

K072939 HE4 EIA, MODEL: 404-10 USJun 9, 2008
236 days to decisionK072939 · Product code: **OIU** · Immunology
Source: <https://www.510kdatabase.net/k072939/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Test, Epithelial Ovarian Tumor Associated Antigen (he4) (OIU)
Date received	Oct 17, 2007
Decision date	Jun 9, 2008
Days to decision	236 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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