

K171103 Lumipulse G TSH-III Immunoreaction CartridgesJul 28, 2017
106 days to decisionK171103 · Product code: **JLW** · Chemistry
Source: <https://www.510kdatabase.net/k171103/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Radioimmunoassay, Thyroid-stimulating Hormone (JLW)
Date received	Apr 13, 2017
Decision date	Jul 28, 2017
Days to decision	106 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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