

**K820378 LD-L TRIS SYSTEM PACK TEST**Mar 8, 1982  
27 days to decisionK820378 · Product code: **CFJ** · Chemistry  
Source: <https://www.510kdatabase.net/k820378/>**SUBMISSION DETAILS**

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|-----------------------|---|
| Decision              | Substantially Equivalent (Cleared)                        |
| Submission type       | Traditional   |
| Device classification | Nad Reduction/nadh Oxidation, Lactate Dehydrogenase (CFJ) |
| Date received         | Feb 9, 1982   |
| Decision date         | Mar 8, 1982   |
| Days to decision      | 27 days   |
| Third-party review    | No  |

**APPLICANT**

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| Company        | <b>Boehringer Mannheim Corp.</b>          |
| Location       | Mchenry, IL, US                           |
| 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/k820378/> 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