

**K212769 DYNEX SmartPLEX MMRV IgG Assay Kit**Sep 29, 2023  
759 days to decisionK212769 · Product code: **OPL** · Microbiology  
Source: <https://www.510kdatabase.net/k212769/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Multiplex Immunoassay For Measles Virus, Mumps Virus, Rubella And Varicella Zoster Virus (OPL)
Date received	Aug 31, 2021
Decision date	Sep 29, 2023
Days to decision	759 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Dynex Technologies, Inc.</b>
Location	Chantilly, VA, US
Contact	Jeff Fisher
510(k) history	1 submissions · 1 cleared · 2023-2023

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k212769/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://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](https://accessdata.fda.gov). - Generated May 26, 2026