

K834084 HYDROXYBUTYRATE DEHYDROGENASE REAGENTFeb 4, 1984
68 days to decisionK834084 · Product code: **JKF** · Chemistry
Source: <https://www.510kdatabase.net/k834084/>**SUBMISSION DETAILS**

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|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Dinitrophenyl Hydrazone Measurement (colorimetric), Hydroxybutyric Dehydroge (JKF) |
| Date received | Nov 28, 1983 |
| Decision date | Feb 4, 1984 |
| Days to decision | 68 days |
| Third-party review | No |

APPLICANT

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|----------------|---|
| Company | Sterling Biochemical, Inc. |
| Location | Mchenry, IL, US |
| 510(k) history | 15 submissions · 15 cleared · 1982-1985 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k834084/>; 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 July 4, 2026