FDA 510(k) Premarket Notification

K081938 ACETAMINOPHEN L3K ASSAY, AND ACETAMINOPHEN L3K ASSAY, MODELS 506-10, 506-30

CLEARED

May 1, 2009
297 days to decision

K081938 · Product code: **LDP** · Toxicology
Source: https://www.510kdatabase.net/k081938/

SUBMISSION DETAILS

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

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