

**K102643 SPOTCHECK NEONATAL GALT MICROPLATE  
REAGENT KIT**Jul 15, 2011  
304 days to decisionK102643 · Product code: **KQP** · Chemistry  
Source: <https://www.510kdatabase.net/k102643/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Fluorescent Proc. (qual.), Galactose-1-phosphate Uridyl Transferase (KQP)
Date received	Sep 14, 2010
Decision date	Jul 15, 2011
Days to decision	304 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Astoria-Pacific, Inc.</b>
Location	Clakamas, OR, US
Contact	JASON C REYNOLDS
510(k) history	9 submissions · 9 cleared · 1997-2013

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k102643/> 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 8, 2026