

K803248 AMES SERA-PAK HEMOGLOBIN REAGENTJan 26, 1981
34 days to decisionK803248 · Product code: **KHG** · Hematology
Source: <https://www.510kdatabase.net/k803248/>**SUBMISSION DETAILS**

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|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Whole Blood Hemoglobin Determination (KHG) |
| Date received | Dec 23, 1980 |
| Decision date | Jan 26, 1981 |
| Days to decision | 34 days |
| Third-party review | No |

APPLICANT

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|----------------|---|
| Company | Miles Laboratories, Inc. |
| Location | Mchenry, IL, US |
| 510(k) history | 158 submissions · 158 cleared · 1976-1988 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k803248/> 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