

**K862630 MYCOPLASMA PNEUMONIAE ANTIBODY LATEX
TEST SYSTEM**Sep 3, 1986
55 days to decisionK862630 · Product code: **GSA** · Microbiology
Source: <https://www.510kdatabase.net/k862630/>**SUBMISSION DETAILS**

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|-----------------------|-------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Antisera, All Mycoplasma Spp. (GSA) |
| Date received | Jul 10, 1986 |
| Decision date | Sep 3, 1986 |
| Days to decision | 55 days |
| Third-party review | No |

APPLICANT

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| Company | Medical Diagnostic Technologies, Inc. |
| Location | Augusta, GA, US |
| Contact | DAVID A WALL |
| 510(k) history | 57 submissions · 57 cleared · 1985-2006 |

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