

K780564 FECATESTJun 30, 1978
85 days to decisionK780564 · Product code: **KHE** · Hematology
Source: <https://www.510kdatabase.net/k780564/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Reagent, Occult Blood (KHE) |
| Date received | Apr 6, 1978 |
| Decision date | Jun 30, 1978 |
| Days to decision | 85 days |
| Third-party review | No |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Otto C. Watzka |
| Location | Mchenry, IL, US |
| 510(k) history | 1 submissions · 1 cleared · 1978-1978 |

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k780564/>; Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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