

K001846 ELECSYS INSULIN CALCHECKJun 28, 2000
9 days to decisionK001846 · Product code: **JJX** · Chemistry
Source: <https://www.510kdatabase.net/k001846/>**SUBMISSION DETAILS**

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Single (specified) Analyte Controls (assayed And Unassayed) (JJX) |
| Date received | Jun 19, 2000 |
| Decision date | Jun 28, 2000 |
| Days to decision | 9 days |
| Third-party review | Yes |
| Summary / Statement | Summary |

APPLICANT

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

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