

K132571 ELECSYS CK-MB STAT IMMUNOASSAY, ELECSYS CK-MB IMMUNOASSAYOct 18, 2013
64 days to decisionK132571 · Product code: JHY · Chemistry
Source: <https://www.510kdatabase.net/k132571/>**SUBMISSION DETAILS**

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|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Colorimetric Method, Cpk Or Isoenzymes (JHY) |
| Date received | Aug 15, 2013 |
| Decision date | Oct 18, 2013 |
| Days to decision | 64 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Roche Diagnostics |
| Location | Indianapolis, IN, US |
| Contact | KELLI TURNER |
| 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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