FDA 510(k) Premarket Notification

CLEARED

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