

**K952818 ENZYME LINKED IMMUNOABSORBENT ASSAY,
TOXOPLASMA GONDII**

Nov 20, 1995
153 days to decision

K952818 · Product code: **GMM** · Microbiology
Source: <https://www.510kdatabase.net/k952818/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Antigens, Iha, Toxoplasma Gondii (GMM)
Date received	Jun 20, 1995
Decision date	Nov 20, 1995
Days to decision	153 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Pyramid Biological Corp.
Location	Van Nuys, CA, US
Contact	JEANETTE R PORRETTA
510(k) history	12 submissions · 12 cleared · 1993-1997

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Device record: <https://www.510kdatabase.net/k952818/>; Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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