

K080003 BINAXNOW G6PD TESTOct 23, 2008
295 days to decisionK080003 · Product code: **JBF** · Hematology
Source: <https://www.510kdatabase.net/k080003/>**SUBMISSION DETAILS**

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Glucose-6-phosphate Dehydrogenase (erythrocytic), Screening (JBF) |
| Date received | Jan 2, 2008 |
| Decision date | Oct 23, 2008 |
| Days to decision | 295 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

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

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