

**K961295 SAPPHIRE LINE FLAT DRAIN/KIT WITH SPI-ARGENT II
W/OR W/OUT TROCAR**

Jun 26, 1996
83 days to decision

K961295 · Product code: **GBX** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k961295/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Irrigation (GBX)
Date received	Apr 4, 1996
Decision date	Jun 26, 1996
Days to decision	83 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Sil-Med Corp.
Location	Mchenry, IL, US
Contact	KAREN K SYLVIA
510(k) history	29 submissions · 28 cleared · 1980-1997

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Device record: <https://www.510kdatabase.net/k961295/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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