

K991166 K-ASSAY MICROALBUMIN CALIBRATOR SETJun 10, 1999
64 days to decisionK991166 · Product code: **JIX** · Chemistry
Source: <https://www.510kdatabase.net/k991166/>**SUBMISSION DETAILS**

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Calibrator, Multi-analyte Mixture (JIX) |
| Date received | Apr 7, 1999 |
| Decision date | Jun 10, 1999 |
| Days to decision | 64 days |
| Third-party review | No |
| Summary / Statement | Statement |

APPLICANT

| | |
|----------------|---|
| Company | Kamiya Biomedical Co. |
| Location | Thousand Oaks, CA, US |
| Contact | COLIN GETTY |
| 510(k) history | 43 submissions · 43 cleared · 1991-2010 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k991166/> 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 20, 2026