

**K080751 ARCHITECT CYCLOSPORINE**Sep 11, 2008  
177 days to decisionK080751 · Product code: **MKW** · Toxicology  
Source: <https://www.510kdatabase.net/k080751/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Cyclosporine (MKW)
Date received	Mar 18, 2008
Decision date	Sep 11, 2008
Days to decision	177 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Fujirebio Diagnostics, Inc.</b>
Location	North Caldwell, NJ, US
Contact	STACEY MOLL
510(k) history	45 submissions · 43 cleared · 1989-2025

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k080751/> 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 24, 2026