

**K854059 MICRO-ELISA HCG EST KIT VISI-CHECK HCG TEST  
KIT NO**Jan 13, 1986  
102 days to decisionK854059 · Product code: JHI · Chemistry  
Source: <https://www.510kdatabase.net/k854059/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Visual, Pregnancy Hcg, Prescription Use (JHI)
Date received	Oct 3, 1985
Decision date	Jan 13, 1986
Days to decision	102 days
Third-party review	No

**APPLICANT**

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Company	<b>Bioclinical Systems, Inc.</b>
Location	St.Louis, MO, US
Contact	BRUCE F WATKINS
510(k) history	13 submissions · 13 cleared · 1985-1995

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**510k Database** - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k854059/>; Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated June 29, 2026