

**K003411 ELECSYS TESTOSTERONE CALSET II**Mar 1, 2001  
119 days to decisionK003411 · Product code: **JIT** · Chemistry  
Source: <https://www.510kdatabase.net/k003411/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Calibrator, Secondary (JIT)
Date received	Nov 2, 2000
Decision date	Mar 1, 2001
Days to decision	119 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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