

**K033982 MODIFICATION TO VYSIS UROVYSION BLADDER
CANCER RECURRENCE TEST**Jan 22, 2004
30 days to decisionK033982 · Product code: **MMW** · Immunology
Source: <https://www.510kdatabase.net/k033982/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	System, Test, Tumor Marker, Monitoring, Bladder (MMW)
Date received	Dec 23, 2003
Decision date	Jan 22, 2004
Days to decision	30 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Vysis
Location	Downers Grove, IL, US
Contact	KERRY J FLOM
510(k) history	9 submissions · 8 cleared · 1996-2004

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k033982/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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