

**K821676 PREG-PHILE B**Jul 16, 1982  
38 days to decisionK821676 · Product code: **JHJ** · Chemistry  
Source: <https://www.510kdatabase.net/k821676/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Agglutination Method, Human Chorionic Gonadotropin (JHJ)
Date received	Jun 8, 1982
Decision date	Jul 16, 1982
Days to decision	38 days
Third-party review	No

**APPLICANT**

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Company	<b>Bio Diagnostic Systems, Inc.</b>
Location	Walker, MI, US
510(k) history	2 submissions · 2 cleared · 1982-1988

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Device record: <https://www.510kdatabase.net/k821676/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).

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