

K160090 Lumipulse G ROMAMay 16, 2016
122 days to decisionK160090 · Product code: **ONX** · Immunology
Source: <https://www.510kdatabase.net/k160090/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ovarian Adnexal Mass Assessment Score Test System (ONX)
Date received	Jan 15, 2016
Decision date	May 16, 2016
Days to decision	122 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

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