

**K041812 MODIFICATION TO ROCHE DIAGNOSTICS
PRECINORM PROTEINS IN URINE/CSF (PUC) AND PRECIPATH
PROTEINS IN URINE/CSF (PUC)**Jul 27, 2004
21 days to decisionK041812 · Product code: JJY · Chemistry
Source: <https://www.510kdatabase.net/k041812/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Multi-analyte Controls, All Kinds (assayed) (JJY)
Date received	Jul 6, 2004
Decision date	Jul 27, 2004
Days to decision	21 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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