

K153361 Lumipulse G 25-OH Vitamin D, Lumipulse G 25-OH Vitamin D CalibratorsApr 15, 2016
147 days to decisionK153361 · Product code: **MRG** · Chemistry
Source: <https://www.510kdatabase.net/k153361/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Test, Vitamin D (MRG)
Date received	Nov 20, 2015
Decision date	Apr 15, 2016
Days to decision	147 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k153361/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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