

K925433 THE STACHROM HEPARIN ASSAY KITMay 23, 1995
937 days to decisionK925433 · Product code: **KFF** · Hematology
Source: <https://www.510kdatabase.net/k925433/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Assay, Heparin (KFF)
Date received	Oct 28, 1992
Decision date	May 23, 1995
Days to decision	937 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	American Bioproducts Co.
Location	Parsippany, NJ, US
Contact	LOC B LE
510(k) history	79 submissions · 75 cleared · 1985-1998

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k925433/> 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 June 28, 2026