

**K870521 TANDEM(R) M-PAK(TM) TOTAL B-HCG IMMUNOENZY.  
ASSAY**Apr 8, 1987  
61 days to decisionK870521 · Product code: JHI · Chemistry  
Source: <https://www.510kdatabase.net/k870521/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Visual, Pregnancy Hcg, Prescription Use (JHI)
Date received	Feb 6, 1987
Decision date	Apr 8, 1987
Days to decision	61 days
Third-party review	No

**APPLICANT**

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Company	<b>Hybritech, Inc.</b>
Location	Mchenry, IL, US
Contact	KABAKOFF, PHD
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/k870521/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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