

**K243979 Aptiva APS IgA Reagent**Feb 6, 2026  
410 days to decisionK243979 · Product code: **MSV** · Immunology  
Source: <https://www.510kdatabase.net/k243979/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System,test,antibodies,b2 - Glycoprotein I (b2 - Gpi) (MSV)
Date received	Dec 23, 2024
Decision date	Feb 6, 2026
Days to decision	410 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Inova Diagnostics, Inc.</b>
Location	San Diego, CA, US
Contact	Melissa Sanchez
Website	<a href="https://www.inovadx.com">https://www.inovadx.com</a>
510(k) history	138 submissions · 136 cleared · 1988-2026

Siemens Healthcare Diagnostics, Inc. is a leading diagnostic device manufacturer based in New York. The company specializes in laboratory diagnostics and clinical chemistry solutions. The company has received FDA 510(k) clearances from total submissions since its first clearance in 2008. Chemistry devices and immunology assays represent the core focus of its regulatory portfolio. The latest FDA 510(k) clearance in 2026 reflects continued active development and market engagement. Recent cleared devices include automated chemistry analyzers, immunoassay systems, and special...

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)

Device record: <https://www.510kdatabase.net/k243979/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://accessdata.fda.gov)).

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