

**K823313 IN VITRO GAMMACOAT B-HCG RADIO. TEST**Dec 22, 1982  
47 days to decisionK823313 · Product code: **JHI** · Chemistry  
Source: <https://www.510kdatabase.net/k823313/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Visual, Pregnancy Hcg, Prescription Use (JHI)
Date received	Nov 5, 1982
Decision date	Dec 22, 1982
Days to decision	47 days
Third-party review	No

**APPLICANT**

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Company	<b>Clinical Assays, Inc.</b>
Location	Mchenry, IL, US
510(k) history	27 submissions · 27 cleared · 1977-1983

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)

Device record: <https://www.510kdatabase.net/k823313/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).

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