

**K013101 WIENER LAB. AMILASA 405 CINETICA AA, WIENER LAB.AMILASA 405 CINETICA UNITEST,WIENER LAB.AMILASA CINETICA AA**

Nov 16, 2001  
60 days to decision

K013101 · Product code: **JFJ** · Chemistry  
Source: <https://www.510kdatabase.net/k013101/>

**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catalytic Methods, Amylase (JFJ)
Date received	Sep 17, 2001
Decision date	Nov 16, 2001
Days to decision	60 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)

Device record: <https://www.510kdatabase.net/k013101/>; Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).

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