

K885292 COBAS MFCMar 22, 1989
85 days to decisionK885292 · Product code: **JQP** · Chemistry
Source: <https://www.510kdatabase.net/k885292/>**SUBMISSION DETAILS**

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Calculator/data Processing Module, For Clinical Use (JQP) |
| Date received | Dec 27, 1988 |
| Decision date | Mar 22, 1989 |
| Days to decision | 85 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |

APPLICANT

| | |
|----------------|---|
| Company | Roche Diagnostic Systems, Inc. |
| Location | Mchenry, IL, US |
| Contact | ALEX WESOLOWSKI |
| 510(k) history | 296 submissions · 296 cleared · 1983-1999 |

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k885292/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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