

**K971393 MYCOPLASMA IGG ELISA TEST SYSTEM**Jul 14, 1997  
96 days to decisionK971393 · Product code: **LJZ** · Microbiology  
Source: <https://www.510kdatabase.net/k971393/>**SUBMISSION DETAILS**

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|-----------------------|--|
| Decision              | Substantially Equivalent (Cleared)                         |
| Submission type       | Traditional  |
| Device classification | Enzyme Linked Immunoabsorbent Assay, Mycoplasma Spp. (LJZ) |
| Date received         | Apr 9, 1997  |
| Decision date         | Jul 14, 1997   |
| Days to decision      | 96 days  |
| Third-party review    | No   |
| Summary / Statement   | Summary  |

**APPLICANT**

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|----------------|---|
| Company        | <b>Immunoprobe, Inc.</b>                |
| Location       | Washington, DC, US                      |
| Contact        | WILLIAM L BOTELER                       |
| 510(k) history | 14 submissions · 14 cleared · 1994-1997 |

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