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K960240
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To: Whom it may concern

Substantial Equivalence 510(k) Summary

Reference: Rüsç Optosafe

The Rüsç Optosafe, sterile, for oral insertion to provide an airway through the patient's mouth and allow fiberoptic tracheal intubation is substantially equivalent in design, use and materials to the Williams Airway Intubator K830767 currently being marketed and sold in inter-state commerce.

The device consists of a clear, implant tested, PVC tube formed into the conventional hooked shape of an oral airway. The tube is bonded with a polyurethane adhesive to a clear implant tested PVC bite block and flange molding. The flange is printed with the manufacturer's name, date code and size (nominal inner diameter of tube).

The device is designed as a single use, sterile, oropharyngeal airway to maintain a patent airway through the mouth to the pharynx and allow fiberoptic tracheal intubation. It will be available in a variety of sizes from 5 to 17 mm inside diameters.

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
11 January 1996