

**K140404 ELECSYS CK-MB STAT IMMUNOASSAY**May 8, 2014  
79 days to decisionK140404 · Product code: **JHY** · Chemistry  
Source: <https://www.510kdatabase.net/k140404/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Colorimetric Method, Cpk Or Isoenzymes (JHY)
Date received	Feb 18, 2014
Decision date	May 8, 2014
Days to decision	79 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Roche Diagnostics</b>
Location	Indianapolis, IN, US
Contact	KELLI TURNER
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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