

K923658 REP IMMUNOFIXNov 2, 1992
102 days to decisionK923658 · Product code: **CFF** · Immunology
Source: <https://www.510kdatabase.net/k923658/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Immuno-electrophoretic, Immunoglobulins, (g, A, M) (CFF)
Date received	Jul 23, 1992
Decision date	Nov 2, 1992
Days to decision	102 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Helena Laboratories
Location	Mchenry, IL, US
Contact	PAT FRANKS
510(k) history	280 submissions · 280 cleared · 1978-2013

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k923658/> 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 14, 2026