

**K082953 ARCHITECT IDIGOXIN AND ARCHITECT IDIGOXIN CALIBRATORS, MODELS 1P32-25 AND IP32-01**

Dec 22, 2008  
80 days to decision

K082953 · Product code: **KXT** · Toxicology  
Source: <https://www.510kdatabase.net/k082953/>

**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Immunoassay, Digoxin (KXT)
Date received	Oct 3, 2008
Decision date	Dec 22, 2008
Days to decision	80 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Biokit, S.A.</b>
Location	Barcelona, ES
Contact	JOAN GUIXER
510(k) history	23 submissions · 23 cleared · 2005-2025

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

Device record: <https://www.510kdatabase.net/k082953/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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