

**K022329 CA 125 II ASSAY FOR THE BAYER ADVIA
INTEGRATED MODULE SYSTEM**Nov 27, 2002
132 days to decisionK022329 · Product code: LTK · Immunology
Source: <https://www.510kdatabase.net/k022329/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Test, Epithelial Ovarian Tumor-associated Antigen (ca125) (LTK)
Date received	Jul 18, 2002
Decision date	Nov 27, 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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