

**K042448 DIAZYME HOMOCYSTEINE ENZYMATIC ASSAY KIT**Oct 29, 2004  
50 days to decisionK042448 · Product code: **JJX** · Chemistry  
Source: <https://www.510kdatabase.net/k042448/>**SUBMISSION DETAILS**

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|                       |   |
|-----------------------|---|
| Decision              | Substantially Equivalent (Cleared)                                |
| Submission type       | Traditional   |
| Device classification | Single (specified) Analyte Controls (assayed And Unassayed) (JJX) |
| Date received         | Sep 9, 2004   |
| Decision date         | Oct 29, 2004  |
| Days to decision      | 50 days   |
| Third-party review    | No  |
| Summary / Statement   | Statement   |

**APPLICANT**

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|----------------|---|
| Company        | <b>General Atomics</b>                            |
| Location       | San Diego, CA, US                                 |
| Contact        | HUAN TRAN   |
| Website        | <a href="http://www.ga.com">http://www.ga.com</a> |
| 510(k) history | 6 submissions · 6 cleared · 2003-2009             |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k042448/> 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 June 23, 2026