

K973057 1.4 FR MAPCATH SENSOR STYLETNov 12, 1997
89 days to decisionK973057 · Product code: **LJS** · General Hospital
Source: <https://www.510kdatabase.net/k973057/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Intravascular, Therapeutic, Long-term Greater Than 30 Days (LJS)
Date received	Aug 15, 1997
Decision date	Nov 12, 1997
Days to decision	89 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Navion Biomedical Corp.
Location	Holbrook, MA, US
Contact	DONALD A KAY
510(k) history	5 submissions · 5 cleared · 1990-1999

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k973057/> 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 1, 2026