

**K941168 CLINICAL ASSAYS GAMMACOAT [125] ESTRADIOL  
RADIOIMMUNOASSAY KIT**Sep 7, 1994  
177 days to decisionK941168 · Product code: **CHP** · Chemistry  
Source: <https://www.510kdatabase.net/k941168/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Radioimmunoassay, Estradiol (CHP)
Date received	Mar 14, 1994
Decision date	Sep 7, 1994
Days to decision	177 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Incstar Corp.</b>
Location	Stillwater, MN, US
Contact	MARY E BEST
510(k) history	58 submissions · 57 cleared · 1987-1997

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k941168/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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