

**K151378 Lumipulse G HE4 Immunoreaction Cartridges,
Lumipulse G HE4 Calibrators**Nov 24, 2015
186 days to decisionK151378 · Product code: **OIU** · Immunology
Source: <https://www.510kdatabase.net/k151378/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Test, Epithelial Ovarian Tumor Associated Antigen (he4) (OIU)
Date received	May 22, 2015
Decision date	Nov 24, 2015
Days to decision	186 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k151378/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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