

K003969 ELECSYS CA 125 II CALSETJan 12, 2001
21 days to decisionK003969 · Product code: **JIS** · Immunology
Source: <https://www.510kdatabase.net/k003969/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Calibrator, Primary (JIS)
Date received	Dec 22, 2000
Decision date	Jan 12, 2001
Days to decision	21 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Roche Diagnostics Corp.
Location	Indianapolis, IN, US
Contact	KAY A TAYLOR
510(k) history	264 submissions · 263 cleared · 1999-2013

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