

**K830837 LA-HISTO ANTIBODY SYSTEM #HL 1001**May 5, 1983  
50 days to decisionK830837 · Product code: **GMJ** · Microbiology  
Source: <https://www.510kdatabase.net/k830837/>**SUBMISSION DETAILS**

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|-----------------------|---|
| Decision              | Substantially Equivalent (Cleared)          |
| Submission type       | Traditional                                 |
| Device classification | Antigens, Histoplasma Capsulatum, All (GMJ) |
| Date received         | Mar 16, 1983                                |
| Decision date         | May 5, 1983                                 |
| Days to decision      | 50 days                                     |
| Third-party review    | No  |

**APPLICANT**

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| Company        | <b>Immuno-Mycologics, Inc.</b>          |
| Location       | Mchenry, IL, US                         |
| 510(k) history | 26 submissions · 26 cleared · 1979-2012 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k830837/> 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 15, 2026