

K953864 SILCLEAR TUBING (MODIFICATION)Nov 6, 1995
91 days to decisionK953864 · Product code: **FPK** · General Hospital
Source: <https://www.510kdatabase.net/k953864/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Tubing, Fluid Delivery (FPK)
Date received	Aug 7, 1995
Decision date	Nov 6, 1995
Days to decision	91 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Degania Silicone , Ltd.
Location	Emek Hayarden, IL
Contact	BETTE LUBIN
510(k) history	19 submissions · 17 cleared · 1988-2026

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k953864/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 14, 2026