

K951538 BESURE ONE-STEP HOME OVULATION PREDICTOR KITJul 11, 1995
99 days to decisionK951538 · Product code: **CEP** · Chemistry
Source: <https://www.510kdatabase.net/k951538/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Radioimmunoassay, Luteinizing Hormone (CEP)
Date received	Apr 3, 1995
Decision date	Jul 11, 1995
Days to decision	99 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Syntron Bioresearch, Inc.
Location	San Diego, CA, US
Contact	CHARLES YU
510(k) history	26 submissions · 26 cleared · 1987-1999

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