

**K011550 HCG STAT PAK ULTRA-FAST**Aug 14, 2001  
88 days to decisionK011550 · Product code: **JHI** · Chemistry  
Source: <https://www.510kdatabase.net/k011550/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Visual, Pregnancy Hcg, Prescription Use (JHI)
Date received	May 18, 2001
Decision date	Aug 14, 2001
Days to decision	88 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k011550/> 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