



Tall Pines Park  
Jaffrey, NH 03452  
(603) 532-7706  
FAX (603) 532-8211 or 6108

K955495

**JUN 27 1995**

To: Whom it may concern

**Substantial Equivalence 510(k) Summary**

Reference: Rüsç Reinforced Tracheal Tube - Cuffed, sterile

The Rüsç Reinforced Endotracheal Tube - Cuffed, sterile for tracheal intubation applied for in this application is substantially equivalent in design, use and materials to the:

Sheridan Reinforced Cuffed Tracheal Tube - K844296

SIMS/Concord/Portex Reinforced Cuffed Silicone Tracheal Tube - K830352

NCC/Mallinckrodt Reinforced Tracheal Tube Cuffed

currently being marketed and sold in inter-state commerce.

The device, which is equivalent to other devices currently being marketed, consists of a clear, implant tested, P.V.C. tube with an encapsulated stainless steel reinforcing spiral. The tube is graduated with multiple centimeter markings to allow easy determination of the intubated length, and is terminated with a fully inserted connector.

The tube is fitted with a low pressure, high volume cuff, which is inflated through a luer-activated valve, pilot balloon, inflation tube and lumen in the wall of the main tube.

The device is a single use, sterile, cuffed tracheal tube for tracheal intubation and indicated for airway management. It will be available in a variety of sizes from 5.0 mm to 11.0 mm internal diameters in steps of 0.5 mm..

Based upon the equivalence in materials, design and intended use between this tube and others presently being marketed and sold, no difference in safety and effectiveness is forecasted.

signed

\_\_\_\_\_  
Authorized, Regulatory Affairs Department  
October 10, 1995