

K973100 PROSTATE SPECIFIC ANTIGEN (PSA) CALIBRATOR

Sep 29, 1997
41 days to decision

K973100 · Product code: **JIT** · Immunology
Source: <https://www.510kdatabase.net/k973100/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Calibrator, Secondary (JIT)
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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Device record: <https://www.510kdatabase.net/k973100/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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