

**K003941 ELECSYS HCG STAT CLASET II**Jan 25, 2001  
35 days to decisionK003941 · Product code: **JIS** · Chemistry  
Source: <https://www.510kdatabase.net/k003941/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Calibrator, Primary (JIS)
Date received	Dec 21, 2000
Decision date	Jan 25, 2001
Days to decision	35 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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