

K964151 BARD AND BTA TESTApr 16, 1997
197 days to decisionK964151 · Product code: **MMW** · Immunology
Source: <https://www.510kdatabase.net/k964151/>**SUBMISSION DETAILS**

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | System, Test, Tumor Marker, Monitoring, Bladder (MMW) |
| Date received | Oct 1, 1996 |
| Decision date | Apr 16, 1997 |
| Days to decision | 197 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Bard Diagnostic Sciences, Inc. |
| Location | Redmond, WA, US |
| Contact | GLEN P FREIBERG |
| 510(k) history | 3 submissions · 3 cleared · 1997-1998 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k964151/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated June 29, 2026