

K953528 ROCHE COBAS-FP REAGENTS FOR VANCOMYCINSep 12, 1995
47 days to decisionK953528 · Product code: **LEH** · Toxicology
Source: <https://www.510kdatabase.net/k953528/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Radioimmunoassay, Vancomycin (LEH)
Date received	Jul 27, 1995
Decision date	Sep 12, 1995
Days to decision	47 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Roche Diagnostic Systems, Inc.
Location	Mchenry, IL, US
Contact	RITA SMITH
510(k) history	296 submissions · 296 cleared · 1983-1999

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k953528/> 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 23, 2026