

JUL 25 1996

K962688

SMDA Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

Product: Montgomery Radiopaque Salivary Bypass Tube

Description: The Montgomery Salivary Bypass Tube is a silicone tube with a funnel-shaped end for use in treating esophageal strictures and fistulas. The tube is available in sizes 8mm, 10mm, 12mm, 14mm, 16mm, 18mm, and 20mm (outside diameter).

Indication For Use:

1. Treatment of pharyngocutaneous fistulas following laryngectomy or laryngoesophagectomy.
2. Management of cervical esophageal and hypopharyngeal strictures and fistulas resulting from a variety of causes including surgery, radiation, advanced malignancy, trauma, and ingestion of caustic agents.

Predicate Device: Montgomery Salivary Bypass Tube.

Testing: Finished device samples passed cytotoxicity testing and were determined to be non-reactive and non-cytotoxic based on Elution Test, USP 23.

Submitted by:  PRESIDENT
Stuart K. Montgomery, President

Date: 7/10/96