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# 510(k) SUMMARY FOR PASSY-MUIR OXYGEN ($O_2$) ADAPTOR FOR USE WITH THE PASSY-MUIR LOW-PROFILE TRACHEOSTOMY AND VENTILATOR SPEAKING VALVES (PMV 2000 AND 2001)

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**Establishment Registration Number:** 2024841

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**Name of the Device:** Passy-Muir Oxygen ($O_2$) Adapter
Product Number PMA 2000

**Common or Usual Name:** Oxygen ($O_2$) Adapter; Accessory $O_2$ Adapter; Supplemental $O_2$ Adapter; Speaking Valve $O_2$ Adapter; Airway Connector; $O_2$ Port; Supplemental $O_2$ Port

**Classification Name:** TBD: Accessory $O_2$ Adapter for the Tracheostomy Speaking Valves

Possible Product Classification Codes:

1. Airway Connector (Extension): Classification Number: 73BZA
   21 CFR 868.5810 - "An airway connector is a device intended to connect a breathing gas source to a tracheal tube, Tracheostomy tube or mask." Formerly a Class II device.

2. Oxygen Mask: Classification Number: 73BYG
   21 CFR 868.5680 - "An oxygen mask is a device placed over a patient's nose, mouth, or Tracheostomy to administer oxygen or aerosols." Formerly a Class II device.

**Predicate Devices:**

1. Trach Ring Adapter (Marquest Medical): Product # 178548, 15mm I.D. x 22 mm OD with side port for supplemental oxygen supply to trach or ET tube

2. Aerosol Tee Connector (Hudson RCI): Product # 1648, 22mm OD horizontal ports with a 15mm ID vertical port

3. Tracheostomy Mask (Hudson RCI): Product # 1075, Adult mask for tracheostomy and laryngectomy aerosol therapy

**Description of Device:** The Passy-Muir $O_2$ Adapter is a one-piece, injection-molded plastic device designed to attach to the outer surface of either one of the Passy-Muir Low-Profile Tracheostomy and Ventilator Speaking Valves (PMV 2000 or PMV 2001) and provide a means for connecting a supplemental oxygen supply tube.

**Intended Use:**

The P-M $O_2$ Adapter is designed for use with the companion PMV 2000 (clear) and PMV 2001 (purple) Low Profile Tracheostomy and Ventilator Speaking Valves. The P-M $O_2$ Adapter allows for improved mobility of those patients requiring a tracheostomy tube, speaking valve, and low flow supplemental oxygen.

**Principles of Operation:**

The P-M $O_2$ Adapter is designed to snap around the body of the low-profile speaking valve, held in place by friction, the mechanical strength of two gripper flanges, and the shape of the device (which hugs the outer profile of the valve). The $O_2$ Adapter is equipped with an integral, tapered tube fitting that provides a friction fit with the inside diameter of flexible, supplemental oxygen tubing (not supplied by Passy-Muir). The low-pressure oxygen (flowing through the flexible oxygen supply tubing) passes first through the tube fitting of the $O_2$ Adapter, then into a duct-like channel created by the juxtaposed walls of the Adapter and the outer surface of the Speaking Valve, exiting *at the front edge* of the valve, where it is either inhaled (along with ambient air) or allowed to dissipate into the atmosphere. This is an inherently *open* system, functioning in the manner of a Tracheostomy mask or an aerosol "T" piece, commonly used in weaning tracheostomized patients of off ventilators.

**Summary of the Basis for the Finding of Substantial Equivalence:**

The safety and effectiveness of supplemental oxygen devices is based on a long history of $O_2$ delivery systems.

Supplemental $O_2$ delivery systems have been used with tracheostomized and ventilator dependent patients since before the passage of the Medical Device Amendments of 1976. The Passy-Muir Oxygen ($O_2$) Adapter and the predicate devices have the same general intended use as a delivery system for low levels of supplemental oxygen. It is similar to the predicate devices as it attaches directly to (or in immediate proximity of) the tracheostomy speaking valve and delivers $O_2$ *in front* of speaking valve diaphragm, usually in an *open system* configuration where $O_2$ delivery is continuous.