

**K970856 CARDIOISOZYME, CK/LD ISOENZYME CONTROL**Apr 8, 1997  
29 days to decisionK970856 · Product code: **JJT** · Chemistry  
Source: <https://www.510kdatabase.net/k970856/>**SUBMISSION DETAILS**

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|-----------------------|---|
| Decision              | Substantially Equivalent (Cleared)            |
| Submission type       | Traditional                                   |
| Device classification | Enzyme Controls (assayed And Unassayed) (JJT) |
| Date received         | Mar 10, 1997                                  |
| Decision date         | Apr 8, 1997                                   |
| Days to decision      | 29 days                                       |
| Third-party review    | No  |
| Summary / Statement   | Statement                                     |

**APPLICANT**

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|----------------|---|
| Company        | <b>Medical Analysis Systems, Inc.</b>     |
| Location       | Mchenry, IL, US                           |
| Contact        | SCOT KINGHORN                             |
| 510(k) history | 107 submissions · 107 cleared · 1978-2004 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k970856/> 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 14, 2026