

**K834000 TANDEM VISUAL HCG IMMUNOENZYMETRIC**Feb 3, 1984  
74 days to decisionK834000 · Product code: **JHI** · Chemistry  
Source: <https://www.510kdatabase.net/k834000/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Visual, Pregnancy Hcg, Prescription Use (JHI)
Date received	Nov 21, 1983
Decision date	Feb 3, 1984
Days to decision	74 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/k834000/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).

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