

**K112624 ELECSYS HE4, ELECSYS HE4 CALSET, ELECSYS
PRECICONTROL HE4, ELECSYS HE4 CALCHECK 5**Sep 10, 2012
368 days to decisionK112624 · Product code: **OIU** · Immunology
Source: <https://www.510kdatabase.net/k112624/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Test, Epithelial Ovarian Tumor Associated Antigen (he4) (OIU)
Date received	Sep 8, 2011
Decision date	Sep 10, 2012
Days to decision	368 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Roche Diagnostics
Location	Indianapolis, IN, US
Contact	JANE PHILLIPS
Website	https://diagnostics.roche.com
510(k) history	182 submissions · 180 cleared · 2005-2026

Roche Diagnostics is a Swiss multinational healthcare company specializing in diagnostic devices and solutions. The company operates its U.S. diagnostics division from Indianapolis. Roche Diagnostics maintains a strong FDA 510(k) regulatory record with FDA 510(k) cleared devices from total submissions since 2005. The company's portfolio spans chemistry devices, immunology assays, microbiology testing, and hematology systems. The latest clearance in 2026 reflects continued innovation and regulatory engagement. Recent cleared devices include glucose monitoring systems, elec...

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Device record: <https://www.510kdatabase.net/k112624/>. Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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