

**K121101 SPOTCHECK NEONATAL TOTAL GALACTOSE
MICROPLATE REAGENT KIT**Jun 20, 2013
435 days to decisionK121101 · Product code: JIA · Chemistry
Source: <https://www.510kdatabase.net/k121101/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzymatic Methods, Galactose (JIA)
Date received	Apr 11, 2012
Decision date	Jun 20, 2013
Days to decision	435 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Astoria-Pacific, Inc.
Location	Clakamas, OR, US
Contact	CHARLES A PETERSON
510(k) history	9 submissions · 9 cleared · 1997-2013

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