provide sufficient flow to maintain the desired CPAP pressure and satisfy peak inspiratory demands of patients at rest.

Testing was performed using five different commercially available CPAP flow generators. These flow generators were selected to provide a representative cross section of flow generators used by patients when prescribed nCPAP therapy.

Each flow generator was adjusted to operate at four different pressure levels. These pressure levels, $5cmH_2O$, $10cmH_2O$, $15cmH_2O$, $20cmH_2O$, represent the maximum range of pressure use during nCPAP therapy.

The results of the testing demonstrates that Nasalflair and Adams Circuit are substantially equivalent at providing flow and pressure appropriate for nCAPA therapy.

EFFECTIVENESS:

Clinical trials have been completed with ten patients using Nasalflair. The patients were informed Nasalflair is not an FDA approved device and consented to use it as such.

Patients were selected who could not tolerate the mechanical pressure needed to create an air tight seal when using the Adams Circuit. The subtle yet important difference between the two interfaces focuses on how the airtight seal is made at the nares openings, and how each affects patient comfort. Adams Circuit head gear needs to maintain tension on the straps that hold the nasal pillows snugly into the nares. The higher the prescribed CPAP pressure, the more tension is required to maintain the airtight fit.

Patients with prescribed CPAP pressure above $10cmH_20$ are frequently unable to tolerate the amount of tension required to get a proper seal. They tolerate the tension for a few days, but then stop the prescribed treatment due to discomfort, soreness, tissue breakdown or persistent leakage.

Nasalflair has replaced Adams Circuit in 10 of these cases. Nasalflair head gear straps do not need to maintain tension to hold the nasal cannulae into the nares. The head gear straps only need to be snug enough to maintain the position of the cannulae in the nares. The airtight seal is made with the inflation of the cuffs on the cannulae in the nares. The cuffs are inflated with the same gas and CPAP pressure the patient is breathing. The higher the CPAP pressure, the higher the cuff inflation pressure. Head gear straps do not need to be made tighter to accomplish an air-tight seal with higher CPAP pressures. Also, pressure from the inflated cuffs is distributed evenly around the cuff surface where it contacts the nares, avoiding pressure points that are usually present with mechanical forces.

Some patients on long term use of Nasalflair reported nasal dryness. Humidity was added into the breathing air which eliminated the nasal dryness. Humidity is routinely added to the air when the Adams Circuit is used. The Nasalflair label cautions that optional humidity may be added to the air to avoid nasal dryness.

Ten patients have now been using Nasalflair for >24 months. They have found Nasalflair to be a safe and effective interface for positive pressure breathing therapy.