

**K921763 TANDEM ICON QSR CKMB IMMUNOENZYMETRIC ASSAY**Jun 9, 1992  
56 days to decisionK921763 · Product code: JHY · Chemistry  
Source: <https://www.510kdatabase.net/k921763/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Colorimetric Method, Cpk Or Isoenzymes (JHY)
Date received	Apr 14, 1992
Decision date	Jun 9, 1992
Days to decision	56 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Hybritech, Inc.</b>
Location	Mchenry, IL, US
Contact	JOANNE MARTINIS
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/k921763/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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