

K946119 ROCHE-TDM ONLEIN(TM) CONTROLSFeb 7, 1995
54 days to decisionK946119 · Product code: **LAS** · Toxicology
Source: <https://www.510kdatabase.net/k946119/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Drug Specific Control Materials (LAS)
Date received	Dec 15, 1994
Decision date	Feb 7, 1995
Days to decision	54 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

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

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