K955831

510(k) Summary of Safety & Efficacy -
Argyle® ASPR-Care™ Closed Suction System

Submitted by: Sherwood Medical Co., 1915 Olive St.,
St. Louis, MO 63103, (314) 241-5700
Contact: Dennis Pozzo, Regulatory Affairs Manager
Date Prepared: November 7, 1995

The Argyle® ASPR-Care™ Closed Suction System is classified as a Tracheobronchial Suction Catheter, Class I device per 21 CFR Section 868.6810 and is a Class I device, Procode: 73BSY.

The Argyle® ASPR-Care™ Closed Suction System consists of three discreet components: a dual swivel T-piece, a sheathed suction catheter, and a suction control valve. When connected together, these components form a closed system suction catheter similar in form and function to the closed system catheters available from Ballard and Concord/Portex.

The device is intended to be used in critical care units to aspirate secretions from patient airways who have endotracheal or tracheostomy tubes and require mechanical ventilation. The system allow for the insertion and withdrawal of a suction catheter into the artificial airway without disconnecting the patient from the ventilator circuit. The components of this system are sterile, single patient use, and disposable.

The objectives of closed suction systems are:

1) to reduce the loss of Positive End-Expiratory Pressure (PEEP) and Fraction of Inspired Oxygen (FIO_2) while suctioning patient airways,

2) to reduce the possibility of hypoxia and cardiac irregularities during suctioning, and

3) to protect the clinician from patient secretions.

The Argyle® ASPR-Care™ Closed Suction System utilizes Sherwood Medical's previously marketed DeLee Tip® Suction Catheter enclosed by a sheath. The major difference between the two devices is the ASPR-Care™ is a closed system suction catheter, whereas the DeLee Tip is an open system.

The Argyle® ASPR-Care™ Closed Suction System is substantially equivalent to the Ballard Medical Products Trach Care™ Closed Suction System and the Concord/Portex Steri-Cath™ Closed Suction System in that:

1. each system is a closed system suction catheter that allows for the aspiration of patient secretions without the loss of mechanical ventilation to patient's who have artificial airways,

2. each system is enclosed in a clear plastic sleeve to protect the clinician from patient secretions,

3. each system comes with an adapter (connector) to eliminate strain between the mechanical ventilator circuit and the endotracheal tube or tracheostomy tube,

4. each system comes with a suction control valve that allows for the application of vacuum (suction) as necessary to remove secretions from the patient's airway,

5. each system allows for the introduction of irrigation to clean the catheter and lavage the patient and

6. each catheter contains depth marks which allows the clinician to determine the depth the catheter has been inserted into the patient's trachea.

The Argyle® ASPR-Care™ System is also comprised of two ancillary adapters; a Bronchoscope and Sputum Trap Adapter.

The bronchoscope adapter is a sterile, single use device comprised of an adapter and a fenestration seal with a plugged orifice. The fenestration seal comes in two sizes, 0.15" and 0.183" diameter orifice. The fenestration seal forms an air-tight seal between the endoscope and the adapter.

The Argyle® ASPR-Care™ Bronchoscope Adapter is intended for use as a seal of the normally closed accessory port of the Closed Suction System Swivel Adapter through which a bronchoscope can be inserted. Having two separate size fenestration seals allows for the appropriate bronchoscope to be inserted into the artificial airway without the loss of ventilation to the patient. This adapter allows the clinician to perform a bronchoscopy without having to disconnect the patient from the ventilator circuit.

The Bronchoscope Adapter is substantially equivalent to the currently marketed Portex Fiberoptic Swivel Adapter in that they both allow for the introduction of a bronchoscope to be inserted into the artificial airway without the loss of ventilation to the patient. Which in turn allows the clinician to perform a bronchoscopy without having to disconnect the patient from the ventilator circuit.

The sputum trap is a sterile, single use device comprised of three components: a manifold (sputum trap cap), a collection vial, and a cap (vial cap).

The Argyle® ASPR-Care™ Sputum Trap allows for the collection of a sputum sample during the routine suctioning of a patient

without having to disconnect the patient from the ventilator circuit. The manifold allows the sputum trap to be connected in-line between the sheathed catheter and Suction Control Valve. Once the sputum sample has been aspirated into the vial, the trap is removed from the circuit and then the sheathed catheter and Suction Control Valve are re-connected. The manifold is then removed from the vial and the vial is sealed with the cap.

The Sputum Trap is substantially equivalent to the currently marketed Argyle® Lukens Specimen Container (preamendment device) in that: 1) they are both used for the collection of a sputum sample taken through a suction catheter during routine suctioning of a patient, 2) they both contain a manifold that allows the trap to be placed in-line in the suction circuit, and 3) they both contain a cap to seal the vial after a sputum sample has been collected and the manifold has been removed.

Per ISO 10993 Part 1 "Biological Evaluation for Medical Devices" the Argyle ASPR-Care™ CSS is classified as a surface device of prolonged contact with mucosal membrane and as such, has passed the following battery of tests; cytotoxicity, sensitization, irritation, systemic toxicity and implantation. The Bronchoscope Adapter (indirect patient contact) and Sputum Trap (non-patient contact) have only undergone and passed cytotoxicity testing.

Sherwood Medical has conducted a battery of tests comparing the performance of the Argyle® ASPR-Care™ Closed Suction System and ancillary components with those devices to which we are claiming substantial equivalence. This testing was conducted to ensure Sherwood's device provides a safe and effective conduit for ventilator gases and allows efficient tracheal and oral suctioning capabilities.

Sherwood Medical also conducted a Failure Modes Affect Analysis (FMEA) on the Argyle® ASPR Care™ Suction System. The FMEA was conducted as part of the device's design process to identify preventive and corrective actions to ensure the device design is safe for its intended use. In addition, the FMEA also identified preventive and corrective actions that will require manufacturing controls.