

**K002353 ELECSYS CA 15-3 CALCHECK**Aug 10, 2000  
8 days to decisionK002353 · Product code: **JIS** · Immunology  
Source: <https://www.510kdatabase.net/k002353/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Calibrator, Primary (JIS)
Date received	Aug 2, 2000
Decision date	Aug 10, 2000
Days to decision	8 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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

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