

**K874545 IMACK-MB TEST PROCEDURE (MODIFICATION)**Dec 18, 1987  
45 days to decisionK874545 · Product code: **JHY** · Chemistry  
Source: <https://www.510kdatabase.net/k874545/>**SUBMISSION DETAILS**

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|-----------------------|--|
| Decision              | Substantially Equivalent (Cleared)           |
| Submission type       | Traditional                                  |
| Device classification | Colorimetric Method, Cpk Or Isoenzymes (JHY) |
| Date received         | Nov 3, 1987                                  |
| Decision date         | Dec 18, 1987                                 |
| Days to decision      | 45 days                                      |
| Third-party review    | No   |

**APPLICANT**

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|----------------|---|
| Company        | <b>Intl. Immunoassay Laboratories, Inc.</b> |
| Location       | Mchenry, IL, US                             |
| Contact        | SHAH, PH.D.                                 |
| 510(k) history | 27 submissions · 27 cleared · 1980-1992     |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k874545/>; 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 29, 2026