

K822731 HEMOTECTOct 18, 1982
35 days to decisionK822731 · Product code: **KHE** · Hematology
Source: <https://www.510kdatabase.net/k822731/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Reagent, Occult Blood (KHE) |
| Date received | Sep 13, 1982 |
| Decision date | Oct 18, 1982 |
| Days to decision | 35 days |
| Third-party review | No |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Bio-Chem Laboratories |
| Location | Mchenry, IL, US |
| 510(k) history | 2 submissions · 2 cleared · 1982-1990 |

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k822731/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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