

K951321 RADIAS NEONATAL T4 ENZYME IMMUNOASSAYAug 24, 1995
154 days to decisionK951321 · Product code: **KLI** · Chemistry
Source: <https://www.510kdatabase.net/k951321/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Immunoassay, Non-radiolabeled, Total Thyroxine (KLI)
Date received	Mar 23, 1995
Decision date	Aug 24, 1995
Days to decision	154 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

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Device record: <https://www.510kdatabase.net/k951321/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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