

K905227 GLUCOSE (HK) REAGENT, UNIVERSALMar 11, 1991
111 days to decisionK905227 · Product code: **CFR** · Chemistry
Source: <https://www.510kdatabase.net/k905227/>**SUBMISSION DETAILS**

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|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Hexokinase, Glucose (CFR) |
| Date received | Nov 20, 1990 |
| Decision date | Mar 11, 1991 |
| Days to decision | 111 days |
| Third-party review | No |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Enzyme Technology, Inc. |
| Location | Nashua, NH, US |
| Contact | PETER KLAMKA |
| 510(k) history | 5 submissions · 5 cleared · 1989-1992 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k905227/>; 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 2, 2026