

K993354 K-ASSAY APO BOct 28, 1999
23 days to decisionK993354 · Product code: **DER** · Chemistry
Source: <https://www.510kdatabase.net/k993354/>**SUBMISSION DETAILS**

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|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Alpha-1-lipoprotein, Antigen, Antiserum, Control (DER) |
| Date received | Oct 5, 1999 |
| Decision date | Oct 28, 1999 |
| Days to decision | 23 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/k993354/> 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