FDA 510(k) Premarket Notification

CLEARED

K142895 LUMIPULSE G1200 System, LUMIPULSE G CA 125II Immunoreaction Cartridges, LUMIPULSE G CA 125II Calibrators

May 21, 2015
230 days to decision

K142895 · Product code: **LTK** · Immunology
Source: https://www.510kdatabase.net/k142895/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Test, Epithelial Ovarian Tumor-associated Antigen (ca125) (LTK)
Date received	Oct 3, 2014
Decision date	May 21, 2015
Days to decision	230 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