FDA 510(k) Premarket Notification

K061820 DIASORIN LIAISON VZV IGG

CLEARED

Feb 26, 2007
243 days to decision

K061820 · Product code: **LFY** · Microbiology
Source: https://www.510kdatabase.net/k061820/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Linked Immunoabsorbent Assay, Varicella-zoster (LFY)
Date received	Jun 28, 2006
Decision date	Feb 26, 2007
Days to decision	243 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**DiaSorin, Inc.**
Location	Ellicott City, MD, US
Contact	Mari Meyer
510(k) history	71 submissions · 70 cleared · 1998-2026