

K942638 SIMULTRAC LH/FSH RADIOUMMUNOASSAY KITSep 7, 1994
96 days to decisionK942638 · Product code: **CEP** · Chemistry
Source: <https://www.510kdatabase.net/k942638/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Radioimmunoassay, Luteinizing Hormone (CEP)
Date received	Jun 3, 1994
Decision date	Sep 7, 1994
Days to decision	96 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Bd Becton Dickinson Vacutainer Systems Preanalytic
Location	Washington, DC, US
Contact	KATHY BIEHL
510(k) history	632 submissions · 625 cleared · 1976-2001

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