

K030546 CRP (II) CALIBRATORSJun 2, 2003
102 days to decisionK030546 · Product code: **JIS** · Immunology
Source: <https://www.510kdatabase.net/k030546/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Calibrator, Primary (JIS) |
| Date received | Feb 20, 2003 |
| Decision date | Jun 2, 2003 |
| Days to decision | 102 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Denka Seiken Co., Ltd. |
| Location | Gosen City, Niigata, JP |
| Contact | TOSHIMI MATSUNAGA |
| 510(k) history | 6 submissions · 6 cleared · 2003-2017 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k030546/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated June 1, 2026