

K964728 STA-LIATEST D-DI TEST KITJun 26, 1997
213 days to decisionK964728 · Product code: **DAP** · Hematology
Source: <https://www.510kdatabase.net/k964728/>**SUBMISSION DETAILS**

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Fibrinogen And Fibrin Split Products, Antigen, Antiserum, Control (DAP) |
| Date received | Nov 25, 1996 |
| Decision date | Jun 26, 1997 |
| Days to decision | 213 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | American Bioproducts Co. |
| Location | Parsippany, NJ, US |
| Contact | ANDREW LOC B. LE |
| 510(k) history | 79 submissions · 75 cleared · 1985-1998 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k964728/> 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 28, 2026