

**K770555 CPK ISOENZYME CONTROL**Jun 3, 1977  
74 days to decisionK770555 · Product code: **JJT** · ChemistrySource: <https://www.510kdatabase.net/k770555/>**SUBMISSION DETAILS**

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|-----------------------|---|
| Decision              | Substantially Equivalent (Cleared)            |
| Submission type       | Traditional                                   |
| Device classification | Enzyme Controls (assayed And Unassayed) (JJT) |
| Date received         | Mar 21, 1977                                  |
| Decision date         | Jun 3, 1977                                   |
| Days to decision      | 74 days                                       |
| Third-party review    | No  |

**APPLICANT**

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|----------------|---|
| Company        | <b>Bio-Reagents &amp; Diagnostics, Inc.</b> |
| Location       | Mchenry, IL, US                             |
| 510(k) history | 4 submissions · 4 cleared · 1976-1978       |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)

Device record: <https://www.510kdatabase.net/k770555/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).

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