

K943252 PRO-STEP LH OVULATION PREDICTION TESTOct 25, 1994
111 days to decisionK943252 · Product code: **CEP** · Chemistry
Source: <https://www.510kdatabase.net/k943252/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Radioimmunoassay, Luteinizing Hormone (CEP)
Date received	Jul 6, 1994
Decision date	Oct 25, 1994
Days to decision	111 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Disease Detection International, Inc.
Location	Irvine, CA, US
Contact	SIEGFRIED KRUTZIK
510(k) history	20 submissions · 20 cleared · 1988-1994

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