

K192524 Lumipulse G CA15-3Sep 4, 2020
357 days to decisionK192524 · Product code: **MOI** · Immunology
Source: <https://www.510kdatabase.net/k192524/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Test, Immunological, Antigen, Tumor (MOI)
Date received	Sep 13, 2019
Decision date	Sep 4, 2020
Days to decision	357 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Fujirebio Diagnostics, Inc.
Location	North Caldwell, NJ, US
Contact	Kristin Maddaloni
510(k) history	45 submissions · 43 cleared · 1989-2025

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