

**K093957 ARCHITECT HE4, ARCHITECT HE4 CALIBRATORS
AND ARCHITECT HE4 CONTROLS, MODELS 2, 2P54, 2P54-01,
2P54-10 SP54-01,**Mar 18, 2010
85 days to decisionK093957 · Product code: **OIU** · Immunology
Source: <https://www.510kdatabase.net/k093957/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Test, Epithelial Ovarian Tumor Associated Antigen (he4) (OIU)
Date received	Dec 23, 2009
Decision date	Mar 18, 2010
Days to decision	85 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

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