

**K962709 SIGMA SYRINGE DELIVERY SYSTEM(MULTI-DOSER
REV. I/MULTI-DOSER REV. II/SINGLE-DOSER REV.
1-10/SINGLE-DOSER REV. 1-20/**

Oct 7, 1996
87 days to decision

K962709 · Product code: **FRN** · General Hospital
Source: <https://www.510kdatabase.net/k962709/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Pump, Infusion (FRN)
Date received	Jul 12, 1996
Decision date	Oct 7, 1996
Days to decision	87 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Sigma Intl.
Location	Medina, NY, US
Contact	PATRICK W PENQUE
510(k) history	3 submissions · 3 cleared · 1994-2004

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k962709/> 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 July 2, 2026