

K802934 MYCOPLASMA PNEUMONIAE ANTIGEN & CONTROLDec 31, 1980
42 days to decisionK802934 · Product code: **GSB** · Microbiology
Source: <https://www.510kdatabase.net/k802934/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Antigens, Cf, All, Mycoplasma Spp. (GSB)
Date received	Nov 19, 1980
Decision date	Dec 31, 1980
Days to decision	42 days
Third-party review	No

APPLICANT

Company	Orion Diagnostica, Inc.
Location	Mchenry, IL, US
510(k) history	28 submissions · 28 cleared · 1980-1994

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Device record: <https://www.510kdatabase.net/k802934/>; Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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