

K010244 SURE CHECK OVULATION PREDICTORMay 2, 2001
97 days to decisionK010244 · Product code: **CEP** · Chemistry
Source: <https://www.510kdatabase.net/k010244/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Radioimmunoassay, Luteinizing Hormone (CEP)
Date received	Jan 25, 2001
Decision date	May 2, 2001
Days to decision	97 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Chembio Diagnostic Systems, Inc.
Location	Medford, NY, US
Contact	FRAN WHITE
510(k) history	6 submissions · 6 cleared · 1992-2001

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