

**K080294 ASTORIA-PACIFIC SPOTCHECK BIOTINIDASE
MICROPLATE REAGENT KIT**

Nov 4, 2008
274 days to decision

K080294 · Product code: **NAK** · Chemistry
Source: <https://www.510kdatabase.net/k080294/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Test, Biotinidase (NAK)
Date received	Feb 4, 2008
Decision date	Nov 4, 2008
Days to decision	274 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k080294/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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