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MAY 10 1996

K954585

To: Whom it may concern

Substantial Equivalence 510(k) Summary

Reference: Rüsç Pediatric Reinforced Tracheal Tube - Uncuffed, sterile

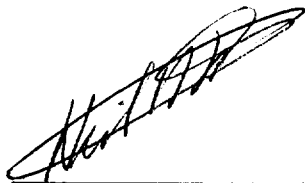
The Rüsç Pediatric Reinforced Tracheal Tube - Uncuffed, sterile for tracheal intubation applied for in this application is substantially equivalent in design, use and materials to the:
Sheridan Reinforced Uncuffed Tracheal Tube - K844296 & K860105
SIMS/Concord/Portex Pediatric Reinforced Silicone Tracheal Tube - K830352
NCC/Mallinckrodt Reinforced tracheal tube uncuffed without Magill curve - K841872
currently in inter-state commerce.

The device, which is equivalent to other devices currently being marketed, consists of a clear 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 device is designed as single use, sterile, uncuffed tracheal tube for oral or nasal tracheal intubation and indicated for airway management. It will be available in a variety of sizes from 2.0 mm to 8.0 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
29 September 1995