

K946163 RADIAS TOTAL T4 ENZYME IMMUNOASSAYFeb 22, 1995
65 days to decisionK946163 · Product code: **KLI** · Chemistry
Source: <https://www.510kdatabase.net/k946163/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Immunoassay, Non-radiolabeled, Total Thyroxine (KLI)
Date received	Dec 19, 1994
Decision date	Feb 22, 1995
Days to decision	65 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Bio-Rad
Location	Mchenry, IL, US
Contact	TREVOR WALL
Website	http://www.bio-rad.com
510(k) history	319 submissions · 319 cleared · 1976-2017

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k946163/> 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 14, 2026