

**K081938 ACETAMINOPHEN L3K ASSAY, AND  
ACETAMINOPHEN L3K ASSAY, MODELS 506-10, 506-30**May 1, 2009  
297 days to decisionK081938 · Product code: LDP · Toxicology  
Source: <https://www.510kdatabase.net/k081938/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Colorimetry, Acetaminophen (LDP)
Date received	Jul 8, 2008
Decision date	May 1, 2009
Days to decision	297 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Genzyme Diagnostics P.E.I., Inc.</b>
Location	Charlottetown, Prin Ed Island, CA
Contact	PENNY J WHITE
510(k) history	2 submissions · 2 cleared · 2008-2009

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k081938/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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