

K003158 ROCHE DIAGNOSTICS CK-MBDec 18, 2000
69 days to decisionK003158 · Product code: **JHW** · Chemistry
Source: <https://www.510kdatabase.net/k003158/>**SUBMISSION DETAILS**

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|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | U.v. Method, Cpk Isoenzymes (JHW) |
| Date received | Oct 10, 2000 |
| Decision date | Dec 18, 2000 |
| Days to decision | 69 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

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

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