

**K850159 TANDEM ICON HCG IMMUNOENZYMETRIC ASSAY  
KIT**Mar 4, 1985  
48 days to decisionK850159 · Product code: JHI · Chemistry  
Source: <https://www.510kdatabase.net/k850159/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Visual, Pregnancy Hcg, Prescription Use (JHI)
Date received	Jan 15, 1985
Decision date	Mar 4, 1985
Days to decision	48 days
Third-party review	No

**APPLICANT**

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

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