

**K920556 TANDEM-E HCG CALIBRATION VERIFICATION
CONTROL SET**Jul 17, 1992
162 days to decisionK920556 · Product code: **JJX** · Chemistry
Source: <https://www.510kdatabase.net/k920556/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Single (specified) Analyte Controls (assayed And Unassayed) (JJX)
Date received	Feb 6, 1992
Decision date	Jul 17, 1992
Days to decision	162 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Hybritech, Inc.
Location	Mchenry, IL, US
Contact	JOANNE MARTINIS
510(k) history	63 submissions · 63 cleared · 1981-1997

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k920556/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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