

K922754 TANDEM-E IGE II CALIBRATION VERIFICATION SETFeb 17, 1993
254 days to decisionK922754 · Product code: **JJX** · Immunology
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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Single (specified) Analyte Controls (assayed And Unassayed) (JJX)
Date received	Jun 8, 1992
Decision date	Feb 17, 1993
Days to decision	254 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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