

K973284 COBAS INTEGRA HDL-CHOLESTEROL DIRECTDec 18, 1997
107 days to decisionK973284 · Product code: **CHH** · Chemistry
Source: <https://www.510kdatabase.net/k973284/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzymatic Esterase--oxidase, Cholesterol (CHH)
Date received	Sep 2, 1997
Decision date	Dec 18, 1997
Days to decision	107 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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