

K012065 WIENER LAB. CREATININA CINETICA AAOct 10, 2001
100 days to decisionK012065 · Product code: **JFY** · Chemistry
Source: <https://www.510kdatabase.net/k012065/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzymatic Method, Creatinine (JFY)
Date received	Jul 2, 2001
Decision date	Oct 10, 2001
Days to decision	100 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Wiener Laboratories Saic
Location	Rosario, Santa Fe, AR
Contact	VIVIANA CETOLA
510(k) history	24 submissions · 24 cleared · 2001-2004

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