

K021151 AMMONIA ASSAY FOR THE ADVIA INTEGRATED MODULAR SYSTEMJul 13, 2002
94 days to decisionK021151 · Product code: JIF · Chemistry
Source: <https://www.510kdatabase.net/k021151/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzymatic Method, Ammonia (JIF)
Date received	Apr 10, 2002
Decision date	Jul 13, 2002
Days to decision	94 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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