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**Substantial Equivalence 510(k) Summary  
Rüsch Oral/Nasal Tracheal Tube, Cuffed- Magill/Murphy**

**To: Whom it May Concern**

**Date: May 10, 1996**

**Submitter/Contact- Name and Address:**

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**Device Details:**

Trade Name: Rüsch Oral/Nasal Tracheal Tube, Cuffed- Magill/Murphy

Common Name: Tracheal Tube

Classification Name: Tube, Tracheal(w/wo Connector 73BTR)

**Predicate Legally Marketed Device:**

Sheridan HVT(TM) Tracheal Tube with X-Ray Line and 15mm.  
Connector High Volume Tapered Low Pressure Murphy Eye

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**Device Description:**

The Rusch Oral/Nasal Tracheal Tube, Cuffed, Magill/Murphy consists of a clear implant tested PVC tracheal tube with radiopaque stripe. The cuff is inflated via a pilot balloon using any lock-tip or luer taper syringe. The main tube is graduated with multiple centimeter markings to allow easy determination of intubated length. A black positioning ring is present on the tube to aid in visualization of the tube. An optional Murphy eye provides an alternative opening. The eye is the difference between the Murphy and the Magill Tube. The device is for Nasal/Oral use.

**Device Intended Use:**

The device is intended for oral or nasal intubation. It is intended for airway management.

**Technological Characteristics of the Device:**

The device is manufactured according to ASTM 1242-89. It is equivalent in design and intended use with the Sheridan product. Both of the products are PVC with the same general appearance.

The Rusch Tracheal Tube comes in sizes 4.5-11.0 inclusive.

**Bench/Laboratory Testing:**

Based on test data, the device conforms to ASTM 1242-89.

The device is biocompatible per the requirements of ISO 10993.