

**K011920 EMIT 2000 DIGOXIN ASSAY, MODEL OSR4H229**

Jul 2, 2001  
 12 days to decision

K011920 · Product code: **KXT** · Toxicology  
 Source: <https://www.510kdatabase.net/k011920/>

**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Enzyme Immunoassay, Digoxin (KXT)
Date received	Jun 20, 2001
Decision date	Jul 2, 2001
Days to decision	12 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Syva Co., Dade Behring, Inc.</b>
Location	San Jose, CA, US
Contact	SUSAN L COLLINS
510(k) history	19 submissions · 19 cleared · 2000-2001

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)

Device record: <https://www.510kdatabase.net/k011920/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).

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