FDA 510(k) Premarket Notification

K190702 Lumipulse G whole PTH

CLEARED

Aug 30, 2019
165 days to decision

K190702 · 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