

K190702 Lumipulse G whole PTHAug 30, 2019
165 days to decisionK190702 · Product code: **CEW** · Chemistry
Source: <https://www.510kdatabase.net/k190702/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Radioimmunoassay, Parathyroid Hormone (CEW)
Date received	Mar 18, 2019
Decision date	Aug 30, 2019
Days to decision	165 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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k190702/> 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 May 14, 2026