

K974845 BTA STAT TEST PRESCRIPTION HOME USEDec 8, 1998
355 days to decisionK974845 · Product code: **MMW** · Immunology
Source: <https://www.510kdatabase.net/k974845/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Test, Tumor Marker, Monitoring, Bladder (MMW)
Date received	Dec 18, 1997
Decision date	Dec 8, 1998
Days to decision	355 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Bard Diagnostic Sciences, Inc.
Location	Redmond, WA, US
Contact	Glen Paul Freiberg
510(k) history	3 submissions · 3 cleared · 1997-1998

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