

K943811 ENZYME-LINKED FLUORESCENT IMMUNOASSAYNov 2, 1994
89 days to decisionK943811 · Product code: **CFT** · Chemistry
Source: <https://www.510kdatabase.net/k943811/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Radioimmunoassay, Prolactin (lactogen) (CFT)
Date received	Aug 5, 1994
Decision date	Nov 2, 1994
Days to decision	89 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Biomerieux Vitek, Inc.
Location	Hazelwood, MO, US
Contact	TERRY MCGOVERN
510(k) history	49 submissions · 49 cleared · 1992-1998

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