

K952044 INSULCAPFeb 13, 1996
288 days to decisionK952044 · Product code: **FMI** · General Hospital
Source: <https://www.510kdatabase.net/k952044/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Needle, Hypodermic, Single Lumen (FMI)
Date received	May 1, 1995
Decision date	Feb 13, 1996
Days to decision	288 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Karen Holtz
Location	Roseville, CA, US
510(k) history	1 submissions · 1 cleared · 1996-1996

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k952044/>; 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 6, 2026