

K952721 RUBASCAN CARD TESTDec 20, 1996
554 days to decisionK952721 · Product code: **LFX** · Microbiology
Source: <https://www.510kdatabase.net/k952721/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Linked Immunoabsorbent Assay, Rubella (LFX)
Date received	Jun 15, 1995
Decision date	Dec 20, 1996
Days to decision	554 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Bd Becton Dickinson Vacutainer Systems Preanalytic
Location	Washington, DC, US
Contact	ROBERT E JAMES
510(k) history	632 submissions · 625 cleared · 1976-2001

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k952721/> 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 21, 2026