

**K812461 TANDEM QUALITATIVE HCG KIT**Oct 13, 1981  
43 days to decisionK812461 · Product code: **JHI** · Chemistry  
Source: <https://www.510kdatabase.net/k812461/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Visual, Pregnancy Hcg, Prescription Use (JHI)
Date received	Aug 31, 1981
Decision date	Oct 13, 1981
Days to decision	43 days
Third-party review	No

**APPLICANT**

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Company	<b>Hybritech, Inc.</b>
Location	Mchenry, IL, US
510(k) history	63 submissions · 63 cleared · 1981-1997

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)

Device record: <https://www.510kdatabase.net/k812461/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).

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