

**K103358 ROMA (HE4 EIA + ARCHITECT CA 125 II)**Sep 1, 2011  
289 days to decisionK103358 · Product code: **ONX** · Immunology  
Source: <https://www.510kdatabase.net/k103358/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent - U
Submission type	Traditional
Device classification	Ovarian Adnexal Mass Assessment Score Test System (ONX)
Date received	Nov 16, 2010
Decision date	Sep 1, 2011
Days to decision	289 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Fujirebio Diagnostics, Inc.</b>
Location	North Caldwell, NJ, US
Contact	DIANA L DICKSON
510(k) history	45 submissions · 43 cleared · 1989-2025

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k103358/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated June 18, 2026