

K813530 HEMOTOLOGY CALIBRATORFeb 22, 1982
67 days to decisionK813530 · Product code: **KSA** · Hematology
Source: <https://www.510kdatabase.net/k813530/>**SUBMISSION DETAILS**

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Calibrator For Red-cell And White-cell Counting (KSA) |
| Date received | Dec 17, 1981 |
| Decision date | Feb 22, 1982 |
| Days to decision | 67 days |
| Third-party review | No |

APPLICANT

| | |
|----------------|---|
| Company | American Dade |
| Location | Mchenry, IL, US |
| 510(k) history | 149 submissions · 149 cleared · 1980-1987 |

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k813530/> 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 May 14, 2026