

**K050231 ELECSYS CA 19-9 IMMUNOASSAY, ELECSYS CA 19-9
CALSET**Jul 6, 2005
161 days to decisionK050231 · Product code: **JIT** · Immunology
Source: <https://www.510kdatabase.net/k050231/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Calibrator, Secondary (JIT) |
| Date received | Jan 26, 2005 |
| Decision date | Jul 6, 2005 |
| Days to decision | 161 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Roche Diagnostics Corp. |
| Location | Indianapolis, IN, US |
| Contact | KAY A TAYLOR |
| 510(k) history | 264 submissions · 263 cleared · 1999-2013 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k050231/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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