FDA 510(k) Premarket Notification

K013785 UROVYSION BLADDER CANCER RECURRENCE KIT

CLEARED

Feb 8, 2002
86 days to decision

K013785 · 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