

**K981897 ROCHE COBAS INTEGRA ALKALINE PHOSPHATASE
IFCC LIQUID REAGENT CASSETTE, ROCHE COBAS INTEGRA
PANCREATIC A-AMYLASE EPS REAE**Aug 26, 1998
86 days to decisionK981897 · Product code: **CJE** · Chemistry
Source: <https://www.510kdatabase.net/k981897/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Nitrophenylphosphate, Alkaline Phosphatase Or Isoenzymes (CJE)
Date received	Jun 1, 1998
Decision date	Aug 26, 1998
Days to decision	86 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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