

K961194

AUG 8 1996

510 (k) Summary

Company: Sil-Med Corporation
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Contact Person: Karen K. Sylvia
QA/QC Manager

Trade Name: *Antimicrobial* Mediastinal Silicone Drain

Common Name: Silicone Drainage Catheter

Classification Name: 79 GBW Introduction/drainage catheter and accessories.
(878.4200)

Description: Silicone perforated tubing, flattened profile, blue radiopaque stripe; surface treated to reduce friction and Antimicrobial; perforations ("eyes") on both flattened surfaces of tubing; external end has cutaway adapter; imprinted with drain size

Predicate Device: Mediastinal Silicone Drain: K942709
Antimicrobial Multi-Luman Venous Catheter: K900263

Intended Use: Catheter for drainage of blood and fluid from mediastinum after chest surgery and/or trauma; for use with suction apparatus

The surface of a silicone device, surface treated with Spi-Argent™ II was challenged with the following organisms and proved effective:

Pseudomonas aeruginosa
Staphylococcus epidermidis

Serratia marcescens
Escherichia coli

Sil-Med Corporation's Antimicrobial Mediastinal Silicone Drain is the same drain as the Mediastinal Silicone Drain, K942709. Sil-Med Corporation is adding "Antimicrobial" to the product labeling only. The silver coating in the Arrow International, Inc. 510(k) Number, K900263 for their Antimicrobial Multi-Luman Central Venous Catheter, is approved for the use of Antimicrobial in their labeling.

Sil-Med Corporation
510(k) Submission: *Antimicrobial* Mediastinal Silicone Drain

25 March 1996