

**K163534 Lumipulse G FSH-N Calibrators**Jan 13, 2017  
28 days to decisionK163534 · Product code: **JIT** · Chemistry  
Source: <https://www.510kdatabase.net/k163534/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Abbreviated
Device classification	Calibrator, Secondary (JIT)
Date received	Dec 16, 2016
Decision date	Jan 13, 2017
Days to decision	28 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

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

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k163534/> 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 June 2, 2026