

K010844 ASTORIA-PACIFIC SPOTCHECK BIOTINIDASE KIT, 50 HOUR, PART NO. 80-8000-13KSep 21, 2001
184 days to decisionK010844 · Product code: **NAK** · Chemistry
Source: <https://www.510kdatabase.net/k010844/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | System, Test, Biotinidase (NAK) |
| Date received | Mar 21, 2001 |
| Decision date | Sep 21, 2001 |
| Days to decision | 184 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Astoria-Pacific, Inc. |
| Location | Clakamas, OR, US |
| Contact | RAYMOND L PAVITT |
| 510(k) history | 9 submissions · 9 cleared · 1997-2013 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k010844/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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