

**K983113 BESURE PLUS ONE-STEP HOME OVULATION
PREDICTOR KIT**Nov 18, 1998
75 days to decisionK983113 · Product code: **CEP** · Chemistry
Source: <https://www.510kdatabase.net/k983113/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Radioimmunoassay, Luteinizing Hormone (CEP)
Date received	Sep 4, 1998
Decision date	Nov 18, 1998
Days to decision	75 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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k983113/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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