

**K091332 AIA-PACK RBC FOLATE**Oct 2, 2009  
149 days to decisionK091332 · Product code: **CGN** · Chemistry  
Source: <https://www.510kdatabase.net/k091332/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Acid, Folic, Radioimmunoassay (CGN)
Date received	May 6, 2009
Decision date	Oct 2, 2009
Days to decision	149 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Tosoh Bioscience, Inc.</b>
Location	Grove City, OH, US
Contact	CHARLES P GILL
510(k) history	20 submissions · 20 cleared · 2007-2025

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k091332/> 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 22, 2026