

**K011031 VYSIS UROVYSION BLADDER CANCER
RECURRENCE KIT**

Aug 3, 2001
120 days to decision

K011031 · Product code: **MMW** · Immunology
Source: <https://www.510kdatabase.net/k011031/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Test, Tumor Marker, Monitoring, Bladder (MMW)
Date received	Apr 5, 2001
Decision date	Aug 3, 2001
Days to decision	120 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.net

Device record: <https://www.510kdatabase.net/k011031/> 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