

**K863861 TANDEM-M IMMUNOENZYMETRIC ASSAY FOR HUM/CHOR/GONA**Nov 21, 1986  
49 days to decisionK863861 · Product code: JHI · Chemistry  
Source: <https://www.510kdatabase.net/k863861/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Visual, Pregnancy Hcg, Prescription Use (JHI)
Date received	Oct 3, 1986
Decision date	Nov 21, 1986
Days to decision	49 days
Third-party review	No

**APPLICANT**

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Company	<b>Hybritech, Inc.</b>
Location	Mchenry, IL, US
Contact	BRUNI, PH.D.
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/k863861/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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