

**K863841 TANDEM OTC HCG PREGNANCY TEST FOR CONSUMER USE**Dec 22, 1986  
82 days to decisionK863841 · Product code: **LCX** · Chemistry  
Source: <https://www.510kdatabase.net/k863841/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Kit, Test, Pregnancy, Hcg, Over The Counter (LCX)
Date received	Oct 1, 1986
Decision date	Dec 22, 1986
Days to decision	82 days
Third-party review	No

**APPLICANT**

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Company	<b>Hybritech, Inc.</b>
Location	Mchenry, IL, US
Contact	BRUNI, 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/k863841/>; Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated June 30, 2026