

K041049 BINAXNOW INFLUENZA A & B TESTAug 10, 2004
110 days to decisionK041049 · Product code: **PSZ** · Microbiology
Source: <https://www.510kdatabase.net/k041049/>**SUBMISSION DETAILS**

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|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Devices Detecting Influenza A, B, And C Virus Antigens (PSZ) |
| Date received | Apr 22, 2004 |
| Decision date | Aug 10, 2004 |
| Days to decision | 110 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Binax, Inc. |
| Location | S. Portland, ME, US |
| Contact | PAM ANGELL |
| 510(k) history | 30 submissions · 30 cleared · 1986-2010 |

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