

K153145 Lumipulse G TP-N Immunoreaction Cartridge SetJul 5, 2016
249 days to decisionK153145 · Product code: **LIP** · Microbiology
Source: <https://www.510kdatabase.net/k153145/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Linked Immunoabsorption Assay, Treponema Pallidum (LIP)
Date received	Oct 30, 2015
Decision date	Jul 5, 2016
Days to decision	249 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/k153145/> Data sourced from FDA 510(k) public records (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. - Generated June 2, 2026