

**K973668 CARDIAC TROPONIN-I (TROP) CALIBRATOR**Oct 20, 1997  
25 days to decisionK973668 · Product code: **JIT** · Chemistry  
Source: <https://www.510kdatabase.net/k973668/>**SUBMISSION DETAILS**

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|                       |                                    |
|-----------------------|------------------------------------|
| Decision              | Substantially Equivalent (Cleared) |
| Submission type       | Traditional                        |
| Device classification | Calibrator, Secondary (JIT)        |
| Date received         | Sep 25, 1997                       |
| Decision date         | Oct 20, 1997                       |
| Days to decision      | 25 days                            |
| Third-party review    | No                                 |
| Summary / Statement   | Summary                            |

**APPLICANT**

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|----------------|---|
| Company        | <b>Dade Intl., Inc.</b>                 |
| Location       | Deerfield, IL, US                       |
| Contact        | REBECCA S AYASH                         |
| 510(k) history | 30 submissions · 30 cleared · 1995-1998 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k973668/> 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 28, 2026