

K932605 COBAS (R) CORE T4 EIAJan 24, 1994
241 days to decisionK932605 · Product code: **KLI** · Chemistry
Source: <https://www.510kdatabase.net/k932605/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Immunoassay, Non-radiolabeled, Total Thyroxine (KLI)
Date received	May 28, 1993
Decision date	Jan 24, 1994
Days to decision	241 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

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