

**K242706 Lumipulse G pTau217/ $\beta$ -Amyloid 1-42 Plasma Ratio**May 16, 2025  
249 days to decisionK242706 · Product code: **SET** · Immunology  
Source: <https://www.510kdatabase.net/k242706/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Immunoassay Blood Test For Amyloid Pathology Assessment (SET)
Date received	Sep 9, 2024
Decision date	May 16, 2025
Days to decision	249 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Fujirebio Diagnostics, Inc.</b>
Location	North Caldwell, NJ, US
Contact	Stacey Dolan
510(k) history	45 submissions · 43 cleared · 1989-2025

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k242706/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated May 13, 2026