

K973099 PROSTATE SPECIFIC ANTIGEN CONTROLSep 29, 1997
41 days to decisionK973099 · 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	Aug 19, 1997
Decision date	Sep 29, 1997
Days to decision	41 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Dade Chemistry Systems, Inc.
Location	Newark, DE, US
Contact	REBECCA S AYASH
510(k) history	13 submissions · 13 cleared · 1996-1997

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