

**K072409 AFINION ACR AND ACR CONTROL**Feb 12, 2008  
169 days to decisionK072409 · Product code: **JFY** · Chemistry  
Source: <https://www.510kdatabase.net/k072409/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzymatic Method, Creatinine (JFY)
Date received	Aug 27, 2007
Decision date	Feb 12, 2008
Days to decision	169 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Axis-Shield Poc AS</b>
Location	San Diego, CA, US
Contact	JORUNN GREVIE LOLLAND
510(k) history	4 submissions · 4 cleared · 2005-2014

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k072409/> 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 7, 2026