

K033007 BAYER ADVIA DIGOXIN ASSAY FOR THE INTEGRATED MODULE SYSTEMNov 14, 2003
49 days to decisionK033007 · Product code: **KXT** · Chemistry
Source: <https://www.510kdatabase.net/k033007/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Immunoassay, Digoxin (KXT)
Date received	Sep 26, 2003
Decision date	Nov 14, 2003
Days to decision	49 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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