

**K912028 URIC ACID (URICASE) REAGENT, UNIVERSAL**Dec 18, 1991  
224 days to decisionK912028 · Product code: **KNK** · Chemistry  
Source: <https://www.510kdatabase.net/k912028/>**SUBMISSION DETAILS**

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|-----------------------|--|
| Decision              | Substantially Equivalent (Cleared)       |
| Submission type       | Traditional                              |
| Device classification | Acid, Uric, Uricase (colorimetric) (KNK) |
| Date received         | May 8, 1991                              |
| Decision date         | Dec 18, 1991                             |
| Days to decision      | 224 days                                 |
| Third-party review    | No                                       |
| Summary / Statement   | Statement                                |

**APPLICANT**

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k912028/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated July 2, 2026