

K955164 S.A.R.S. II (SEMI-AUTOMATIC-RECONSTITUTING-SYSTEM)Mar 20, 1996
128 days to decisionK955164 · Product code: **FMF** · General Hospital
Source: <https://www.510kdatabase.net/k955164/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Syringe, Piston (FMF)
Date received	Nov 13, 1995
Decision date	Mar 20, 1996
Days to decision	128 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Habley Medical Technology Corp.
Location	Laguana Hills, CA, US
Contact	MARY M MCNAMARA
510(k) history	5 submissions · 5 cleared · 1987-1996

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k955164/>; 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 June 30, 2026