

**K904102 REFLOTRON CREATINE KINASE TEST TABS**Sep 27, 1990  
21 days to decisionK904102 · Product code: **CGS** · Chemistry  
Source: <https://www.510kdatabase.net/k904102/>**SUBMISSION DETAILS**

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|-----------------------|---|
| Decision              | Substantially Equivalent (Cleared)                    |
| Submission type       | Traditional   |
| Device classification | Nad Reduction/nadh Oxidation, Cpk Or Isoenzymes (CGS) |
| Date received         | Sep 6, 1990   |
| Decision date         | Sep 27, 1990  |
| Days to decision      | 21 days   |
| Third-party review    | No  |

**APPLICANT**

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|----------------|---|
| Company        | <b>Boehringer Mannheim Corp.</b>          |
| Location       | Mchenry, IL, US                           |
| Contact        | JOHN D STEVENS                            |
| 510(k) history | 340 submissions · 340 cleared · 1976-1999 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k904102/>; 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 May 22, 2026