

K163544 Lumipulse G ProlactinJan 12, 2017
27 days to decisionK163544 · Product code: **JIT** · Chemistry
Source: <https://www.510kdatabase.net/k163544/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Calibrator, Secondary (JIT)
Date received	Dec 16, 2016
Decision date	Jan 12, 2017
Days to decision	27 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

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