

**K090239 PROGASTRO CD ASSAY**Apr 16, 2009  
73 days to decisionK090239 · Product code: **LLH** · Microbiology  
Source: <https://www.510kdatabase.net/k090239/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Reagents, Clostridium Difficile Toxin (LLH)
Date received	Feb 2, 2009
Decision date	Apr 16, 2009
Days to decision	73 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Prodesse, Inc.</b>
Location	Waukesha, WI, US
Contact	KRISTINE SCHRAUFNAGEL
510(k) history	6 submissions · 6 cleared · 2008-2009

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k090239/> 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