

K901805 REP(R) IMMUNOFIXJun 6, 1990
47 days to decisionK901805 · Product code: **DAH** · Immunology
Source: <https://www.510kdatabase.net/k901805/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Gamma Globulin, Antigen, Antiserum, Control (DAH)
Date received	Apr 20, 1990
Decision date	Jun 6, 1990
Days to decision	47 days
Third-party review	No

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/k901805/>; 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