

**K884074 IMMUNOCHEMICAL DETERMINATION OF  
IMMUNOGLOBULIN G**Oct 27, 1988  
30 days to decisionK884074 · Product code: **DAH** · Immunology  
Source: <https://www.510kdatabase.net/k884074/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Gamma Globulin, Antigen, Antiserum, Control (DAH)
Date received	Sep 27, 1988
Decision date	Oct 27, 1988
Days to decision	30 days
Third-party review	No

**APPLICANT**

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Company	<b>Orion Diagnostica, Inc.</b>
Location	Mchenry, IL, US
Contact	TIMO RAINES
510(k) history	28 submissions · 28 cleared · 1980-1994

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**510k Database** - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k884074/>; 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 30, 2026