

**K042519 GAMMA-B 1,25-DIHYDROXY VITAMIN D**Dec 1, 2004  
76 days to decisionK042519 · Product code: **MRG** · Chemistry  
Source: <https://www.510kdatabase.net/k042519/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	System, Test, Vitamin D (MRG)
Date received	Sep 16, 2004
Decision date	Dec 1, 2004
Days to decision	76 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Immunodiagnostic Systems , Ltd.</b>
Location	Tyne And Wear, GB
Contact	PAUL PUNTIN
510(k) history	23 submissions · 23 cleared · 1994-2021

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k042519/> 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 29, 2026