

K083260 ELECSYS MYOGLOBIN STAT, AND ELECSYS MYOGLOBINOct 16, 2009
345 days to decisionK083260 · Product code: **DDR** · Chemistry
Source: <https://www.510kdatabase.net/k083260/>**SUBMISSION DETAILS**

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|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Myoglobin, Antigen, Antiserum, Control (DDR) |
| Date received | Nov 5, 2008 |
| Decision date | Oct 16, 2009 |
| Days to decision | 345 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Roche Diagnostics |
| Location | Indianapolis, IN, US |
| Contact | JACK ROGERS |
| 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/k083260/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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