

K022178 CA 15-3 ASSAY FOR THE ADVIA INTEGRATED MODULAR SYSTEMNov 12, 2002
132 days to decisionK022178 · Product code: **MOI** · Immunology
Source: <https://www.510kdatabase.net/k022178/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Test, Immunological, Antigen, Tumor (MOI)
Date received	Jul 3, 2002
Decision date	Nov 12, 2002
Days to decision	132 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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