

K991181 MODIFICATION OF N PROTEIN STANDARD SLJun 1, 1999
55 days to decisionK991181 · Product code: **JIX** · Chemistry
Source: <https://www.510kdatabase.net/k991181/>**SUBMISSION DETAILS**

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Calibrator, Multi-analyte Mixture (JIX) |
| Date received | Apr 7, 1999 |
| Decision date | Jun 1, 1999 |
| Days to decision | 55 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Dade Behring, Inc. |
| Location | Newark,, DE, US |
| Contact | CAROLYN K GEORGE |
| 510(k) history | 343 submissions · 343 cleared · 1978-2010 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k991181/> 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 19, 2026