

K944458 ACCU-CHEK INSTANT PLUS CHOLESTEROL TESTMar 6, 1996
541 days to decisionK944458 · Product code: **CHH** · Chemistry
Source: <https://www.510kdatabase.net/k944458/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzymatic Esterase--oxidase, Cholesterol (CHH)
Date received	Sep 12, 1994
Decision date	Mar 6, 1996
Days to decision	541 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Boehringer Mannheim Corp.
Location	Mchenry, IL, US
Contact	MIKE FLIS
510(k) history	340 submissions · 340 cleared · 1976-1999

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k944458/> 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 22, 2026