

**K940267 ACE CLINICAL CHEMISTRY SYSTEM**May 3, 1994  
102 days to decisionK940267 · Product code: **KXT** · Chemistry  
Source: <https://www.510kdatabase.net/k940267/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Immunoassay, Digoxin (KXT)
Date received	Jan 21, 1994
Decision date	May 3, 1994
Days to decision	102 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Schiapparelli Biosystems, Inc.</b>
Location	Fairfield, NJ, US
Contact	MARK A SPAIN, PH.D.
510(k) history	24 submissions · 24 cleared · 1993-1999

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