

K012397 URISYS 2400 URINE TEST STRIPSep 26, 2001
61 days to decisionK012397 · Product code: **JIL** · Chemistry
Source: <https://www.510kdatabase.net/k012397/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Method, Enzymatic, Glucose (urinary, Non-quantitative) (JIL)
Date received	Jul 27, 2001
Decision date	Sep 26, 2001
Days to decision	61 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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