

K961295

JUN 26 1996

### 510 (k) Summary

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

**Trade Name:** *Flat Suction Drain/Kit with Spi-Argent™II (with and without Trocar)*

**Common Name:** Silicone Drainage Catheter

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

**Description:** Two joined silicone tubing sections; flat drain section is partially perforated for fluid collection, is ribbed to prevent collapse as suction is applied, and has blue radiopaque stripe; round tubing is connected to suction reservoir inlet; offered with an introduction Trocar attached as an option; silver ion surface treated to ease insertion and removal.

**Predicate Device:** Mediastinal Silicone Drain: K942709  
Sil-Slip Flat Suction Drain/Kit (with and without Trocar): K926408

**Intended Use:** For post-operative drainage of serosanguineous fluids and blood away from operative site; for use with suction reservoir as a closed wound drain system

Sil-Med Corporation's Flat Suction Drain/Kit with Spi-Argent™II, (with and without Trocar) is the same drain as the Sil-Slip Flat Suction Drain/Kit (with and without Trocar), K926408. The surface treatment is the same as the surface treatment on Sil-Med Corporation's Mediastinal Silicone Drain, K942709. No further claims will be made for the Flat Suction Drain/Kit with Spi-Argent™II than made on K942709.

Sil-Med Corporation  
510(k) Submission: *Flat Suction Drain/Kit with Spi-Argent™II*  
*(with and without Trocar)*

03 April 1996