

**K921206 HCG CONTROL**Apr 29, 1992  
47 days to decisionK921206 · Product code: **JJX** · Chemistry  
Source: <https://www.510kdatabase.net/k921206/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Single (specified) Analyte Controls (assayed And Unassayed) (JJX)
Date received	Mar 13, 1992
Decision date	Apr 29, 1992
Days to decision	47 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Polymedco, Inc.</b>
Location	Cortlandt Manor, NY, US
Contact	FRANK J COVIELLO
510(k) history	19 submissions · 19 cleared · 1992-2011

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k921206/> 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 18, 2026