

**K050493 QUANTIA IGE**Aug 16, 2005  
169 days to decisionK050493 · Product code: **DGC** · Immunology  
Source: <https://www.510kdatabase.net/k050493/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ige, Antigen, Antiserum, Control (DGC)
Date received	Feb 28, 2005
Decision date	Aug 16, 2005
Days to decision	169 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/k050493/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated June 28, 2026