

K013785 UROVYSION BLADDER CANCER RECURRENCE KITFeb 8, 2002
86 days to decisionK013785 · Product code: **MMW** · Immunology
Source: <https://www.510kdatabase.net/k013785/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	System, Test, Tumor Marker, Monitoring, Bladder (MMW)
Date received	Nov 14, 2001
Decision date	Feb 8, 2002
Days to decision	86 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Vysis
Location	Downers Grove, IL, US
Contact	RUSSEL K ENNS
510(k) history	9 submissions · 8 cleared · 1996-2004

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k013785/> 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 May 14, 2026