

**K912439 TANDEM-E TSH CALIBRATION VERIFICATION CONTROL SET**

Aug 28, 1991  
86 days to decision

K912439 · Product code: **JJX** · Chemistry  
Source: <https://www.510kdatabase.net/k912439/>

**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Single (specified) Analyte Controls (assayed And Unassayed) (JJX)
Date received	Jun 3, 1991
Decision date	Aug 28, 1991
Days to decision	86 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/k912439/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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