

K935134 ONE STEP LH TESTJan 11, 1994
75 days to decisionK935134 · Product code: **CEP** · Chemistry
Source: <https://www.510kdatabase.net/k935134/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Radioimmunoassay, Luteinizing Hormone (CEP)
Date received	Oct 28, 1993
Decision date	Jan 11, 1994
Days to decision	75 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Tcpi, Inc.
Location	Ft. Lauderdale, FL, US
Contact	CLEVE W LAIRD, PH.D.
510(k) history	14 submissions · 14 cleared · 1992-1998

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