

K080147 ELECSYS PROBNP II CALCHECKFeb 27, 2008
36 days to decisionK080147 · Product code: **JJX** · Chemistry
Source: <https://www.510kdatabase.net/k080147/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Single (specified) Analyte Controls (assayed And Unassayed) (JJX)
Date received	Jan 22, 2008
Decision date	Feb 27, 2008
Days to decision	36 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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