

**K242505 Elecsys Cortisol III**Jul 17, 2025  
329 days to decisionK242505 · Product code: **JFT** · Chemistry  
Source: <https://www.510kdatabase.net/k242505/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Fluorometric, Cortisol (JFT)
Date received	Aug 22, 2024
Decision date	Jul 17, 2025
Days to decision	329 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Roche Diagnostics</b>
Location	Indianapolis, IN, US
Contact	Chunhong (Emma) Tao
Website	<a href="https://diagnostics.roche.com">https://diagnostics.roche.com</a>
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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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)

Device record: <https://www.510kdatabase.net/k242505/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](https://accessdata.fda.gov)).

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