

K023841 AMMONIA ASSAY FOR THE ADVIA 1650Dec 24, 2002
36 days to decisionK023841 · Product code: **JIF** · Immunology
Source: <https://www.510kdatabase.net/k023841/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzymatic Method, Ammonia (JIF)
Date received	Nov 18, 2002
Decision date	Dec 24, 2002
Days to decision	36 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Bayer Diagnostics Corp.
Location	Medfield, MA, US
Contact	ANDRES HOLLE
510(k) history	32 submissions · 32 cleared · 2000-2003

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