

**K031048 CARESTART HCG COMBO ONE-STEP PREGNANCY TEST AND CARESTART PLUS HCG COMBO ONE-STEP PREGNANCY TEST**Jun 16, 2003  
75 days to decisionK031048 · Product code: **JHI** · Chemistry  
Source: <https://www.510kdatabase.net/k031048/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Visual, Pregnancy Hcg, Prescription Use (JHI)
Date received	Apr 2, 2003
Decision date	Jun 16, 2003
Days to decision	75 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Access Bio Incorporate</b>
Location	North Brunswick, NJ, US
Contact	YOUNG HO CHOI
510(k) history	4 submissions · 4 cleared · 2003-2005

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k031048/>; 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