

K842146 HISTOPAQUE-1077Jul 27, 1984
58 days to decisionK842146 · Product code: **JCF** · Hematology
Source: <https://www.510kdatabase.net/k842146/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Lymphocyte Separation Medium (JCF)
Date received	May 30, 1984
Decision date	Jul 27, 1984
Days to decision	58 days
Third-party review	No

APPLICANT

Company	Sigma Chemical Co.
Location	Mchenry, IL, US
Website	https://www.sigmaaldrich.com
510(k) history	231 submissions · 231 cleared · 1976-1994

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k842146/>; 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