

**K963055 IMMUNOWELL MYCOPLASMA PNEUMONIA
ANTIBODY (IGG) TEST 3120**

May 2, 1997
269 days to decision

K963055 · Product code: **LJZ** · Microbiology
Source: <https://www.510kdatabase.net/k963055/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Enzyme Linked Immunoabsorbent Assay, Mycoplasma Spp. (LJZ)
Date received	Aug 6, 1996
Decision date	May 2, 1997
Days to decision	269 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Genbio
Location	San Diego, CA, US
Contact	Bryan Kiehl
510(k) history	10 submissions · 10 cleared · 1996-2001

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k963055/> Data sourced from FDA 510(k) public records (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. - Generated June 29, 2026