FDA 510(k) Premarket Notification

CLEARED

K033982 MODIFICATION TO VYSIS UROVYSION BLADDER CANCER RECURRENCE TEST

Jan 22, 2004
30 days to decision

K033982 · 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