

K902422 NEEDLE, ASPIRATION & INJECTION, DISPOSABLEJun 6, 1991
371 days to decisionK902422 · Product code: **FMI** · General HospitalSource: <https://www.510kdatabase.net/k902422/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Needle, Hypodermic, Single Lumen (FMI)
Date received	May 31, 1990
Decision date	Jun 6, 1991
Days to decision	371 days
Third-party review	No

APPLICANT

Company	Gainor Medical Europe, Ltd.
Location	Mcdonough, GA, US
Contact	MARK GAINOR
510(k) history	13 submissions · 13 cleared · 1990-1994

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k902422/> 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 26, 2026